**DEPARTMENT OF AGRICULTURE**

**Animal and Plant Health Inspection Service**

**9 CFR Parts 50, 51, 71, 76, 77, 78, 86, 93, and 161**

**[Docket No. APHIS–2011–0044]**

**RIN 0579–AD65**

# Brucellosis and Bovine Tuberculosis; Update of General Provisions

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** We are proposing to consolidate the regulations governing bovine tuberculosis, and those governing brucellosis. As part of this consolidation, we are proposing to transition the tuberculosis and brucellosis programs away from a State classification system based in disease prevalence. Instead, States and Tribes would implement animal health plans that identify sources of the diseases within the State or Tribal lands and specify mitigations to address the risk posed by those sources. The consolidated regulations would also set forth standards for surveillance, epidemiological investigations, and affected herd management that must be incorporated into each animal health plan, with certain limited exceptions; would provide revised conditions for the interstate movement of cattle, bison, and captive cervids; and would provide revised conditions for APHIS approval of tests, testing laboratories, and testers for bovine tuberculosis or brucellosis. Finally, we are proposing to revise the bovine tuberculosis- and brucellosis-related import requirements for cattle and bison to make these requirements clearer and assure that they more effectively mitigate the risk of introduction of these diseases into the United States.

**DATES:** We will consider all comments that we receive on or before March 15, 2016.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to: *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0044.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2011–0044, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0044* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

**FOR FURTHER INFORMATION CONTACT:** *Domestic regulatory provisions:* Dr. C. William Hench, Senior Staff Veterinarian, Ruminant Health Programs, VS, APHIS, 2150 Centre Avenue, Building B–3E20, Fort Collins, CO 80526–8117; (970) 4947378. *Import-related regulatory provisions:* Dr. Langston Hull, National Import Export Services, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737; (301) 851–3300.

**SUPPLEMENTARY INFORMATION:**

## Background

### I. Purpose of the Regulatory Action

#### *a. Need for the Regulatory Action*

Bovine tuberculosis is a contagious and infectious granulomatous disease caused by the bacterium *Mycobacterium bovis.* Although commonly defined as a chronic debilitating disease, bovine tuberculosis can occasionally assume an acute, rapidly progressive course. While any body tissue can be affected, lesions are most frequently observed in the lymph nodes, lungs, intestines, liver, spleen, pleura, and peritoneum. Although cattle are considered to be the true hosts of *M. bovis,* the disease has been reported in several other species of livestock, most notably bison and captive cervids. There have also been instances of infection in other domestic and nondomestic animals, as well as in humans.

Brucellosis is a contagious disease, caused by bacteria of the genus *Brucella,* that affects both animals and humans. The disease mainly affects cattle, bison, and swine; however, goats, sheep, horses, and humans are susceptible as well. In its principal animal hosts, it causes loss of young through spontaneous abortion or birth of weak offspring, reduced milk production, and infertility. There is no economically feasible treatment for brucellosis in livestock. In humans, brucellosis initially causes flu-like symptoms, but the disease may develop into a variety of chronic conditions, including arthritis. Humans can be treated for brucellosis with antibiotics.

These diseases were widely prevalent in the United States during the early 1900s. As recently as 1917, 1 in 20 cattle herds within the United States was affected with bovine tuberculosis, and, in 1934, 1 in 10 adult cattle within the United States was a reactor (*i.e.,* tested positive) for brucellosis.

Such prevalence prompted the establishment of a National Cooperative State/Federal Eradication Program for bovine tuberculosis (referred to below as the bovine tuberculosis program) and a National Cooperative State/Federal Eradication Program for brucellosis (referred to below as the brucellosis program). The programs sought to eradicate the diseases from the nation's cattle herds by quickly responding to brucellosis and bovine tuberculosis outbreaks, identifying and quarantining affected herds, and depopulating these herds. To foster producer compliance with herd depopulation, the United States Department of Agriculture (USDA) regularly compensated the owners of depopulated herds.

In support of these programs, USDA issued regulations. These regulations established State classification systems for brucellosis and bovine tuberculosis based on disease prevalence within a State. The regulations further required that these prevalence levels be supported by surveillance (inspection and periodic testing) of cattle within the State and specified that, for a State to maintain its classification, affected herds within a State had to be depopulated within a certain period of time. Finally, the regulations specified testing requirements and movement restrictions for cattle moved interstate from certain classes of States.

Since their inception, these regulatory programs have proven extremely successful in reducing the prevalence of brucellosis and bovine tuberculosis within the United States. Based on routine inspection conducted by USDA's Food Safety Inspection Service (FSIS) of cattle slaughtered at slaughtering establishments, brucellosis currently affects less than 0.001 percent of all domestic program herds, and bovine tuberculosis less than 0.001 percent of all such herds. Under the standards of the World Organisation for Animal Health (OIE), these prevalence levels, excluding consideration of other OIE standards, are, in and of themselves, consistent with a ''free'' status for brucellosis and bovine tuberculosis.

However, in recent years, several factors have arisen to impede our brucellosis and bovine tuberculosis eradication efforts. First, reservoirs of brucellosis and bovine tuberculosis have been identified in wildlife populations in certain areas of the

country. These affected wildlife populations pose a risk of transmitting brucellosis or bovine tuberculosis to livestock in the areas on a recurring basis, potentially resulting in brucellosis and bovine tuberculosis becoming endemic in livestock in certain areas of the country.

Second, since USDA established regulatory programs for brucellosis and bovine tuberculosis, the cattle industry within the United States has changed substantially, and other ruminant industries have arisen. Cattle producers have increasingly relied on imported cattle to supplement their domestically raised stock, exposing the domestic herd to animals that originate from regions with diverse risk statuses. Cattle herd sizes have increased significantly, and market channels have become increasingly complex. Additionally, producers of bison and captive cervids, two species that are also susceptible to brucellosis and bovine tuberculosis, have established industries, and interstate movement of bison and captive cervids has increased accordingly.

These industry changes have led us to reevaluate the programs' traditional reliance on whole herd depopulation as the sole means of managing affected herds. As the prevalence levels for brucellosis and bovine tuberculosis have decreased within the United States, funds allocated to Federal and State departments of agriculture to indemnify the owners of depopulated herds have similarly decreased. As a result, because of current herd sizes, which are often significantly larger than when the programs were established, if brucellosis or bovine tuberculosis is detected in a herd and the herd is depopulated, it is often difficult, if not impracticable, to indemnify the owner for all animals that are destroyed. Similarly, because of current marketing practices, USDA has become increasingly aware of the impacts on local and regional markets that may be caused by whole herd depopulation of a large herd. Accordingly, in the past decade, USDA has evaluated the efficacy of other methodologies to deal with affected herds.

In 2009, USDA's Animal and Plant Health Inspection Service (APHIS) issued concept papers that outlined these factors and suggested several modifications to the brucellosis and bovine tuberculosis programs that would address the factors. Suggested modifications included:

- Crafting national surveillance plans for the programs to target areas within the United States where prevalence levels may be higher than the national average.
- Enhancing existing efforts to mitigate disease transmission from wildlife to livestock.
- Developing regulatory alternatives to whole-herd depopulation.

The comment period for each concept paper was 60 days. By the close of the comment period for the brucellosis concept paper, we had received 344 comments, from State departments of agriculture, advocacy groups, livestock producers, and private citizens. By the close of the comment period for the bovine tuberculosis concept paper, we had received 73 comments, from State departments of agriculture, representatives for foreign governments, advocacy groups, representatives for the cattle industry within the United States, cattle producers, and private citizens. While several commenters expressed concern regarding some of the suggested modifications, commenters did not present information that called into question the approaches presented in the two documents.

Accordingly, APHIS subsequently issued a rule and order that modified aspects of the brucellosis and bovine tuberculosis programs in accordance with the concept papers. In April 2010, APHIS issued a Federal Order [1] that allows States to retain the highest bovine tuberculosis classification, accredited-free, regardless of the number of affected herds in the State, provided that all affected herds in the State that are not depopulated are quarantined; an affected herd plan is developed for each of these herds to prevent the spread of tuberculosis; the herds are subject to periodic testing and animals that do not test negative are destroyed; and the State conducts sufficient surveillance to identify tuberculosis in other animals. Since most States had accredited-free status at the time the order was issued, the order was meant, in part, to result in depopulation no longer being considered the sole means of dealing with affected herds within the bovine tuberculosis program.

On December 27, 2010, APHIS published an interim rule [2] in the **Federal Register** (75 FR 81090–81096, Docket No. APHIS–2009–0083). Among other things, this rule required States with the highest classification for brucellosis, Class Free, that also have brucellosis in wildlife to develop and implement a brucellosis management plan approved by APHIS that specifies surveillance and mitigation measures for these wildlife reservoirs. The interim rule was intended, in part, to couple the brucellosis program's traditional focus on response to disease in domestic herds with a new focus on sources of disease introduction.

Concurrent with the issuance of this order and rule, APHIS also formed a bovine tuberculosis/brucellosis working group. The working group, composed of Federal, State, and Tribal representatives, was tasked with crafting a regulatory framework for consolidating the brucellosis and bovine tuberculosis programs into a single, streamlined program. Using the concept papers, the April 2010 Federal Order, and the December 2010 interim rule as reference points, and after extended discussion and dialogue with stakeholders, the working group drafted a framework comprising eight elements, or interrelated regulatory concepts: Program (State) requirements; zoning; surveillance; affected herd management and epidemiological investigations; indemnity; interstate movement controls; importation requirements; and approval procedures related to official tests and laboratories. On May 5, 2011, APHIS made the draft regulatory framework document available on Regulations.gov for review and comment.[3]

We took comment on the draft regulatory framework document for 60 days, ending July 5, 2011. We received 37 comments by that date. They were from State departments of agriculture, an organization representing dairy cattle producers throughout the United States, organizations representing the cattle industry, a wildlife conservation organization, and several private citizens. Based on the draft regulatory framework document and the comments we received, we have developed and are issuing this proposed rule.

However, in response to comments received on the framework document and ongoing discussion with stakeholders, this proposed rule does not include several of the regulatory requirements suggested in the framework. We discuss significant divergences immediately below, by element.

Element 1, State (Program) Requirements, suggested creating a control or advisory board of Federal, State, and Tribal experts to provide APHIS with recommendations regarding

[1] To view the Federal Order, go to *http://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1031&context=michbovinetb.*

[2] To view the interim rule, go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2009-0083-0001.*

[3] To view the framework or the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0044.*

State compliance with regulatory requirements as well as recommendations regarding State status classifications.

Many commenters supported the establishment of such a board, but stated that the board should have industry representation. The commenters put forth a number of scenarios in which industry personnel would have specialized expertise that Federal, State, and Tribal personnel would not possess.

We agree that industry personnel often possess such technical expertise, and foresee circumstances where we may need to solicit such expertise under a consolidated brucellosis and tuberculosis program. However, a board with industry representation that provides general recommendations to APHIS would be considered an advisory committee under the Federal Advisory Committee Act (5 U.S.C., appendix, FACA), and would thus be subject to the requirements of that Act. FACA requires advisory committees to follow an extensive protocol before convening a meeting of the committee, and this protocol could, in certain instances, preclude the advisory board from providing APHIS with timely advice regarding program activities.

Accordingly, instead of an advisory board, APHIS would solicit the opinion of technical experts at the Federal, State, Tribal, and industry level as circumstances warrant under the consolidated brucellosis and bovine tuberculosis program.

Element 2, Zoning, suggested that, if reservoirs of bovine tuberculosis or brucellosis are identified in an area of the United States and the outbreak cannot be eradicated within 1 year, then zoning the area for the disease or diseases should be considered as a management method. It further suggested that, if zoning is pursued, the zones should not be limited by geopolitical boundaries unless warranted.

A number of State departments of agriculture pointed out that their jurisdiction over matters of livestock health ends at State boundaries. The commenters expressed concern that, if a single zone was composed of areas in multiple States, and one of the States failed to adhere to the requirements of the regulations, all of States would be subject to remedial measures, even though the other States have no jurisdiction over the activities conducted in that State.

In light of the commenters' concerns, while this proposed rule does allow for zones, which we term recognized management areas, States would request recognition of those areas within their particular State, and the boundaries of the recognized management area would not extend beyond State borders.

Element 5, Indemnity, proposed streamlining the process for the payment of indemnity for animals destroyed because of brucellosis or bovine tuberculosis by means of an appraisal calculator.

Several commenters supported the use of such a calculator in theory, but stated that they would need to see a demonstration of such a calculator in order to assess its accuracy and viability as a means of appraisal.

We agree that streamlining the indemnity regulations in the manner proposed in the framework document presupposes deployment of such a calculator. Since the calculator is still being developed and tested, we have decided not to propose to modify the indemnification process in the manner suggested by the framework document in this proposed rule. As a result, this proposed rule would not modify current indemnity practices, which rely on fair market value as determined by an appraiser, for bovine tuberculosis, and on either a fixed rate or fair market value as determined by an appraiser, for brucellosis.

Finally, element 7, Import Requirements, set forth a number of suggested post-entry requirements for ruminants imported into the United States to address the risk that such ruminants may pose of introducing brucellosis or bovine tuberculosis into the United States.

Several commenters suggested that, in light of our limited resources, APHIS would be better served by evaluating our existing import requirements for ruminants to determine whether, in every instance, they mitigate the risk of introduction of brucellosis or bovine tuberculosis.

We have conducted such a risk evaluation. We have concluded that the current import requirements do not always mitigate such risk, and are proposing to amend them accordingly.

Legal Authority for the Regulatory Action

Under the Animal Health Protection Act (AHPA, 7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture has the authority to issue orders and promulgate regulations to prevent the introduction into the United States and the dissemination within the United States of any pest or disease of livestock. APHIS' regulations in 9 CFR chapter I, subchapter C contain requirements for the interstate movement of livestock to prevent the dissemination of diseases of livestock within the United States. APHIS' regulations in 9 CFR chapter I, subchapter D contain requirements for the importation of livestock to prevent the introduction or dissemination of diseases of livestock into the United States.

## II. Summary of the Major Provisions of the Proposed Rule

This proposed rule would remove the regulations governing the bovine tuberculosis program, currently found in 9 CFR part 77, and those governing the aspects of the brucellosis program that pertain to cattle and bison, currently found in 9 CFR part 78, subparts B and C. In their place, it would add a new part to the regulations, 9 CFR part 76. This part, which would be titled ''Part 76—Brucellosis and Bovine Tuberculosis,'' would contain regulations governing a national program designed to eradicate both diseases from cattle, bison, and captive cervids (''program animals'') in the United States.

As the regulations in 9 CFR parts 77 and 78 currently do, these proposed regulations would provide a system to classify States for brucellosis and bovine tuberculosis. However, the classification system would no longer be based on the prevalence level of these diseases within a State. Rather, the system would be based on whether a State has drafted an animal health plan to address the diseases, whether APHIS has approved this plan, and whether the State has implemented and is maintaining the activities specified within the plan. We would also allow Tribes to submit plans and request brucellosis and bovine tuberculosis statuses apart from the State in which their Tribal lands are located. In order for APHIS to have adequate assurances that States and Tribes have implemented and are maintaining the activities and measures specified in their plan, the classification system would also be based, in part, on regular and timely submission of reports regarding these activities and measures.

In an animal health plan, the State or Tribe would have to specify whether any known sources of brucellosis or bovine tuberculosis exist within the State or Tribal lands; this is no change from current obligations within the brucellosis and bovine tuberculosis programs with regard to alerting APHIS when new sources of brucellosis or bovine tuberculosis are discovered in State or Tribal lands. If there are known sources of those diseases in the State or Tribal lands, the State or Tribe would have to conduct surveillance of those sources and of the cattle, bison, or captive cervids that may come in

contact with the sources, and would have to specify mitigations that address the risk of disease spread to these at-risk populations.

Regardless of whether there are known sources of disease in the State or Tribal lands, States and Tribes would also have to provide APHIS with demographics regarding cattle, bison, and captive cervids within the State, a list of personnel assigned to implement and perform activities and maintain and enforce measures associated with their animal health plans, and confirmation that the State or Tribe has a legal and regulatory basis for the activities specified within the animal health plan. Additionally, States or Tribes would have to agree to conduct epidemiological investigations and affected herd management in accordance with the protocols set forth in the sections of the regulations that would pertain to these activities, or would have to submit an alternate method to APHIS for evaluation and approval.

The proposed rule includes protocols for epidemiological investigations into an investigation of individual cattle, bison, or captive cervids that have had non-negative test results for brucellosis. This proposal includes protocols for four types of epidemiological investigations:

- Investigations arising because individual cattle, bison, or captive cervids have been determined to be infected with brucellosis or bovine tuberculosis;
- Investigations arising because a herd of cattle, bison, or captive cervids has been determined to be affected with brucellosis or bovine tuberculosis;
- Investigations arising because animals other than cattle, bison, or captive cervids have been determined to be infected with brucellosis or bovine tuberculosis, and cattle, bison, or captive cervids in the area surrounding these animals have been determined by APHIS to be at-risk because of exposure to this source; and
- Investigations arising because brucellosis or bovine tuberculosis has been detected at a calf raiser or feedlot, where cattle or bison from disparate premises of origin are brought together for feeding purposes.

States and Tribes could manage affected herds through whole-herd depopulation or a test-and-remove protocol. The minimum standards for a test-and-remove protocol would be similar to those found in the April 2010 Federal Order.[4]

States and Tribes would have the option of requesting recognition of a management area within the State or Tribal lands. The management area would be a clearly delineated geographical area of the State or Tribal lands in which the State or Tribe has detected brucellosis or bovine tuberculosis, in which the State or Tribe has determined that there is a risk of transmission of brucellosis or bovine tuberculosis to program animals, and in which the State or Tribe has taken or proposes to take measures to control the spread of the brucellosis or bovine tuberculosis within and from the area and/or to eradicate the disease within the area. These measures would have to include restrictions on the movement of cattle, bison, and captive cervids from the recognized management area, as well as certain other measures. Recognized management areas would allow States and Tribes to designate certain areas of the State or Tribal lands as posing a greater risk of brucellosis and bovine tuberculosis spread than other areas within the State or Tribal lands, without risking a possible redesignation of the State or Tribe to a lower State or Tribal classification.

The regulations would also provide conditions for the interstate movement of cattle, bison, and captive cervids. Except for cattle and bison that belong to certain, high-risk categories, the conditions for interstate movement of most cattle and bison would be based on the status of the State or Tribe from which the cattle or bison are moved. Cattle and bison from a State or Tribe with the lowest status would be considered to pose a substantial risk of transmitting brucellosis and/or bovine tuberculosis, and thus would be subject to testing prior to interstate movement.

Captive cervids would be subject to testing for both brucellosis and bovine tuberculosis prior to interstate movement, regardless of the status of the State or Tribe from which they are moved. Such testing would be necessary because FSIS does not currently conduct slaughter inspection of captive cervids and because the actual prevalence of brucellosis and bovine tuberculosis within the domestic captive cervid industry are largely unknown.

Finally, the proposed rule would revise the conditions for the importation of cattle and bison that are contained in 9 CFR part 93 and that address the risk the imported cattle or bison may pose of disseminating brucellosis or bovine tuberculosis. The current regulations, which may be divided into requirements that are generally applicable to most exporting countries and country-specific requirements that are applicable to Canada, Mexico, and Ireland, do not account for changes in disease programs or disease prevalence that could increase or decrease the risk of spread of brucellosis or bovine tuberculosis posed by the importation of cattle or bison from foreign regions.

Accordingly, we evaluated this risk to determine whether to modify the current regulations, and, if so, how. The risk evaluation examines two possible modifications: (1) Adopting international standards developed by the OIE or (2) applying the U.S. prevalence-based requirements delineated in the current Uniform Methods and Rules[5] for the bovine tuberculosis and brucellosis programs within the United States to the importation of bovines from foreign regions.

The risk evaluation finds that, based on current import practices, both the OIE standards and our domestic requirements could help mitigate to a certain extent the risk that cattle and bison imported into the United States may present of spreading brucellosis or bovine tuberculosis. However, only the domestic requirements, applied to foreign regions, would reduce such risk to negligible levels. Additionally, the domestic requirements would mitigate such risk while leaving substantially unchanged our current country-specific requirements regarding the importation of steers and spayed heifers into the United States. Steers and spayed heifers currently account for the majority of live cattle and bison imported into the United States.

The provisions of this proposed rule are based on the findings of this risk evaluation. The proposed rule would remove most of the brucellosis- and bovine tuberculosis-specific requirements for the importation of cattle and bison from the regulations. In their place, the proposed rule would establish a system, modeled on the domestic requirements, that would classify a region[6] of the world based

[4] See footnote 1.

[5] The bovine tuberculosis Uniform Methods and Rules are located here: *https://www.aphis.usda.gov/animal_health/animal_diseases/tuberculosis/downloads/tb-umr.pdf.* The brucellosis Uniform Methods and Rules are located here: *https://www.aphis.usda.gov/animal_health/animal_diseases/brucellosis/downloads/umr_bovine_bruc.pdf.*

[6] A region is defined in § 93.400 as ''any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following: (1) A national entity (country); (2) a part of a national entity (zone, county, department, municipality, parish, Province, State, etc.); (3) parts of several national entities combined into an area; or (4) a group of national entities (countries) combined into a single area.''

both on its brucellosis or bovine tuberculosis prevalence and on whether it has a program for brucellosis or bovine tuberculosis that meets certain standards. The classifications would be as follows: Level I through V for bovine tuberculosis, and Level I through III for brucellosis. The regulations would allow regions to request evaluation for a particular classification, would establish a process by which APHIS would evaluate such requests, and would allow APHIS to lower a region's classification based on emerging evidence. Finally, the proposed rule would establish conditions for the importation of cattle and bison that correspond to the bovine tuberculosis or brucellosis classification of the region from which the cattle or bison will be exported.

**III. Costs and Benefits**

Economic effects of the proposed rule are not expected to be significant. Bovine tuberculosis affects less than 0.001 percent of domestic program herds, and brucellosis also less than 0.001 percent. There would be few on-the-ground operational changes for States or producers. Most reporting requirements in areas where bovine tuberculosis and brucellosis are not found, as well as surveillance, movement limitations, testing, and reporting in areas where either disease is present, would continue with little alteration.

Certain additional costs incurred by States, Tribes, and producers as a result of this proposed rule are expected to total between $3.0 million and $8.5 million. States and Tribes would incur costs in developing the proposed animal health plans for bovine tuberculosis and brucellosis, which would build significantly on existing operations with respect to these diseases. We anticipate that all 50 States and at least 3 Tribes would develop animal health plans. We estimate that the aggregate one-time cost of developing all of these animal health plans would be between about $750,000 and $2.9 million.

States and Tribes would also be required to report on the results of epidemiological investigations. We expect that the total annual cost for all States and Tribes of this reporting would be between $119,000 and $142,000.

We expect that, under current circumstances, four or five States are likely to develop recognized management area plans as proposed in this rule as part of their animal health plans. We estimate that the aggregate one-time cost of developing these four or five plans would be between $56,000 and $274,000.

The proposed rule would impose new interstate movement restrictions on rodeo, event, and exhibited cattle and bison, as well as additional costs of testing for producers of such cattle and bison. Costs of tuberculosis and brucellosis testing, about $10 to $15 per test, are small when compared to the value of the cattle tested or to production costs.

Given the volume of interstate movement of rodeo, event, and exhibited cattle and bison, the proposed testing requirements could cost owners of these cattle and bison, in aggregate, between about $2.0 million and $4.8 million annually.

Because the testing requirements in this rule are for interstate movement, the annual impact for an individual would depend on the number of animals moved interstate in a given year. It should be noted that there is overlap between APHIS' proposed testing requirements and current State and event requirements for testing of rodeo, event, and exhibition cattle and bison, which would reduce the net impact. A number of States, particularly those on major event circuits, already require tuberculosis and brucellosis testing before cattle can enter the State. There is not, however, consistency across States as to the timing of the testing relative to entry. Additionally, a number of these States have indicated to APHIS that they adopted the requirements because of the lack of Federal requirements. If this proposed rule is finalized and they rescind those requirements, this rule could eliminate that inconsistency. We request public comment from States with such requirements regarding whether they would, in fact, rescind them based on our proposed requirements.

This rule will also impose testing requirements for brucellosis for captive cervids moved interstate for any purpose other than immediate slaughter. We do not currently have information regarding the number of captive cervids moved interstate. However, based on the number of deer farms within the United States, industry estimates that between 5 and 10 percent of captive cervids within the United States are moved interstate annually, and brucellosis testing costs, we estimate the total annual testing costs would range between about $124,000 and $382,000.

The proposed rule would also establish a new system for classifying foreign regions regarding bovine tuberculosis and brucellosis and establishing the conditions under which cattle and bison could be imported into the United States. All foreign regions that currently export cattle to the United States would be evaluated under this new process before the conditions are put into effect. Conditions could change for a particular region following evaluation under this new system.

That being said, based on our knowledge of the current brucellosis and bovine tuberculosis programs and prevalence rates of our trading partners, we do not expect requirements for the importation of cattle and bison from foreign regions to change significantly as a direct result of this proposed rule. There are two specific exceptions to this, however. These exceptions would involve additional testing for breeding cattle from Mexico intended for export to the United States. Because most bovine exporting regions in Mexico do not currently have established brucellosis programs, they would automatically be classified in the lowest brucellosis category in this proposal and an additional whole herd brucellosis test would be required for imports of sexually mature and sexually intact cattle, *i.e.,* breeding cattle, from those regions. In addition, exporting regions currently considered Accreditation Preparatory (AP) for tuberculosis would likely be classified as Level IV under this proposal and an additional whole herd tuberculosis test would be required for imports of breeding cattle from those regions.

The impact of these additional test requirements is expected to be very limited. A very small number of breeding cattle are imported from Mexico. From 2010 through 2014, 26 breeding cattle were imported from Mexico on average annually. An even smaller number come from regions of Mexico that would be subject to additional whole herd tuberculosis testing requirements as well as the additional whole herd brucellosis testing. In 2014, only six breeding cattle were imported from such regions of Mexico. The cost of the additional testing would be dependent on the size of the herd from which bovines destined for export originate and the cost of administering a brucellosis and/or a tuberculosis test within that region of Mexico. The additional cost would represent a small portion of the value of the imported bovines. Assuming the costs of brucellosis and tuberculosis testing in the United States and in Mexico are similar, the combined additional testing would be equivalent to between 1.2 and 1.9 percent of the average per head value ($1,560) of imported Mexican breeding bovines, 2009–2014.

As discussed immediately above, we expect that the economic effects of this rule on foreign producers of cattle and bison would be minimal. With regard to domestic production, we expect that the benefits would justify the costs. While direct effects of this proposed rule for producers should be small, whether the entity affected is small or large, consolidation of the brucellosis and bovine tuberculosis regulations would benefit the affected livestock industries. The use of animal health plans would require States to identify and monitor potential sources of disease transmission in their State, leading to more focused, flexible and responsive disease management and reducing the number of producers that incur costs when disease concerns arise in an area.

The Role of the Program Standards Document

In several instances, the proposed rule provides general standards for activities conducted by a State or Tribe with an animal health plan that has been approved by APHIS, such as surveillance, epidemiological investigations, and affected herd management. In these instances, the proposed regulations do not specify in detail the procedures that would meet these standards in different situations.

To that end, APHIS is also making a Program Standards document available for review and comment along with the proposed rule.[7] The Program Standards document is a guidance document to help States and Tribes meet the standards of the proposed regulations. The Program Standards document does this by providing States and Tribes with an APHIS-approved method for conducting certain activities. These APHIS-approved methods would not be requirements, and States and Tribes could submit alternate procedures that they believe to meet the performance standards in the regulations to APHIS for evaluation and approval. However, if a State or Tribe follows the methods in the Program Standards document, they would be assured of complying with the regulations.

The Program Standards document also provides guidance regarding the types of information a State or Tribe should include in its animal health plan, templates for the various reports that we would require, flowcharts regarding the processes by which APHIS would evaluate animal health plans and redesignate States or Tribes to lower classifications for brucellosis or bovine tuberculosis, and other information.

We encourage individuals to read the proposed rule in conjunction with the Program Standards document. We also seek specific comment regarding ways in which the Program Standards document could be amended to make it more useful for potentially regulated entities.

Proposed Part 76

Definitions (§ 76.0)

Section 76.0 would contain definitions of the following terms: *Accredited herd for bovine tuberculosis, accredited herd for brucellosis, accredited veterinarian, Administrator, affected herd management plan, animal identification number (AIN), annual report form, APHIS, APHIS representative, bison, bovine tuberculosis, brucellosis, calf raiser, captive cervid, depopulate, epidemiologist designated by the District Director, exposed, feedlot, herd, herd test, immediate slaughter, interstate certificate of veterinary inspection (ICVI), livestock, location-based numbering system, location identification (LID) number, management area, National Uniform Eartagging System (NUES), official Brucella vaccine, official brucellosis vaccination program, official eartag, official eartag shield, official identification number, officially identified, official seal, official test, official tester, official testing laboratory, owner, permit for movement of restricted animals, premises identification number (PIN), program animals, Program Standards document, qualified accredited veterinarian, quarantine feedlot, quarantine pen, reactor, recognized slaughtering establishment, reporting period, responsible person, spayed heifers, specifically approved stockyard, State, State or Tribal animal health official, State or Tribal representative, steers, suspect, test-eligible animal, Tribe,* and *United States.*

If a definition of one of these terms exists in the AHPA, we would define the term as it is defined in the AHPA. Thus, we would define *livestock, State,* and *United States* as these terms are defined in the AHPA.

Similarly, the AHPA provides that *Indian tribe* has the same meaning within the Act that it has in section 450b of title 25 of the U.S. Code. That title, also referred to as the Indian Self-Determination and Education Assistance Act, defines Indian tribe as ''any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 *et seq.*], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.''

If a term in proposed part 76 is not defined in the AHPA, our next reference points would be the existing definitions in 9 CFR parts 77 and 78. To that end, several terms would have the same meaning as they currently do within parts 77 and 78. We would define *Administrator, animal identification number (AIN), APHIS representative, location-based numbering system, National Uniform Eartagging System (NUES), official eartag, official eartag shield, official identification number,* and *recognized slaughtering establishment* as these terms are currently defined in both part 77 and part 78.

Similarly, *accredited veterinarian* is defined in a substantially similar manner in parts 77 and 78, but with minor differences in syntax and scope. However, the definition in part 78 is more common within 9 CFR. Hence, we would define *accredited veterinarian* as it is defined in that part.

The term *captive cervid* is currently defined in part 77, but not part 78. This is because captive cervids are currently regulated under the bovine tuberculosis program, but not under the brucellosis program. We would therefore define the term *captive cervid* as it is currently defined in part 77.

We would define the remaining terms in the following manner.

We would define an *accredited herd for bovine tuberculosis* as a herd that, in accordance with APHIS' standards for accreditation, has tested negative for bovine tuberculosis using an official test and is subject to measures that lower the risk of bovine tuberculosis introduction into the herd through the addition of animals to the herd. Similarly, we would define an *accredited herd for brucellosis* as a herd that, in accordance with APHIS' standards for accreditation, has tested negative for brucellosis using an official test and is subject to measures that lower the risk of brucellosis introduction into the herd through the addition of animals to the herd. These definitions would further provide that APHIS' standards for accreditation are described in the Program Standards document.

The standards for accreditation for bovine tuberculosis and brucellosis in the Program Standards document would be substantively similar to the current

[7] The Program Standards document is available at the Web address listed in this document beneath the heading **ADDRESSES** and at the following address: *http://www.aphis.usda.gov/animal_health/animal_dis_spec/cattle.*

standards for accreditation of herds within the bovine tuberculosis program, which are found in the document ''Bovine Tuberculosis Eradication, Uniform Methods and Rules, Effective January 1, 2005'' [8] and the current standards for certification of herds as free of brucellosis, which are found in part 78. However, certain aspects of the existing standards, such as the minimum age of animals that must be tested and the intervals between testing for reaccreditation, are linked to the current prevalence-based State classification system, which would be obsolete under the provisions of this proposed rule. Moreover, the existing standards do not reflect certain practices, such as testing of certain non-natural additions to a herd, that we have long required operationally in order for us to reach a determination that animals in the herd are free of brucellosis or bovine tuberculosis, and which would be included in the standards in the Program Standards document. Thus, there would be several differences between the current standards for herd accreditation or certification and the standards within the Program Standards document.

We wish to solicit specific public comment regarding one of these differences. Currently, if a State has a zone for bovine tuberculosis or an area covered by a brucellosis management plan, in other words, an area in which a source of bovine tuberculosis or brucellosis is known to exist, we allow herds in the area to be accredited for bovine tuberculosis or certified free of brucellosis.

However, we have discovered bovine tuberculosis or brucellosis in several accredited herds in such areas, sometimes no more than a few months after the date of reaccreditation. In each case, there was evidence that the herds probably became affected through contact with infected wildlife.

Our standards for accreditation, both our current standards and those proposed, are based on an evaluation of mitigation measures an owner has put in place to address the risk of bovine tuberculosis or brucellosis introduction into his or her herd through the addition of animals to the herd. Our standards do not evaluate the risk posed to a herd by wildlife reservoirs of bovine tuberculosis or brucellosis. We note, moreover, that it is significantly more difficult to mitigate the risk of disease transmission that is posed by wildlife reservoirs than it is to mitigate the risk of disease transmission that is posed by adding animals to a herd. In short, while we have confidence that accredited or certified herds that do not reside in areas with known disease reservoirs present a low risk of becoming affected with bovine tuberculosis or brucellosis, we do not have the same degree of confidence regarding herds in areas with known reservoirs of disease.

For this reason, our proposed standards would not allow herds in areas with known reservoirs of disease, which we would term management areas (see below), to be accredited for bovine tuberculosis or brucellosis. We also would not allow owners of currently accredited herds in such areas to seek reaccreditation if this rule is finalized. We request comment from these owners and all interested parties regarding the likely impacts to their operations, if any, that this change in policy would bring about.

Apart from herds in recognized management areas, herds that are accredited for bovine tuberculosis would continue to be considered accredited herds if this proposed rule is finalized, and herds that are certified brucellosis-free herds would be considered accredited herds for brucellosis. Owners of these herds would not be held to the differing standards of the Program Standards document until the time that the herds would have to be tested for reaccreditation. Moreover, as the definitions of *accredited herd for bovine tuberculosis* and *accredited herd for brucellosis* would provide, States could submit an alternate accreditation standard to the Administrator for evaluation and approval at any point by sending a written request to APHIS, provided that the standard is at least equally stringent to that within the Program Standards document.

We would define *annual report form* as the annual report form authorized by the Administrator for State and Tribal use to fulfill the requirements of proposed part 76. The report form, which would consolidate and streamline existing annual report forms for the brucellosis and bovine tuberculosis programs, would be located on the APHIS Web site. A draft template for the annual report form is located in the Program Standards document.

On a related matter, we would define the *reporting period* covered by the annual report as October 1 of one year through September 30 of the following year. This is the current reporting period for annual reports within the bovine tuberculosis program. (We recognize that the reporting period for annual reports within the brucellosis program is currently staggered, and corresponds to the date on which a State was assigned its current status. If this rule is finalized, we would collaborate with States to transition them over to this new, uniform reporting period.)

We would define *APHIS* as the Animal and Plant Health Inspection Service of the United States Department of Agriculture.

We would define *bison* as domestically produced or captive bison. As provided in the definition of *program animals* (see below), bison would be considered one of the species covered by part 76. However, wild bison are not considered livestock within our proposed regulations, and our definition of *bison* would reflect this. We would also include this definition so that, for the sake of brevity, we may refer to the species covered by the regulations as bison, rather than domestically produced or captive bison, throughout part 76.

We would define *bovine tuberculosis* as the contagious, infectious, and communicable disease caused by *Mycobacterium bovis,* which is also referred to as tuberculosis.

Currently, part 77 refers to the disease as tuberculosis, and provides, in the definition of *tuberculosis,* that the disease is also referred to as bovine tuberculosis. However, in recent years, we have referred to the disease as bovine tuberculosis in order to provide clarity regarding the causal agent regulated by the bovine tuberculosis program and to differentiate between this agent and *Mycobacterium tuberculosis,* the most common cause of tuberculosis in humans.

We would define *brucellosis* as the contagious, infectious, and communicable disease caused by *Brucella abortus,* and would specify that it is also known as Bangs disease, undulant fever, and contagious abortion. Currently, in the definition of *brucellosis* in part 78, we consider all bacteria within the genus *Brucella* to be causal agents for brucellosis. However, this is primarily because another species of *Brucella, Brucella suis,* which is the most common cause of brucellosis in swine, is also regulated in part 78. *Brucella abortus* is the most common cause of brucellosis in cattle, bison, and captive cervids, the species that would be regulated under the consolidated brucellosis and bovine tuberculosis program. Hence, as we stated in the draft regulatory framework document, *Brucella abortus* would be the disease agent regulated under proposed part 76.

(We would continue to regulate *Brucella suis* in swine under part 78 and would continue to investigate

[8] To view the Uniform Methods and Rules, go to *http://www.aphis.usda.gov/animal_health/animal_diseases/tuberculosis/downloads/tb-umr.pdf.*

occurrences of *Brucella suis* infection in ruminants as part of our national program for swine brucellosis. In addition, based on comments received on the draft regulatory framework document, we request specific public comment on whether to initiate rulemaking to establish a certification program for *Brucella melitensis* in goats.)

We would define *calf raiser* as a cattle production operation in which calves, yearlings, and other sexually immature cattle are brought together and maintained until they are of sufficient size or sexual maturity to move to their next stage of production. As we mentioned previously in this document, because cattle from disparate premises of origin are often brought together for feeding purposes at such operations, the provisions of part 76 that pertain to epidemiological investigations, which would be contained in proposed § 76.7, would specify a different protocol for epidemiological investigations arising because an infected animal is discovered at a calf raiser than for epidemiological investigations arising at other premises where such commingling does not occur or is far less frequent.

We would define *program animals,* that is, the species covered by proposed part 76, as cattle, bison, and captive cervids.

We would define *depopulate* as to destroy program animals in a herd at a location, in a manner, and within a timeframe as specified within an affected herd management plan. We would define an *affected herd management plan* as an affected herd management plan designed by the herd owner, the owner's veterinarian if so requested, and a State, Tribal, or APHIS representative to control and eradicate bovine tuberculosis and/or brucellosis within the herd. The definition of *affected herd management plan* would further specify that an affected herd management plan must be approved by a State or Tribal animal health official and the Administrator.

The current definition of *depopulate* within part 77, ''to destroy all livestock in a herd by slaughter or by death otherwise,'' does not contain a reference to affected herd management plans. However, as a matter of Agency policy, we have generally required affected herd management plans to be put in place prior to depopulation of any brucellosis- or bovine tuberculosis-affected herd. Among other benefits, such plans help ensure that brucellosis- or bovine tuberculosis-affected herds are depopulated in a sanitary manner and owners of depopulated herds put measures in place to prevent the future introduction of brucellosis or bovine tuberculosis into herds at their premises.

The definition in part 77 also specifies that all animals within a herd must be destroyed in order for the herd to be considered depopulated. However, within the brucellosis program, there have been several instances in recent years in which we have considered a herd to be depopulated although certain animals within the herd were removed from the herd for diagnostic purposes, and not destroyed. In such instances, the affected herd management plan established for the affected herd provided the specific conditions under which these animals would be moved in order to ensure that they presented no risk of spreading brucellosis to other animals. Moreover, although the bovine tuberculosis program does not currently allow for such a practice, we can envision instances in which it might prove beneficial in order for us to determine the actual prevalence of the disease within an affected herd. Accordingly, we would not specify that all animals within a herd must be destroyed in order for the herd to be considered depopulated.

On a related matter, part 50, which provides conditions under which the Administrator may pay indemnity for animals destroyed because of bovine tuberculosis, effectively precludes indemnity from being offered if animals are removed from an affected herd prior to depopulation of the herd. Therefore, we are proposing to remove paragraph (f) of § 50.14, which contains this prohibition.

We would define *epidemiologist designated by the District Director* as an epidemiologist selected by the APHIS District Director, in consultation with State or Tribal animal health officials, to perform the function required. This definition is modeled on the definition of *designated epidemiologist* currently found in part 78, but also reflects a recent reorganization of APHIS' Veterinary Services program that changed the manner in which this position is designated.

We would define *exposed* as an animal that has had association with infected program animals, livestock, or other sources of brucellosis or bovine tuberculosis such that an epidemiologist designated by the District Director determines the animal may be infected.

We would define *feedlot* as a facility for assembling and feeding program animals.

We would define *quarantine pen* as an area within a feedlot that is approved by APHIS as having sufficient biosecurity measures in place to assemble and feed exposed program animals, without risk of spread of brucellosis or bovine tuberculosis to other susceptible animals at the facility. Similarly, we would define *quarantine feedlot* as a facility that is approved by APHIS as having sufficient biosecurity measures in place to assemble and feed exposed program animals, without risk of spread of brucellosis or bovine tuberculosis to other susceptible animals at the facility. The definitions of *quarantine pen* and *quarantine feedlot* would also both specify that program animals may only be moved interstate from such facilities if their movement is to a recognized slaughtering establishment, or another quarantine pen or quarantine feedlot.

We recognize that certain subsectors within the cattle industry refer to feedlots as feedyards. We request specific public comment regarding which nomenclature to use.

In proposed § 76.10, we would allow program animals classified as exposed to brucellosis or bovine tuberculosis to be moved interstate to quarantine pens and quarantine feedlots, among other approved locations.

We would define *herd* as all livestock under common ownership or supervision that are grouped on one or more parts of any single premises (lot, farm, or ranch) for at least 4 months; or all livestock under common ownership for at least 4 months on two or more premises which are geographically separated but on which animals from the different premises have been interchanged or had contact with each other. This definition would be modeled on the definition currently found in part 78, but would include a provision, currently found in part 77's definition, that livestock must be under common ownership or supervision for at least 4 months in order to be considered a herd. We consider this provision necessary in order to differentiate herds from animals maintained at a calf raiser's premises or at a feedlot for a short period of time.

*Herd test* would have different meanings for brucellosis and bovine tuberculosis. For brucellosis, it would mean the following:

- In any area of a consistent State other than a recognized management area, testing of all sexually intact animals within a herd that are 18 months of age or older, as well as all sexually intact animals in the herd that are less than 18 months of age and were not born into the herd, except those sexually intact animals that are less than 18 months of age and originate directly from a currently accredited herd for brucellosis.

• In any area of a provisionally consistent State other than a recognized management area, testing of all sexually intact animals within a herd that are 12 months of age or older, as well as all sexually intact animals in the herd that are less than 12 months of age and were not born into the herd, except those sexually intact animals that are less than 12 months of age and originate directly from a currently accredited herd for brucellosis.

• In any area of an inconsistent State, or in a recognized management area for brucellosis, testing of all sexually intact animals within a herd that are 6 months of age or older, as well as all sexually intact animals in the herd that are less than 6 months of age and were not born into the herd, except those sexually intact animals that are less than 6 months of age and originate directly from a currently accredited herd for brucellosis.

For bovine tuberculosis, *herd test* would mean the following:

• In any area of a consistent State other than a recognized management area, testing of all animals within a herd that are 18 months of age or older, as well as all animals in the herd that are less than 18 months of age and were not born into the herd, except those animals that are less than 18 months of age and originate directly from a currently accredited herd for bovine tuberculosis.

• In any area of a provisionally consistent State other than a recognized management area, testing of all animals within a herd that are 12 months of age or older, as well as all animals in the herd that are less than 12 months of age and were not born into the herd, except those animals that are less than 12 months of age and originate directly from a currently accredited herd for bovine tuberculosis.

• In any area of an inconsistent State and in a recognized management area for bovine tuberculosis, testing of all animals within a herd that are 6 months of age or older, as well as all animals in the herd that are less than 6 months of age and were not born into the herd, except those animals that are less than 6 months of age and originate directly from a currently accredited herd for bovine tuberculosis.

We would exempt sexually neutered animals from herd tests for brucellosis because there is no scientific evidence suggesting they can transmit brucellosis.

The minimum testing ages specified within this definition correlate to the degree of risk of exposure to brucellosis or bovine tuberculosis that we would associate with the area in which the herd resides. We encourage all interested persons to review this definition within the context of subsequent discussions in this proposed rule regarding our proposed State and Tribal classification system (see ''*State or Tribal classifications (§ 76.3)*'' below) and recognized management areas (see ''*Recognized management areas (§ 76.5)*'' below).

We would define *immediate slaughter* as consignment directly to a recognized slaughtering establishment. In proposed §§ 76.14 and 76.15, we would allow cattle and bison to be moved interstate without testing for brucellosis or bovine tuberculosis from States and Tribes with the lowest status for these diseases, inconsistent, provided that the animals are destined for immediate slaughter.

We would define *interstate certificate of veterinary inspection (ICVI)* in a manner that is similar to the definition currently found in parts 77 and 78. However, whereas the current definition specifies that a document other than an ICVI may be used in order to provide an alternative to typing or writing individual animal identification on an ICVI, but still requires an ICVI to accompany this document, we would allow a document to take the place of an ICVI altogether, provided that the following conditions are met:

• The document is agreed upon by the shipping and receiving States or Tribes as an acceptable alternative to an ICVI;

• The document is a State or Tribal form or APHIS form that requires individual identification of animals;

• Each copy of the document identifies each animal to be moved, but any information pertaining to other animals, and any unused space on the document for recording animal identification, is crossed out in ink;

• The following information is written in ink in the identification column on the original and each copy and is circled or boxed, also in ink, so that no additional information can be added: The name of the document and either the unique serial number on the document or, if the document is not imprinted with a serial number, both the name of the person who prepared the document and the date the document was signed; and

• A copy of the document accompanies the program animals during interstate movement.

During the comment period for the rule that proposed to establish animal identification requirements for livestock moving interstate (76 FR 50082–50110, Docket No. APHIS–2009–0091), several commenters urged us to consider whether ''event passports'' and other similar documents could be used in lieu of ICVIs for animals, such as rodeo steers, that move frequently in interstate commerce. The rule that finalized that proposal specified, in its preamble, that such documents could be used in lieu of ICVIs. Our proposed definition would also allow such documents to be used.

We would define *location identification (LID) number* and *premises identification number (PIN)* as these terms are currently defined in parts 77 and 78, with the following modification: We would remove references to group identification of livestock from the definitions. We would do this because proposed part 76 would not allow for group identification of program animals.

We would define *management area* as a clearly delineated geographical area in which a State or Tribe has detected brucellosis or bovine tuberculosis, has determined that there is a risk of transmission of brucellosis or bovine tuberculosis to program animals, and has taken or proposes to take measures to control the spread of the brucellosis or bovine tuberculosis within and from the area and/or to eradicate the disease within the area. We discuss management areas at length below, in our discussion of proposed § 76.5.

We would define *official brucellosis vaccination program* as a brucellosis vaccination program that consists of, at a minimum:

• Vaccination of program animals with an official *Brucella* vaccine, which we would define as a vaccine for brucellosis that has been approved by the Administrator and produced under license of USDA;

• Tattooing to specify the animals' vaccination status; and

• Identification of the animals with an official eartag designed to specify the animals' vaccination status.

We would define *officially identified:*

• For cattle and bison, as identified by means of an official eartag.

• For captive cervids, as identified by an official eartag, by a tattoo containing an official identification number, or by other identification devices acceptable to APHIS and the shipping and receiving States or Tribes.

With regard to cattle and bison, we recognize that parts 77 and 78 currently allow other identification devices to be used as official identification. However, the regulations in those parts were issued during a time when there were not minimal national standards within 9 CFR for identification of cattle and bison that move in interstate commerce. Thus, the official identification requirements in parts 77 and 78 had to function as those standards for the cattle and bison industries within the United States. Accordingly, because the

requirements had to be broadly applicable, we allowed them to incorporate a degree of flexibility regarding the types of identification we would authorize as official identification.

However, 9 CFR now contains minimal national standards for identification of cattle and bison that move in interstate commerce, in part 86; these were added in 2013 (78 FR 2040–2075; Docket No. APHIS–2009–0091). We believe that the identification requirements in that part are sufficient for most cattle and bison that are moved in interstate commerce; hence, we would not include official identification requirements for those animals in part 76, and would instead instruct persons to consult part 86 for the relevant identification requirements. We would only specify identification requirements in part 76 for classes of animals that we believe present a higher-than-average risk of transmitting brucellosis or bovine tuberculosis to other animals. We believe that it is important to be able to effectively trace the movement of such animals in interstate commerce. Because official eartags contain unique identifiers and are tamper-evident, we consider them to provide the most reliable means of achieving this degree of traceability.

While 9 CFR part 86 contains minimal national standards for identification of cattle and bison that move in interstate commerce, it currently defers to part 77, which we are proposing to remove from the regulations, for official identification requirements for captive cervids. Part 77 currently allows captive cervids to be officially identified by means of an official eartag, a brand, or a tattoo providing unique identification of the cervid.

However, we are not aware of any captive cervid producers who brand their cervids for purposes of official identification. Moreover, we are aware of a number of identification devices, such as subcutaneous RFID transponders, that could be used for unique identification of captive cervids. Thus, our proposed definition of *officially identified* for captive cervids would not refer to brands, but would allow for such alternate devices when agreed upon by APHIS and the shipping and receiving States or Tribes to constitute such official identification.

We would define *official seal* as a serially numbered, metal or plastic strip, consisting of a self-locking device on one end and a slot on the other end, which forms a loop when the ends are engaged and which cannot be reused if opened, or a serially numbered, self-locking button. Current definitions of *official seal* within 9 CFR do not specify that a strip used for an official seal may be plastic, and do not allow a serially numbered, self-locking button to be used in lieu of such a strip. However, we have long used both plastic strips and self-locking buttons to seal means of conveyance containing infected, reactor, suspect, or exposed animals, and have found such seals to be as reliable as metal strips.

We would define *official test* as any test that is approved by the Administrator for determining the presence or absence of brucellosis or bovine tuberculosis in program animals that is conducted and reported by an official tester. If an official test is applied to a program animal, it would have to be identified by means of an official eartag. If this eartag uses the National Uniform Eartagging System, one of the official identification systems that has been approved by APHIS, the eartag would have to indicate the State or Tribe in which it was applied; if it uses the Animal Identification Number system, another approved official identification system, it would have to indicate the premises on which it was applied. Finally, if an animal that is tested already has such an eartag, the information on this eartag would have to recorded by the tester. These provisions regarding unique identification of tested animals would codify long-standing Agency policies that we consider necessary to maintain accurate records regarding the application of official tests for program purposes.

We would define *official tester* as any person associated with the conducting and reporting of official tests within an official testing laboratory, or any person authorized by the Administrator to conduct and report official tests outside of a laboratory environment. Proposed § 76.17 would contain the conditions under which the Administrator may authorize a person to conduct and report official tests outside of a laboratory environment.

We would define *official testing laboratory* as a laboratory approved by the Administrator in accordance with part 76 to conduct official tests. Proposed § 76.17 would contain this laboratory approval process.

We would define *owner* as any person who has legal or rightful title to program animals whether or not they are subject to a mortgage. This definition would mirror the definition of *owner* currently provided in parts 50, 51, and 79 of 9 CFR.

We would define *permit for movement of restricted animals* as a document that is issued by an APHIS representative, State or Tribal representative, or accredited veterinarian and that authorizes the restricted interstate movement of livestock to certain specified destinations. In proposed § 76.10, we would require this document, which is currently VS Form 1–27, to accompany reactor, suspect, and exposed program animals that are moved interstate.

We would define *Program Standards document* as a document providing guidance related to the regulations contained in part 76. Substantive changes to Program Standards document would be announced through notices published in the **Federal Register**. These notices would request public comment on the changes.

We would define *qualified accredited veterinarian* as that term is defined in 9 CFR part 160.

We would define *reactor* as:

- For brucellosis, a program animal that has had non-negative test results to an official test such that an epidemiologist designated by the District Director has determined that there is a high likelihood that the animal is infected with brucellosis, and a low likelihood of false positive test results.
- For bovine tuberculosis, a program animal that has had non-negative test results to an official test such that an epidemiologist designated by the District Director has determined that further action is warranted to make a final determination regarding the animal's disease status.

We believe these differing definitions for *reactor* to be warranted because, while reactors for bovine tuberculosis have usually tested non-negative to both an official screening test and secondary (corroboratory) test and must be taken to necropsy or slaughter for a final determination of disease status, reactors for brucellosis often are classified based on test results to a screening test that fell within parameters that strongly suggested the presence of brucellosis in the animal.

We would define *responsible person* as the individual who is immediately responsible for implementation and maintenance of an animal health plan within a State or Tribe, who is authorized to amend the plan as circumstances warrant, and who will assume responsibility for the State or Tribe's compliance with all provisions of the plan and all requirements in part 76.

We would define *spayed heifers* as sexually neutered female cattle or bison, and would define *steers* as sexually neutered male cattle or bison.

We would define *specifically approved stockyard* as premises where program animals are assembled for sale purposes and which meet the standards set forth in § 71.20 and are approved by APHIS. This definition is substantively similar to the definition currently found in part 78, but would add a clarification, currently absent in that definition, that all specifically approved stockyards must be approved by APHIS. Proposed § 76.10 would allow reactor, suspect, and exposed program animals to be moved interstate to specifically approved stockyards, among other approved locations.

We would define *State or Tribal animal health official* as the State or Tribal official responsible for livestock and poultry disease control and eradication programs in a State or Tribe, and would define *State or Tribal representative* as an individual employed in animal health work by a State or Tribe, or a political division of a State or Tribe, and authorized by that State or Tribe to perform the function involved. These definitions would be modeled on the definitions of *State animal health official* and *State representative* that are currently found in multiple parts within 9 CFR, but would reflect the fact that we would now authorize a Tribe to submit an animal health plan and request a brucellosis or bovine tuberculosis classification apart from the State in which the Tribal lands are located.

We would define *suspect* as a program animal that has had non-negative test results to an official test for brucellosis or bovine tuberculosis that lead an epidemiologist designated by the District Director to determine that the animal should not be classified as a reactor, but cannot be classified as free of brucellosis or bovine tuberculosis.

Unless the Administrator specifies or approves an alternate testing age, *test-eligible animal* would mean:

- For brucellosis, all sexually intact program animals in a herd that are 6 months of age or older, and all program animals in the herd that are less than 6 months of age and were not born into the herd, except those program animals that are less than 6 months of age and originate directly from an accredited herd for brucellosis.
- For bovine tuberculosis, all program animals in a herd that are 12 months of age or older, and all program animals in the herd that are less than 12 months of age and were not born into the herd, except those program animals that are less than 12 months of age and originate directly from an accredited herd for bovine tuberculosis; except that, if the herd is located on a calf raiser's premises, all program animals in the herd that are 2 months of age or older are considered test-eligible for bovine tuberculosis.

We consider a definition of *test-eligible animal* to be necessary because, in proposed § 76.7, each protocol for an epidemiological investigation would require States and Tribes to determine the disease status of test-eligible animals in certain herds.

We recognize that currently, in § 78.1, sexually intact cattle and bison are not considered test-eligible for brucellosis until they are at least 18 months of age. However, in part 78, the term test-eligible is applied in a generic sense to animals that are sexually mature and sexually intact. We agree that, in the absence of a known disease risk, 18 months of age is an appropriate threshold for test-eligibility for brucellosis within the United States.

However, in proposed part 76, we would reserve the term *test-eligible* for animals in herds that may have harbored or come in contact with a brucellosis- or bovine tuberculosis-infected animal, and that therefore could potentially be affected with brucellosis and bovine tuberculosis. In such instances, there is a known disease risk, the infected animal, and it would be prudent to determine the disease status of all animals in the herd that could potentially be infected with brucellosis or bovine tuberculosis because of that disease risk. Because animals as young as 6 months of age may transmit brucellosis, we would consider them test-eligible for the purposes of proposed part 76.

Authority of the Administrator (§ 76.1)

Proposed § 76.1 would state that, notwithstanding the provisions of part 76, the Administrator is authorized pursuant to the AHPA to prohibit or restrict the movement in commerce of any animals, if the Administrator considers that prohibition or restriction to be necessary to prevent the dissemination of brucellosis or bovine tuberculosis within the United States. It would further state that, pursuant to the Act, the Administrator may also hold, seize, quarantine, treat, destroy, dispose of, or take other remedial action with respect to any animal, article, or means of conveyance that is moving or has moved in interstate commerce, if the Administrator has reason to believe that animal, article, or means of conveyance may carry, have carried, or have been affected with or exposed to brucellosis or bovine tuberculosis at the time of interstate movement.

While this section would be a restatement of our authority under the AHPA, we consider it necessary to include it within proposed part 76. This is because the regulations in part 76 would be predicated on the low prevalence for brucellosis and bovine tuberculosis within the United States, and would provide adequate mitigations for the majority of instances in which cattle, bison, and captive cervids are moved interstate. There may, however, be certain unlikely scenarios, such as a significant outbreak of brucellosis or bovine tuberculosis within a State or Tribe, which the regulations in part 76 would not be adequate to address.

If such a scenario were to occur, the Administrator would take such action as he or she deems appropriate to address the risk that cattle, bison, or captive cervids moved interstate from the State or Tribe may present of disseminating brucellosis or bovine tuberculosis. This could include issuing an order placing additional restrictions on the interstate movement of cattle, bison, or captive cervids from the State or Tribe, or issuing an order prohibiting the movement of cattle, bison, or captive cervids from that State or Tribe until the outbreak is addressed.

Animal Health Plan Requirements (§ 76.2)

The State and Tribal classification system for brucellosis and bovine tuberculosis within proposed part 76 would be based on whether a State or Tribe has drafted an animal health plan to address the diseases, whether APHIS has approved this plan, and whether the State or Tribe has implemented and is performing the activities and enforcing the measures specified in the plan. (We consider activities to be all actions that a State or Tribe specifies in its animal health plan that are not mitigation measures. We consider measures to be those mitigations specified within the plan.) Proposed § 76.2 would describe the process for States or Tribes to submit an animal health plan, the categories of information that must be contained in any animal health plan, the review process for animal health plans, the notice-based process by which we would make the plans publicly available for review and comment, our follow-up actions on any such notice, the process for requesting amendments to an animal health plan, and providing for compliance reviews and audits following approval of an animal health plan.

Proposed paragraph (a) of § 76.2 would provide that, in order for a State or Tribe to be given the highest classification, consistent, or the intermediate classification, provisionally consistent, in our new

classification system, a State or Tribe would have to submit an animal health plan to APHIS via the mail as provided within the Program Standards document, or submit the plan electronically as specified within the Program Standards document. (Proposed § 76.3 describes the State and Tribal classification system at length.)

At a minimum, in order to be considered complete, each animal health plan would have to contain the following categories of information:

- Confirmation that the State or Tribe has a legal and regulatory basis for the activities and measures specified within the plan.
- A description of the organization and infrastructure of the animal health and wildlife authorities within the State or Tribe. The description would have to include the animal health and wildlife work force within the State or Tribe that is available to implement or perform activities and maintain and enforce measures specified within the animal health plan, and would have to demonstrate that the State or Tribe has sufficient resources to implement, maintain, and enforce its animal health plan.
- The name and contact information for the responsible person that the State or Tribe has designated to oversee implementation, performance, and enforcement of activities and measures carried out under the plan within the State or Tribe, and the name and contact information for the person that the State or Tribe has designated to oversee implementation, performance, and enforcement of wildlife activities and measures carried out under the plan. States or Tribes could designate a single individual to serve in multiple roles.
- A description of program animal demographics within the State or Tribal lands. This description would have to include the approximate number and types of program animal herds within the State or Tribal lands, the approximate number of animals in those herds, and the approximate number and geographic distribution of any animal concentration points within the State or Tribal lands. (The Program Standards document would provide examples of what would constitute an animal concentration point.)
- A description of the surveillance activities for brucellosis or bovine tuberculosis in animals within the State or Tribal lands that are being conducted or would be conducted under the animal health plan. (We would include a footnote, footnote 1, directing individuals to proposed § 76.6 for minimum requirements regarding surveillance activities conducted under an animal health plan.)
- A description of the known sources of brucellosis or bovine tuberculosis that pose a risk of disease introduction into program animals within the State or Tribal lands, and an assessment of the likelihood of transmission of brucellosis or bovine tuberculosis from these sources to program animals within the State or Tribal lands. This description would have to include each of the following:
  - The approximate number of herds or wildlife populations within the State or Tribal lands that are known sources of brucellosis or bovine tuberculosis, and the approximate number of animals in these herds or populations;
  - The approximate prevalence of brucellosis or bovine tuberculosis infection in those populations, the geographic distribution of the populations within the State or Tribal lands, and any other factors that make the populations a potential source of brucellosis or bovine tuberculosis transmission to program animals within the State or Tribal lands;
  - The potential for exposure of program animals within the State or Tribal lands to these known source populations;
  - Factors, other than mitigation measures that are or would be implemented by the State or Tribe, that may influence this potential for exposure (the Program Standards document would provide illustrative examples of such factors); and
  - An assessment of the likelihood of transmission of brucellosis or bovine tuberculosis from known source populations to program animals within the State or Tribal lands.
- If the State or Tribe has identified known source populations of brucellosis or bovine tuberculosis that pose a risk of disease introduction into program animals within the State or Tribal lands, a description of the measures that the State or Tribe has implemented or would implement to prevent and/or mitigate the risk that program animals within the State or Tribal lands will become infected with brucellosis or bovine tuberculosis.
- A description of the epidemiological investigation and affected herd management activities that the State or Tribe has taken or would take in response to occurrences of brucellosis and bovine tuberculosis within program animals in the State or Tribal lands. (We would include a footnote, footnote 2, directing individuals to proposed § 76.7 for minimum requirements regarding epidemiological investigation and affected herd management activities conducted under an animal health plan.)

We recognize that the draft template for an animal health plan in the Program Standards document contains two additional information categories, one pertaining to the bovine tuberculosis program certification offered to qualified accredited veterinarians within the State or Tribe, the other to State and Tribal oversight of the official tests administered by these veterinarians. The information a State or Tribe supplies within these categories would not be directly included in our evaluation of the animal health plan for purposes of determining whether or not to propose to approve it, but rather to aid in the implementation and maintenance of our national program certification for bovine tuberculosis. We discuss this program certification at greater length below, in our discussion under the heading ''*Official tests for brucellosis and bovine tuberculosis, official testing laboratories, and official testers (§ 76.17).*''

Proposed paragraph (b) of § 76.2 would state that APHIS will review the plan submitted by the State or Tribe for completeness. This initial review would ensure that the State or Tribe has provided information in each of categories listed above, or has provided an explanation regarding why the information category is not applicable to the State or Tribe.

Once we determine a plan to be complete, APHIS would conduct formal review and evaluation of the plan. First, we would determine whether the State or Tribe has identified sources of brucellosis or bovine tuberculosis within the State and Tribal lands. If the State or Tribe has stated that no sources of the disease are known to exist in the State or Tribal lands, we would expect the State or Tribe to provide a justification in support of this statement, including documentation of the surveillance or other activities that led to this conclusion. If we consider the statement to be justified, we would evaluate the epidemiological investigation and affected herd management activities that the State or Tribe states it would take in responses to occurrences of brucellosis or bovine tuberculosis within program animals in the State or on Tribal lands, whether the State or Tribe has legal and regulatory authority for these activities, and whether the State or Tribe has sufficient personnel to implement and, if necessary, effectively carry out these activities and enforce these measures.

If the State or Tribe does identify sources of brucellosis or bovine

tuberculosis in the State or Tribal lands, we would evaluate the likelihood of transmission of brucellosis or bovine tuberculosis from known source populations to program animals in light of the information provided by the State or Tribe regarding the prevalence of the diseases within the sources, potential for exposure of program animals to these sources, and factors that may influence this exposure. We would also evaluate the mitigation measures specified by the State or Tribe to determine whether they are adequate to prevent transmission of brucellosis or bovine tuberculosis from source populations to program animals, and would evaluate the surveillance activities specified by the State or Tribe to determine whether they would be sufficient to detect changes in prevalence levels of disease in the source population, or the presence of disease in program animals exposed to these source populations. Finally, we would evaluate whether the State or Tribe has adequate legal and regulatory authority and personnel to carry out the activities specified within the plan.

If this rule is finalized, it is possible that certain smaller States and Tribes would wish to coordinate brucellosis or bovine tuberculosis program activities or share personnel with neighboring States or Tribes. Guidance regarding how these consolidated efforts should be described in the State or Tribe's animal health plan is provided in the Program Standards document.

There could be instances when APHIS lacks technical expertise to evaluate certain provisions within a State or Tribe's animal health plan. For example, if a State or Tribe identifies free-ranging wildlife as a source population of brucellosis or bovine tuberculosis within the State or Tribal lands, but states that the movement patterns of the wildlife effectively preclude contact with program animals within the State or Tribal lands, that the risk of transmission of brucellosis or bovine tuberculosis from those wildlife populations to these program animals is correspondingly remote, and that mitigation activities to address this risk are therefore not necessary, it is possible that APHIS would not possess the knowledge of the movement patterns necessary to evaluate this claim. In such instances, APHIS would share a copy of the plan with Federal, State, Tribal, and/or industry experts for technical review and comment regarding the issue or issues for which we lack expertise.

Upon conclusion of review of the plan, we would make a determination regarding whether or not to propose to approve the plan. If we determine not to propose to approve the plan, we would contact the State or Tribe that submitted the plan and set forth the deficiencies identified in the plan that preclude us from proposing to approve it.

Proposed paragraph (c) of § 76.2 would provide that we could propose to approve a State or Tribal animal health plan unconditionally, or on the condition that the State or Tribe implement certain provisions of its plan within a specified period of time that it cannot implement immediately upon approval of the plan. We anticipate that this latter, conditional approval would be reserved for plans that set forth what we consider to be adequate activities and effective measures to address the risk of introduction of brucellosis or bovine tuberculosis into program animals within the State or Tribal lands, but that indicate that the State or Tribe will need to amend laws and/or regulations in order to have sufficient legal and regulatory authority to implement the plan. We request specific comment regarding whether there are other scenarios that should lead us to approve a plan conditionally.

Regardless of whether we propose to approve a plan unconditionally, or on the condition that the State or Tribe implement certain provisions of its plan within a specified period of time, we would publish a notice in the **Federal Register** announcing our proposed approval of the plan and making the plan available for public review and comment.

Prior to issuance of this notice, we would consult with the responsible person identified in the plan in order to ensure that the State or Tribe is prepared for us to make the plan, proposed amendments to the plan, and all reports required by the regulations in part 76 publicly available. We consider this provision to be necessary because, as we stated in the draft regulatory framework document, and as several commenters on that document concurred, transparency regarding the regulatory activities for brucellosis and bovine tuberculosis that a State or Tribe is conducting would be a foundation for the success and acceptance of the program both domestically and internationally.

Proposed paragraph (d)(1) of § 76.2 would set forth the determinations that we could make following a notice proposing unconditional approval of an animal health plan. If no comments are received on this notice, or if the comments received do not affect APHIS' conclusion that a plan may be approved unconditionally, we would publish a subsequent notice in the **Federal Register** announcing that the plan has been approved unconditionally, and designating the State or Tribe as a consistent State or Tribe.

If the comments received on the notice suggest the plan should be approved, but that the State or Tribe cannot implement certain provisions of its animal health plan immediately upon approval of the plan, and after reviewing the information, we agree, we would publish a subsequent notice in the **Federal Register** announcing that the plan has been approved conditionally, and designating the State or Tribe as a provisionally consistent State or Tribe. This notice would also specify the provisions of the plan that APHIS has determined cannot be implemented immediately and the time period in which they would have to be implemented. The notice could also specify restrictions on the interstate movement of program animals or other program requirements that would apply to the State or Tribe while it is in provisionally consistent status.

Finally, if the comments received suggest that the plan should not be approved, and, after reviewing the information, we agree, we would publish a subsequent notice in the **Federal Register** describing the comments that we received, our reevaluation of the plan in light of those comments, and our reasons why we cannot approve the plan.

Proposed paragraph (d)(2) of § 76.2 would set forth the determinations that we could make following a notice proposing conditional approval of an animal health plan. If no comments are received on the notice, or if the comments received do not affect our conclusion that the plan may be approved on the condition that the State or Tribe implement certain provisions of its plan within a specified period of time that it cannot implement immediately upon approval of the plan, we would publish a subsequent notice in the **Federal Register** announcing that the plan has been approved conditionally, and designating the State or Tribe as a provisionally consistent State or Tribe. This notice would specify the provisions of the plan that we have determined cannot be implemented immediately and the time period in which they must be implemented. The notice could also specify restrictions on the interstate movement of program animals or other program requirements that apply to the State or Tribe while it is in provisionally consistent status.

Alternatively, if the comments received suggest that the plan should not be approved, and, after reviewing the information, we agree, we would

publish a subsequent notice in the **Federal Register** describing the comments that we received, our reevaluation of the plan in light of those comments, and our reasons why we cannot approve the plan.

Proposed paragraph (e) would provide that, if we approve a State or Tribal animal health plan conditionally, designate the State or Tribe as provisionally consistent, and specify the period of time in which the State or Tribe must implement all provisions of its plan, we would publish a subsequent notice in the **Federal Register** announcing whether the State or Tribe has implemented all provisions of the plan within that period of time. If the State or Tribe has, the notice would announce that we consider the plan unconditionally approved, and have redesignated the State or Tribe as a consistent State or Tribe. If the State or Tribe has not, the notice would announce that we have withdrawn approval of the plan, and have redesignated the State or Tribe as an inconsistent State or Tribe. This second notice would be necessary in order to ensure that States and Tribes take appropriate action to be able to implement all provisions of their animal health plan in a timely manner.

Proposed paragraph (f) of § 76.2 would contain the processes for amendments to an animal health plan. Proposed paragraph (f)(1) of § 76.2 would provide that, if APHIS determines that the activities or measures specified in an approved animal health plan no longer correspond to the risk of spread of brucellosis or bovine tuberculosis, for example, if sources of brucellosis or bovine tuberculosis are discovered in a State or on Tribal lands in which no sources were previously known to exist, we would make ongoing approval of the plan contingent on the State or Tribe amending the plan in a manner that we approve of. The amended plan would have to be submitted to APHIS via the mail as provided within the Program Standards document, or electronically as provided in the Program Standards document.

Alternatively, if a State or Tribe wishes to amend its animal health plan, the State or Tribe would have to submit proposed amendments to the plan to us via the mail or electronically as provided in the Program Standards document. Amendments proposed by the State or Tribe would be subject to the notice-based approach specified in proposed paragraphs (b) through (d) of proposed § 76.2, although we anticipate that provisional approval of an amendment would be used sparingly, if at all.

Proposed paragraph (g) would state that APHIS reserves the right to conduct a review of States or Tribes at any point for compliance with their approved animal health plan. Such a compliance review could include site visits and/or documentation review.

State or Tribal Classifications (§ 76.3)

Proposed § 76.3 would contain the revised three-tier State and Tribal classification system of ''consistent,'' ''provisionally consistent,'' and ''inconsistent.'' It would also contain the considerations that would lead us to initially classify a State or Tribe as a consistent State or Tribe, and those considerations that may lead us to redesignate the State or Tribe to a lower classification. Finally, it would specify the measures that a State or Tribe must take in order to regain consistent status following a redesignation.

Proposed paragraph (a) of § 76.3 would provide that each State is classified as consistent, provisionally consistent, or inconsistent for brucellosis, and consistent, provisionally consistent, or inconsistent for bovine tuberculosis. It would also provide that Tribes are classified as consistent, provisionally consistent, or inconsistent for these diseases, provided that they have submitted a Tribal animal health plan to APHIS and we have approved it.

Proposed paragraph (b) of § 76.3 would set forth the conditions that would lead us to initially designate a State or Tribe as consistent, provisionally consistent, or inconsistent.

We would initially designate a State or Tribe as a consistent State or Tribe for brucellosis and bovine tuberculosis if we approve the State or Tribe's animal health plan unconditionally, that is, without provisos, in accordance with the process set forth in paragraph (d) of proposed § 76.2.

We would initially designate a State or Tribe as a provisionally consistent State or Tribe if we approve the State or Tribe's animal health plan on the condition that it implement certain provisions of its plan within a specified period of time that it cannot implement immediately upon approval of the plan, in accordance with the process set forth in paragraph (d) of proposed § 76.2.

We anticipate that, if this rule is finalized, we would receive animal health plans from all 50 States. We also anticipate that, even if commenters disclose deficiencies in the initial iteration of a State's plan that preclude us from approving it, a subsequent iteration of the plan would be approved.

However, in the event that a State elects not to draft an animal health plan, there would come a time when we would have to designate the State as inconsistent for brucellosis and bovine tuberculosis in order to fully implement the State and Tribal classification system and ascribe the appropriate regulatory requirements for the interstate movement of cattle and bison from that State (see proposed §§ 76.14 and 76.15). The date on which this would occur would be announced through a notice in the **Federal Register**.

If we do not receive an animal health plan from a Tribe, the Tribe would be considered part of the State in which the lands reside for purposes of the regulations in part 76. Hence we would not initially designate a Tribe as inconsistent for opting not to submit an animal health plan to APHIS.

Proposed paragraph (c) would contain the conditions that could lead us to redesignate a State or Tribe to a lower classification. Proposed paragraph (c)(1) would contain conditions that may lead us to redesignate a consistent State or Tribe as a provisionally consistent State or Tribe. We could redesignate the State or Tribe as provisionally consistent if:

- The State or Tribe fails to implement or perform an activity or maintain a measure specified within its animal health plan, and we determine that this failure may result in the spread of brucellosis or bovine tuberculosis.
- The State or Tribe fails to submit an annual report as specified in paragraph (a) of § 76.4.
- The State or Tribe fails to submit an initial epidemiological investigation situation report within 14 days of the period of time specified in paragraph (c) of § 76.4 for submitting such a report.
- The State or Tribe fails to submit an updated epidemiological investigation situation report as specified in paragraph (d) of § 76.4.
- On more than one occasion, the State or Tribe fails to submit a closing report as specified in paragraph (e) of § 76.4.
- The State or Tribe fails to meet national surveillance levels as these are specified within the National Surveillance Plans for brucellosis or bovine tuberculosis or as these are specified within an alternate State or Tribal plan that has been approved by APHIS. (We would include a footnote, footnote 3, directing individuals to paragraph (a) of § 76.6 for further information regarding this regulatory requirement.)
- The State or Tribe fails to conduct targeted surveillance of wildlife source

populations as specified in paragraph (b)(1) of § 76.6.

• The State or Tribe fails to conduct targeted surveillance of at-risk program animals as specified in paragraph (b)(2) of § 76.6.

• The State or Tribe has failed to conduct an investigation of a program animal with non-negative test results for brucellosis in accordance with paragraph (a) of § 76.7, or to send a report regarding those activities as specified in paragraph (b) of § 76.4.

Many of these conditions for redesignation would hinge on a State or Tribe's failure to meet certain regulatory requirements of part 76 either fully or in a timely fashion. Accordingly, we will discuss our rationale for these conditions below, within the context of our discussion of the regulatory requirements themselves. However, generally speaking, we would redesignate a State or Tribe as provisionally consistent if the State or Tribe fails to take or document an action that would otherwise demonstrate that it has fully implemented its animal health plan and is performing the activities and maintaining the measures specified in its animal health plan.

Proposed paragraph (c)(2) of § 76.3 would contain the conditions that may lead us to redesignate a State or Tribe as an inconsistent State or Tribe.[9] We could redesignate the State or Tribe as inconsistent if:

• The State or Tribe fails to implement or perform an activity or maintain a measure specified within its animal health plan, or fails to amend the plan in response to a request from APHIS, and APHIS determines that this failure has resulted or may result in the spread of brucellosis or bovine tuberculosis.

• On more than one occasion, the State or Tribe fails to submit an annual report as specified in paragraph (a) of § 76.4.

• On more than one occasion, the State or Tribe fails to submit an initial epidemiological investigation situation report within 14 days of the period of time specified in paragraph (c) of § 76.4 for submitting such a report.

• On more than one occasion, the State or Tribe fails to submit an updated epidemiological investigation situation report as specified in paragraph (d) of § 76.4.

• APHIS has terminated recognition of the State or Tribe's management area.

• The State or Tribe refuses to participate in or otherwise conduct surveillance as specified in paragraph (a) of § 76.6.

• On more than one occasion, the State or Tribe has failed to conduct an investigation of a program animal with non-negative test results for brucellosis in accordance with paragraph (a) of § 76.7, or to send a report regarding those activities as specified in paragraph (b) of § 76.4.

• The State or Tribe fails to conduct epidemiological investigations as specified in paragraph (b) of § 76.7.

• The State or Tribe fails to conduct affected herd management as specified in paragraph (e) of § 76.7.

Like the conditions that could lead us to redesignate a consistent State or Tribe as provisionally consistent, most of the conditions that could result in us redesignating the State or Tribe as inconsistent would stem from the State or Tribe's failure to meet certain regulatory requirements of part 76, and, therefore, will be discussed within the context of those requirements. However, as a general rule, we would redesignate a consistent State or Tribe as inconsistent if we determine that the State or Tribe has failed to take actions necessary to prevent brucellosis or bovine tuberculosis from being transmitted to program animals within the State or Tribe or necessary in order to prevent infected program animals from being moved interstate without appropriate mitigations. We would also redesignate the State or Tribe as inconsistent if, because of the State or Tribe's repeated failure to submit required reports, we lacked sufficient information regarding regulatory activities conducted in the State or Tribe, and thus had to consider program animals moved interstate from the State or Tribe to present an unknown risk of transmitting brucellosis and/or bovine tuberculosis to other animals.

Proposed paragraph (c)(3) of § 76.3 would contain conditions that could lead us to redesignate a provisionally consistent State or Tribe as inconsistent. In addition to the conditions that could lead us to redesignate a consistent State or Tribe as inconsistent, if the State or Tribe fails to implement provisions of its animal health plan or take required remedial measures within the period of time specified by APHIS for implementing these provisions or taking these measures, we would redesignate the State or Tribe as an inconsistent State or Tribe.

Proposed paragraph (d)(1) of § 76.2 would contain our notice-based redesignation process. It would state that, when APHIS redesignates a consistent State or Tribe as a provisionally consistent State or Tribe, we would publish a notice in the **Federal Register** announcing this redesignation. The notice would also state the reason or reasons that led to the redesignation and the remedial measures we consider necessary for the State or Tribe to complete in order to regain consistent status.

As much as possible, the remedial measures that we would specify in the notice would directly correlate to the reason for the redesignation. For example, if a State or Tribe is delinquent in submitting its annual report, the notice would require the report to be submitted.

Depending on the reason for the redesignation, the notice could also specify restrictions on the interstate movement of program animals or other program requirements that would apply to the State or Tribe while it is in provisionally consistent status. For example, if a State or Tribe is able to determine one of the herds in which a program animal with a non-negative test for brucellosis has resided, but cannot determine whether this herd also represents the herd of origin for the animal, the notice may place restrictions on the interstate movement of that herd, pending further investigation of the matter.

It is possible that, because the conditions that could lead us to redesignate a consistent State or Tribe as provisionally consistent vary, while a State or Tribe is in provisionally consistent status for one reason, such as failing to conduct an investigation of a program animal with non-negative test results for brucellosis, the State or Tribe could act or fail to act in a manner that would have otherwise led us to redesignate it to provisionally consistent status, such as failing to turn in a required report. In such instances, we would publish a notice in the **Federal Register** announcing what has occurred, and specifying additional remedial measures that the State or Tribe must take to regain consistent status.

If a State or Tribe completes the remedial measures we require for it to regain consistent status, we would publish a notice in the **Federal Register** announcing that we have redesignated the State or Tribe as a consistent State or Tribe. If the State or Tribe fails to take the required remedial measures, we would publish a notice in the **Federal Register** announcing that we have redesignated the State or Tribe as an inconsistent State or Tribe. Thus, provisionally consistent status would be

[9] We acknowledge that many of these conditions are substantially similar to those that could result in redesignation of a State to provisionally consistent status. A side-by-side comparison of the conditions for redesignation of a State to provisionally consistent and inconsistent status is found on pages 33–36 of the Program Standards document that accompanies this proposed rule.

a temporary classification; no State or Tribe would be classified as provisionally consistent indefinitely.

Whenever we immediately redesignate a consistent or provisionally consistent State or Tribe as an inconsistent State or Tribe, we would publish a notice in the **Federal Register** announcing this redesignation. In order for such a State or Tribe to regain consistent status, it would have to take appropriate remedial measures, as determined by APHIS, to address the issue or issues that led to redesignation to inconsistent status. It would also have to submit amendments to its animal health plan that reflect these measures, and submit any outstanding annual reports, initial investigation reports, initial or updated epidemiological investigation situation reports, and closing reports (see our discussion of proposed § 76.4 later in this document).

Finally, proposed paragraph (f) of § 76.3 would provide that lists of all consistent, provisionally consistent, and inconsistent States and Tribes would be located on the APHIS Web site. The lists would also be available at district VS offices.

Reporting Requirements (§ 76.4)

Proposed § 76.4 would contain reporting requirements for the consolidated brucellosis and bovine tuberculosis program. Proposed paragraph (a) of § 76.4 would provide that, within 60 days of the end of the reporting period (September 30), States would have to submit a completed annual report form to APHIS as provided in the Program Standards document.[10] This report form would provide us with information regarding the surveillance activities that the State has taken in the last reporting period.

Additionally, if a State has submitted an initial epidemiological situation report to us regarding detection of an affected herd within the State, but not submitted a corresponding closing report regarding this investigation (see below), we would require the State to submit additional information regarding epidemiological activities related to that incident undertaken during the reporting period within the annual report form. Finally, if the information contained in a State's animal health plan is no longer current, and the State has not already submitted proposed amendments to the plan to APHIS that incorporate these changes, the State would have to provide a summary of any changes to the information that have occurred during the reporting period along with the annual report form.

As we mentioned previously in this document, our approval of a State's animal health plan would depend on whether source populations of brucellosis or bovine tuberculosis exist within the State, and, if so, whether the State has specified adequate measures within the plan to address the risk that these sources present of spreading brucellosis and bovine tuberculosis to program animals. For States that do not have known source populations, and thus that do not have mitigation measures specified within their animal health plan, the activities summarized in the annual report form would provide us with evidence supporting the ongoing absence of such source populations and the corresponding lack of need for such mitigations. For States that have such populations, the annual report form would provide information regarding the efficacy of the State's mitigation measures in preventing the introduction of brucellosis and/or bovine tuberculosis into program animals. In a similar vein, by providing us with updated information regarding ongoing epidemiological investigations and, if necessary, updates to its animal health plan, a State would provide assurances to us that it is exercising due diligence in responding to disease outbreaks, and adequate maintenance and oversight of measures carried out under its animal health plan.

Without such information, we could determine that the risk that program animals moved interstate from the State present of transmitting brucellosis and/or bovine tuberculosis is uncertain or unknown. Hence, States that fail to submit an annual report form and supplementary updates in a timely fashion on one occasion could be redesignated to provisionally consistent status, and States that fail to do so on more than one occasion could be redesignated as inconsistent.

Proposed § 76.7 would contain requirements regarding epidemiological investigation activities that a State conducts. Because epidemiological investigations are conducted when animals are determined to be infected with or otherwise fail to test negative for a disease, in the absence of direct APHIS oversight of these investigations, regular reporting regarding the investigations would be of paramount importance to us in determining whether a State is accurately delineating the scope of a potential outbreak and taking adequate measures to preclude disease spread. Thus, proposed paragraphs (b) through (e) of § 76.4 would contain reporting requirements that pertain to epidemiological investigations.

Proposed paragraph (b) would provide that, whenever a State initiates an investigation of an animal with non-negative test results for brucellosis or an animal determined to be infected with brucellosis or bovine tuberculosis in accordance with proposed § 76.7, the State would have to provide a report regarding the investigation within 15 days of initiation of the investigation. Proposed paragraph (b) would differentiate between animals with non-negative test results for brucellosis and animals that are determined to be infected with brucellosis because secondary (corroboratory) tests to determine the presence or absence of brucellosis in program animals sometimes yield results that fall within the range of positive test results, but are sufficiently ambiguous to preclude the individuals conducting the test from making a determination that the animal is infected with brucellosis. We would not make such a differentiation for animals with non-negative test results for bovine tuberculosis, because such animals are customarily taken to necropsy for a determination regarding the presence or absence of infection.

Proposed paragraph (c) of § 76.4 would state that, whenever a State initiates an epidemiological investigation of an affected herd in accordance with § 76.7, the State must provide a report of that epidemiological investigation to APHIS within 15 days of the date when the State is notified that an animal from the herd has been determined to be infected with brucellosis or bovine tuberculosis.

Because, in the absence of such initial reports, APHIS would lack information regarding the discovery of known or potentially infected animals within a State, and thus could be unable to evaluate whether the State is acting in a manner that is likely to delineate the scope of disease infection, States that fail to submit such reports in a timely manner on one occasion could be redesignated as provisionally consistent, and States that fail to submit such reports in a timely manner on multiple occasions could be redesignated as inconsistent.

Epidemiological investigations often take several months to complete, and a particularly complex investigation may take several years. Additionally, activities that a State may take in the first 15 days of an investigation may be inconclusive. Therefore, proposed paragraph (d) of § 76.4 would provide that every 4 weeks following submission

[10] A draft template of the annual report form is found in Appendix 3 of the Program Standards document.

of an initial situation report or initial epidemiological situation report, and more frequently at the Administrator's request, a State would have to submit subsequent reports updating information in the initial situation report or epidemiological investigation situation report. (Generally speaking, we would require States to submit reports on a more frequent basis if the investigation was particularly complex, *e.g.,* when it encompassed many herds or animals or covered a large geographical area.)

Because these reports would help us determine whether a State is taking adequate measures to respond to a disease outbreak, failure to submit such updates on one occasion could result in redesignation to provisionally consistent status; failure to do so on more than one occasion could result in redesignation to inconsistent status.

Proposed paragraph (e) of § 76.4 would state that, within 60 days following the conclusion of an epidemiological investigation of an affected herd, a State must submit a closing report to APHIS. In proposed § 76.7, we consider an epidemiological investigation of an affected herd complete if a State identifies, places interstate and intrastate movement restrictions on, and, determines the disease status of all test-eligible animals in:

- Any herd into which program animals from the affected herd may have been moved;
- Any herd which program animals in the affected herd may have originated from or resided in; and
- Any herd, individual program animals, or other animals that are susceptible to brucellosis or bovine tuberculosis that may have commingled with or otherwise been exposed to the affected herd, as determined by the Administrator and communicated to the State.

Since a State that concludes an epidemiological investigation would have taken measures that we consider adequate to delineate the scope of disease infection in herds of program animals in the State, failure to submit a closing report, unlike failure to submit other reports, would not necessarily lead us to consider program animals in the State an unknown risk of transmitting brucellosis or bovine tuberculosis. Hence, failure to submit a timely closing report on one occasion would not necessarily result in redesignation to provisionally consistent status. However, failure to submit a closing report on more than one occasion could be indicative of greater regulatory lapses; accordingly, it would be likely to result in redesignation to provisionally consistent status.

As we mentioned previously in this document, proposed § 76.5 would allow States to request APHIS recognition of a management area for brucellosis or bovine tuberculosis within the State. Proposed paragraph (f) of § 76.4 would provide that additional reporting requirements for States with such areas are specified in paragraph (f) of § 76.5.

Proposed paragraph (g) of § 76.4 would state that, if a consistent State is redesignated as provisionally consistent, additional reporting requirements for the State may be specified in the notice in the **Federal Register** that announces such redesignation. For example, if a State is redesignated as provisionally consistent for failing to conduct adequate surveillance of wildlife source populations for brucellosis or bovine tuberculosis, we could require the State to provide periodic updates regarding implementation of this surveillance.

Proposed paragraph (h) of § 76.4 would state that the requirements in § 76.4 pertain to Tribes, provided that that they have submitted a Tribal animal health plan to APHIS for review and approval in accordance with the process set forth in § 76.2, and APHIS has approved the animal health plan. Otherwise, we would expect activities conducted on Tribal lands within a State to be reflected in any report that the State submits.

Recognized Management Areas (§ 76.5)

Bovine tuberculosis is known to exist in a portion of Michigan immediately south of the Upper Peninsula and in a portion of Michigan northeast of the Huron National Forest. Because bovine tuberculosis is endemic within wildlife in those areas, there are periodic detections of the disease in program animals in the areas, and Michigan has long had control measures in place to prevent the spread of bovine tuberculosis from these two areas. However, because part 77 relies on a prevalence-based State classification system, if Michigan were considered as a single geographical region, it would not have the highest classification for bovine tuberculosis, accredited-free, although the majority of the State has not detected bovine tuberculosis in program animals.

Hence, part 77 allows a State to request a different classification for zones in the State that have a higher prevalence for bovine tuberculosis than other areas of the State, provided, among other requirements, that the State conducts surveillance of animal species in the zone to detect bovine tuberculosis infection in those animals, has a regulatory framework in which detections of bovine tuberculosis in livestock or wildlife in the zone are reported to State animal health officials, demonstrates to APHIS that it has sufficient financial and legal resources to enforce the zone, and enters into a memorandum of understanding with APHIS regarding any other additional conditions for zone recognition that we determine necessary in order to approve a State's request.

Brucellosis is endemic in wildlife in a geographical area consisting of portions of Montana, Idaho, and Wyoming, referred to below as the Greater Yellowstone Area, or GYA. To prevent the spread of brucellosis from this area, we issued the December 2010 interim rule referenced previously in this document. This rule had the effect of requiring Montana, Idaho, and Wyoming to draft brucellosis management plans in which they specified surveillance of and mitigation measures for wildlife reservoirs within their portion of the GYA.

In the draft regulatory framework document, we proposed an approach that would have consolidated aspects of these two approaches to zoning. We proposed that, if brucellosis or bovine tuberculosis was detected in a region of the United States and the States or Tribes with land in that region were unable to eradicate the disease within a year, the States or Tribes would have to develop a long-term containment plan in order to retain consistent status. We proposed that the containment plan would have to be based on epidemiological information gathered from the outbreak regarding livestock or wildlife populations in the region and extent of disease within these livestock and wildlife populations. We also proposed that the plans would have to consider strategies such as herd testing of program animals within the region, movement restrictions on program animals moved out of the region, and traceability, *i.e.,* official identification and recordkeeping requirements, for these program animals to prevent the spread of disease from the region. Finally, we proposed that all containment plans would have to be eradication-based.

Commenters were generally supportive of the concept of long-term containment plans. However, several commenters had concerns with aspects of our proposed approach. Commenters pointed out that, under the approach, if a region that was covered by a containment plan encompassed a geographical area in multiple States, States could be held accountable for

regulatory lapses in a neighboring State. The commenters pointed out that a State has little authority regarding animal health activities conducted in other States, and that the approach in the framework document could result in States being reclassified to lower statuses for reasons beyond their control.

Similarly, commenters also pointed out that, while most State animal health authorities may monitor wildlife reservoirs of brucellosis or bovine tuberculosis, their authority to conduct such monitoring is limited to instances in which these reservoirs present a risk of transmitting disease to livestock in the State. Accordingly, they expressed concern that the approach in the document would require States to draft containment plans if brucellosis or bovine tuberculosis were discovered in wildlife, in the absence of any demonstrable risk of program animals becoming infected.

Several commenters stated that eradication of brucellosis or bovine tuberculosis in areas in which it has become endemic, particularly in wildlife populations, would prove difficult, if not impracticable, and suggested that containment plans would not necessarily have to be eradication-based to be effective.

Finally, several commenters suggested that States not be forced to draft containment plans, but, rather, have the option to do so upon determining that a containment plan would help prevent the spread of brucellosis or bovine tuberculosis within the State.

In light of these comments, proposed § 76.5 would establish a process for States or Tribes to request recognition of management areas for brucellosis or bovine tuberculosis in the State or Tribal lands. As we mentioned previously in this document, a management area would be a clearly delineated geographical area in which a State or Tribe has detected brucellosis or bovine tuberculosis, has determined that there is a risk of transmission of brucellosis or bovine tuberculosis to program animals, and has taken or proposes to take measures to control the spread of the brucellosis or bovine tuberculosis within and from the area and/or to eradicate the disease within the area.

Proposed paragraph (a) of § 76.5 would state that a State or Tribe may request APHIS recognition of a management area within the State or Tribal lands. Thus States and Tribes would not be required to request recognition of management areas, and could retain consistent status even if they elect not to establish a management area. However, if a source of brucellosis or bovine tuberculosis is known to exist in a State or on Tribal lands, and the State or Tribe elects not to establish and request APHIS recognition of a management area, the State or Tribe would have to provide evidence in their animal health plan that all program animals in the State or Tribal lands are not similarly exposed to this source, or would have to consider all program animals in the State or Tribe commensurate with respect to risk and propose mitigations in their animal health plan accordingly.

Proposed paragraph (b)(1) of § 76.5 would require a State or Tribe without an animal health plan that has been approved by APHIS to request recognition of a management area when it submits an animal health plan to APHIS. Proposed paragraph (b)(2) of § 76.5 would require a State or Tribe with an approved animal health plan to request recognition of a management area by submitting an amendment to its animal health plan regarding the management area.[11] Proposed paragraph (c) of § 76.5 would contain requirements for a request to recognize a management area. Proposed paragraph (c)(1) would contain requirements for States or Tribes without zones for bovine tuberculosis or areas covered by a brucellosis management plan at the time a rule that finalizes this proposed rule becomes effective.

Such States or Tribes would have to include the following categories of information as part of a request to recognize a management area:

- A description of the geographical area that the State or Tribe requests to be recognized as a management area. The description would have to specify continuous and uninterrupted boundaries for the management area.
- A description of the assessments and activities that the State or Tribe has conducted or plans to conduct to support the specified boundaries for the management area and a timeline of implementation of these activities. At a minimum, the activities specified would have to provide assurances that the boundaries for the management area continually reflect current epidemiological knowledge about the extent of disease and risk of transmission of disease within and from the area, and would have to include:
  - Epidemiological investigations.
  - Surveillance activities within the management area to determine or further delineate sources of brucellosis and/or bovine tuberculosis.
  - Surveillance activities outside the boundaries of the management area sufficient to detect brucellosis or bovine tuberculosis infection in program animals that originate from or are otherwise related to the management area.

The activities would have to include epidemiological investigations because such investigations would be necessary to determine the scope of infection within the area.

The activities would have to include surveillance within the management area to determine or further delineate sources of brucellosis and/or bovine tuberculosis because, in certain instances, epidemiological investigations may not be able, on their own, to discover a disease reservoir of brucellosis or bovine tuberculosis within an area. For example, Federal and State officials within Michigan conducted independent epidemiological investigations for several years before they discovered that wild cervid populations in the northeast of the State were serving as a common source of infection. This discovery played a key role in delineating the geographical area covered by their zone request.

The activities would have to include surveillance activities outside the boundaries of the management area because, historically, after a State has set the initial boundaries of an area in which it knows brucellosis or bovine tuberculosis to exist, affected herds have been discovered beyond these boundaries.

- A description of the known sources of brucellosis or bovine tuberculosis that pose a risk of disease introduction into program animals within and surrounding the management area, and an assessment of the likelihood of spread of brucellosis or bovine tuberculosis from these sources to program animals. This description would have to include:
  - The approximate number of herds, individual program animals, and susceptible wildlife populations within the management area and in the area surrounding the management area as this surrounding area is determined in consultation with an epidemiologist designated by the District Director.
  - The number of affected herds or wildlife populations detected within the management area since the first investigation or surveillance activity specified by the State or Tribe in their request was conducted, the approximate number of animals in these herds or source populations, and the approximate prevalence of brucellosis

[11] A template for a request for recognition of a management area is found in Appendix 8 of the Program Standards document.

or bovine tuberculosis infection in these herds or populations during that time period.

○ The potential for exposure of program animals to these known affected herds or wildlife populations.

○ Any factors, other than mitigation measures maintained by the State or Tribe, that may influence this potential for exposure.

○ An assessment of the likelihood of transmission of brucellosis or bovine tuberculosis from known affected herds or wildlife populations to program animals within and surrounding the management area.

The information that we would require regarding source populations in a request for recognition of a management area is modeled on the information regarding source populations that we would require in an animal health plan. However, while States and Tribes would have to provide the geographic distribution of source populations within their animal health plan, we would not require this information in a request for recognition of a management area. This is because we would expect the boundaries of the management area to reflect the geographic distribution of the source populations.

• A description of the measures that the State or Tribe has implemented or would implement to mitigate the risk that program animals within the State or Tribal lands will become infected with brucellosis or bovine tuberculosis, a timeline for implementation of these measures, and the means by which the State or Tribe has monitored and enforced or plans to monitor and enforce these measures. For all management areas, measures would have to include conditions for the movement of program animals from the management area, herd testing of at least a targeted representative sample of herds of program animals within the area, and change-of-ownership testing of all test-eligible program animals that reside within the area. For management areas for brucellosis, the measures would also have to include an official brucellosis vaccination program.

We would require the State or Tribe to specify conditions for the movement of program animals from the management area because we would not consider the unrestricted movement of program animals from the management area to be appropriate given the presence of brucellosis or bovine tuberculosis within the area. We would require herd testing and change-of-ownership testing within the management area because, although such testing is not a mitigation, it would allow us to evaluate the efficacy of the mitigations implemented within the management area by the State or Tribe. We would require implementation of an official brucellosis vaccination program for management areas for brucellosis because we consider program animals in a management area for brucellosis to be at risk of becoming infected with brucellosis, and vaccination is an effective prophylactic tool to prevent such infection.

• A citation of or hyperlink to the laws and regulations that authorize the State or Tribe's establishment of the management area.

• A description of the personnel that the State or Tribe has used or plans to use in order to implement or perform activities or maintain measures associated with the management area. This description would have to demonstrate that the State or Tribe has sufficient personnel to implement and perform these activities and maintain these measures, and would have to include:

○ The name, contact information, and affiliation of the person within the State or Tribe who would assume responsibility for implementation and performance of activities and maintenance and enforcement of measures associated with the management area.

○ The name, contact information, and affiliation of all personnel assigned to the implementation and performance of activities and maintenance and enforcement of measures associated with the management area.

○ The role or roles assigned to these personnel.

• Information demonstrating that all program animals that are moved from the management area are or will be required to be officially identified prior to movement.

We would require official identification of program animals moved from the area in order to facilitate traceback if any of these animals are determined to be infected with brucellosis or bovine tuberculosis.

Proposed paragraph (c)(2) of § 76.5 would state that, if a State had a geographical area designated as a zone for bovine tuberculosis or covered by a brucellosis management plan prior to the effective date of a rule finalizing this proposed rule, and the State wishes the geographical area to continue to be recognized as a management area, the State's request for recognition of that area as a management area would only need to contain those categories of information that the State has not already submitted to APHIS.

Proposed paragraph (d) of § 76.5 would provide that APHIS would review each proposal for recognition of a management area in accordance with the process set forth in proposed § 76.2 for review of an animal health plan or amendment to an animal health plan.

Proposed paragraph (e) of § 76.5 would provide that, in communicating our determination to approve or not approve an animal health plan or amendment to an animal health plan in accordance with the process set forth in § 76.2, we would also communicate our determination to recognize or not recognize the requested management area. It would also provide that, if we recognize the management area, the request for recognition of the area would be considered to be part of the State or Tribe's animal health plan. Finally, it would provide that we would not recognize a management area in a State or on Tribal lands if we determine not to approve that State or Tribe's animal health plan. We would not recognize the area because, if concerns regarding the approach that the State or Tribe presents in its animal health plan preclude us from approving the plan, these same concerns would preclude us from evaluating the adequacy of the measures specified in the request for recognition of the management area.

As we mentioned previously in this document, proposed paragraph (f) of § 76.5 would contain additional reporting requirements for States and Tribes with recognized management areas. It would require that, in addition to the annual reporting requirements contained in paragraph (a) of § 76.4, States or Tribes with recognized management areas would have to submit a separate annual report form for each recognized management area in the State or Tribe. These reports would provide context for the information contained in the annual report form for the entire State or Tribe by disclosing which portion of the information contained on that form pertains to activities conducted within the management area.

Proposed paragraph (g) of § 76.5 would provide that, if a State or Tribe with a recognized management area wishes to expand or contract the geographical boundaries of the management area, or determines that any information in its request for recognition of the management area has substantively changed, the State or Tribe would have to submit amendments to its animal health plan that reflect these changes to APHIS in accordance with the process set forth in proposed § 76.2.

Proposed paragraph (h) of § 76.5 would deal with termination of management areas. Proposed paragraph (h)(1) would provide that, if a State or Tribe wishes APHIS to recognize the State or Tribe's termination of the management area, it would have to submit amendments to its animal health plan that reflect this termination in accordance with the process set forth in proposed § 76.2. The State or Tribe would also have to provide APHIS with an explanation why the management area was terminated. Depending on the information provided in this explanation, we may also expect the State or Tribe to submit amendments to its animal health plan that address any additional risk of introduction of brucellosis or bovine tuberculosis into program animals that may arise because of termination of the management area.

Proposed paragraph (h)(2) of § 76.5 would provide that, if we determine that a State or Tribe has failed to implement or maintain measures specified within its request for recognition of a management area for brucellosis or bovine tuberculosis, we would terminate recognition of all management areas for the disease or diseases within the State or Tribal lands. We would also redesignate the State or Tribe as an inconsistent State or Tribe for the disease or diseases. This is because States and Tribes with management areas would have known sources of brucellosis or bovine tuberculosis within them, and a State or Tribe's failure to implement or maintain measures to address the risk of disease transmission presented by this source would necessarily lead us to the conclusion that the disease status of program animals within the State or Tribal lands is uncertain or unknown.

If we redesignate a State or Tribe as an inconsistent State or Tribe for brucellosis or bovine tuberculosis, we would also terminate recognition of all management areas for that disease within the State or Tribal lands as part of this redesignation. This is because if we redesignate a State or Tribe as inconsistent, it would indicate that we have significant concerns regarding the control program for brucellosis or bovine tuberculosis within the State or Tribal lands, including activities and measures conducted within the management area.

Proposed paragraph (h)(3) of § 76.5 would provide that, if a State or Tribe requests recognition of termination of a management area, we would review the request in accordance with the process set forth in proposed § 76.2 for review of an amendment to an animal health plan.

Proposed paragraph (h)(4) of § 76.5 would provide that we would communicate our determination regarding termination of a recognized management area in accordance with the process set forth in § 76.2 for communication of a determination regarding amendments to an animal health plan.

Surveillance Requirements (§ 76.6)

As we mentioned in our discussion of proposed § 76.2, States and Tribes would have to provide a description of surveillance activities for brucellosis or bovine tuberculosis in animals within the State or Tribal lands that are being conducted or would be conducted in the State or Tribe. Proposed § 76.6 would provide minimum requirements regarding these surveillance activities.

Proposed paragraph (a) of § 76.6 would require all States to agree to participate in the National Surveillance Plans for Brucellosis and Bovine Tuberculosis, which would be located on the APHIS Web site, or to conduct equivalent surveillance in a manner approved by APHIS.

Participation in the National Surveillance Plan for Bovine Tuberculosis would require States to perform monitoring of slaughter inspection within the State that is conducted by State meat inspection personnel. Pursuant to FSIS regulations, all cattle and bison slaughtered for wholesale or retail purposes at a recognized slaughtering establishment within the United States are inspected for evidence of tuberculosis by either FSIS or State meat inspection personnel.

States would also be required to monitor caudal fold testing for bovine tuberculosis within the State that is conducted by qualified accredited veterinarians (see discussion later in this document, under the heading ''Official tests for brucellosis and bovine tuberculosis, official testing laboratories, and official testers (§ 76.17)'').

If we do not require a State to conduct brucellosis surveillance or provide data regarding ongoing brucellosis surveillance conducted in the State, the State would still be considered a participant in the National Surveillance Plan for Brucellosis. Participation for certain States could be made contingent on designated recognized slaughtering establishments in the States collecting blood samples for official testing from a prescribed percentage of cattle and bison slaughtered at the establishments. This slaughter surveillance requirement currently exists in part 78, and we considered it necessary to incorporate it into the National Surveillance Plan in order to maintain an appropriate measure of passive surveillance for brucellosis throughout the United States given the reservoirs of the disease in certain areas of the United States.

APHIS could also request certain States to provide additional data on routine surveillance for brucellosis in their State that is conducted at areas of high concentration and frequent commingling of cattle and bison, such as livestock markets, cattle feeders' premises, and regional exhibitions.

We are aware that States may prefer to draft their own surveillance plan rather than participate in the National Surveillance Plans for Brucellosis and Bovine Tuberculosis. We would allow States to do so, provided that they propose to conduct what we consider to be equivalent surveillance to that specified in the National Plans and we approve the plans.

If a State fails to meet the surveillance levels set forth in the National Surveillance Plans or their own approved plans, this could result in redesignation to provisionally consistent or inconsistent status. We consider the possibility of such redesignations to be appropriate because failure to conduct adequate surveillance could adversely impact our ability to estimate the prevalence levels for brucellosis or bovine tuberculosis within a State. Similarly, surveillance data collected under the plans would be necessary for us to determine the national prevalence for brucellosis and bovine tuberculosis in the United States, and because, as we mentioned previously in this document, the regulations in part 76 would be predicated on the United States having low national prevalence levels for the diseases. Thus, if we were to lack sufficient data to determine these prevalence levels, this would deprive us of our primary means of evaluating the ongoing efficacy of the regulations in part 76.

If a consistent or provisionally consistent State refuses to participate in the plans or draft and implement their own, this would result in redesignation to inconsistent status. Additionally, if an inconsistent State refuses to participate in the plans or draft and implement their own, the interstate movement of program animals from that State would be subject to such restrictions or prohibitions as the Administrator considers necessary to prevent the dissemination of brucellosis or bovine tuberculosis from the State; we would announce such restrictions in a notice in the **Federal Register**.

We believe such remedial measures would be appropriate for three reasons. First, this refusal to conduct

surveillance would significantly and adversely impact our ability to gauge national prevalence levels for brucellosis or bovine tuberculosis. Second, this refusal would render it difficult for us to evaluate whether a State's animal health plan is addressing the risk of spread of brucellosis or bovine tuberculosis within and from the State; as it is today, slaughter surveillance would remain our primary gauge of determining brucellosis or bovine tuberculosis risks within a State under the consolidated brucellosis and bovine tuberculosis program. Third, this refusal would deprive us of assurances that program animals moved interstate from the State do not present a risk of transmitting brucellosis or bovine tuberculosis to other animals.

Proposed paragraph (b) of § 76.6 would contain additional surveillance requirements for States that have known sources of brucellosis or bovine tuberculosis.

Proposed paragraph (b)(1) would contain requirements for surveillance of wildlife source populations. It would state that, if a consistent or provisionally consistent State has identified a known source of brucellosis or bovine tuberculosis transmission within wildlife in the State in its animal health plan and determined that this source population presents a risk of transmitting brucellosis or bovine tuberculosis to program animals, in order to maintain consistent or provisionally consistent status, the State would have to conduct surveillance of that source population in a manner approved by APHIS as sufficient to detect brucellosis or tuberculosis in an animal within the source population. A consistent State that fails to conduct such surveillance would be redesignated as provisionally consistent, while a provisionally consistent State that fails to conduct such surveillance could be redesignated as inconsistent.

Proposed paragraph (b)(2) of § 76.6 would provide requirements for targeted surveillance of at-risk populations, that is, populations that are at risk of becoming infected with brucellosis or bovine tuberculosis because of transmission of the diseases from source populations. It would provide that, if a consistent or provisionally consistent State has identified a known source of brucellosis or bovine tuberculosis transmission in the State in its animal health plan and has determined that this source population presents a risk of transmitting brucellosis or bovine tuberculosis to program animals, in order to maintain consistent or provisionally consistent status, the State would have to conduct annual herd testing of all herds of at-risk program animals, or alternatively, a statistically representative sample of those herds, as determined by APHIS. A consistent State that fails to conduct such surveillance would be redesignated as provisionally consistent. A provisionally consistent State that fails to conduct such surveillance would be redesignated as inconsistent.

Such testing would be necessary in order to help us evaluate the efficacy of any mitigation measures the State has implemented to prevent transmission of brucellosis or bovine tuberculosis from known source populations to program animals. Hence, failure to conduct such testing would result in redesignation.

Proposed paragraph (c) of § 76.6 would provide requirements for surveillance within recognized management areas. It would require States to conduct surveillance within the management area in the manner specified within that section of the State's animal health plan that pertains to the management area. Since States or Tribes would have to specify surveillance activities in any request for APHIS to recognize a management area, failure to conduct such surveillance would constitute failure to implement or maintain a measure specified in the request. Hence failure to conduct such surveillance would result in termination of recognition of the management area and redesignation of the State as an inconsistent State.

Proposed paragraph (d) of § 76.6 would provide that, if a consistent State is redesignated as provisionally consistent, additional surveillance requirements for the State may be specified in the notice in the **Federal Register** that announces this redesignation.

Proposed paragraph (e) of § 76.6 would provide that the requirements in the section pertain to Tribes, provided that they have submitted a Tribal animal health plan to APHIS for review and approval in accordance with the process set forth in § 76.2, and APHIS has approved the animal health plan.

Epidemiological Investigations and Affected Herd Management (§ 76.7)

Proposed § 76.7 would contain minimum requirements regarding epidemiological investigation and affected herd management activities conducted under an animal health plan.

Proposed paragraph (a) of § 76.7 would provide that, if a program animal has a non-negative test result for brucellosis, within 15 days of receiving notification of these results, the State in which the animal was detected would have to initiate an investigation to determine the herd from which the animal originated and all herds in which it has resided.

As we mentioned previously in this document, historically, there have been occasions when secondary (corroboratory) tests to determine the presence or absence of brucellosis in program animals have yielded results that fell within the range of positive test results, but were sufficiently ambiguous to preclude the individuals conducting the test from making a determination that the animals were infected with brucellosis. However, when we have traced such animals back through production channels to their herd of origin, we have discovered animals that are infected with brucellosis.

For this reason, a consistent State that fails to conduct such an investigation on one occasion would be redesignated as provisionally consistent, while a consistent or provisionally consistent State that fails to conduct such an investigation on multiple occasions could be redesignated as inconsistent.

Proposed paragraph (b) § 76.7 would provide protocols related to other epidemiological investigations. These protocols would be consistent with generally accepted best practices for epidemiological investigations.

Proposed paragraph (b)(1) would provide a protocol for epidemiological investigations following a determination that a program animal is infected with brucellosis or bovine tuberculosis, without a concurrent determination that it has belonged to an affected herd. Such investigations would usually be initiated by discovery of an infected animal at slaughter, but could also be initiated when an animal is determined to be infected with brucellosis or bovine tuberculosis after testing positive for the disease at a livestock market, auction barn, exhibition, or other point where the animal is segregated from its herd for commercial purposes.

In such instances, within 15 days of the determination that the program animal is infected, the State in which the infected animal was detected would have to identify the herd from which the infected animal originated and all herds in which it has resided, impose the restrictions specified in proposed §§ 76.9 and 76.10 on the interstate movement of animals from those herds, impose substantially similar restrictions on the intrastate movement of program animals from the herds, and begin determining the disease status of all test-eligible animals in the herds. (Proposed § 76.9 would prohibit the movement of animals from a herd containing a reactor or suspect for brucellosis or tuberculosis, other than

the movement of the reactor or suspect itself, until the disease status of all test-eligible animals in the herd is determined. Proposed § 76.10 would provide conditions for the interstate movement of reactor, suspect, and exposed program animals.)

Proposed paragraph (b)(2) would provide a protocol for epidemiological investigations following a determination that a herd of program animals is affected with brucellosis or bovine tuberculosis. In such instances, within 15 days of this determination, the State in which the herd resides would have to identify and impose the restrictions specified in proposed §§ 76.9 and 76.10 on the interstate movement of the following animals, impose substantially similar restrictions on intrastate movement, and begin determining the disease status of all test-eligible animals in those herds:

- Any herd into which program animals from the affected herd may have been moved; and
- Any herd from which program animals in the affected herd may have originated or in which they may have resided; and
- Any herd, individual program animals, or other animals that are susceptible to brucellosis or bovine tuberculosis that may have commingled with or otherwise been exposed to the affected herd, as determined by the Administrator and communicated to the State.

Proposed paragraph (b)(3) of § 76.7 would require that, if the State in which an infected animal or affected herd was detected determines that any of the herds specified in proposed paragraph (b)(2) are located in a different State than the infected animal or affected herd, the State in which the infected animal or affected herd was detected would have to notify both that State and APHIS, in writing, within 3 days. APHIS notification would have to be submitted to the address provided within the Program Standards document. This notification would allow surrounding States to conduct their own epidemiological investigations in a timely manner, and would help APHIS to oversee and coordinate any aspects of the investigations related to interstate commerce.

Proposed paragraph (b)(4) would provide a protocol for epidemiological investigations following a determination that a non-program animal is infected with brucellosis or bovine tuberculosis, if the Administrator determines that this animal presents a risk of transmitting brucellosis or bovine tuberculosis to program animals. In such instances, the State or States surrounding the detection would have to identify all herds that may have been exposed to brucellosis or bovine tuberculosis because of this detection, as determined by the Administrator and communicated to the States. The States would also have to impose the restrictions specified in §§ 76.9 and 76.10 on the interstate movement of animals from those herds, impose substantially similar restrictions on intrastate movement, and determine the disease status of all test-eligible animals in those herds. We would impose this requirement on all States surrounding the infected animal, as determined by the Administrator, because, if migratory wildlife is discovered to be infected with brucellosis or bovine tuberculosis near a State's border, the migration patterns of this wildlife could have exposed program animals in other States to the disease.

Proposed paragraph (b)(5) of § 76.7 would provide a protocol for epidemiological investigations if an animal infected with brucellosis or bovine tuberculosis is discovered on or has been determined to have originated from a calf raiser's premises or feedlot, that is, a location where there is frequent commingling of cattle or bison that originate from different premises. In such instances, the State in which the calf raiser's premises or feedlot is located would have to conduct an epidemiological investigation of that premises or feedlot according to a method that has been approved by the Administrator. A draft of an approved method for conducting such an investigation is set forth in the Program Standards document.

While the protocols and procedures set forth in proposed paragraph (b) are grounded in generally accepted best practices for conducting epidemiological investigations, we recognize that, in certain instances, a State may exercise due diligence in conducting such investigations, yet either not be able to determine all potentially affected herds, or not be able to do so within the timeframe specified within the regulations. In such instances, States could submit an alternate protocol for conducting an epidemiological investigation to APHIS to the address provided in the Program Standards document. If the Administrator authorizes this protocol, the State could employ it in lieu of the protocols contained in the regulations, without risking a possible redesignation to a lower status (see our discussion below of proposed paragraph (d) of § 76.7).

Proposed paragraph (c) would establish conditions for determining whether a herd is affected with brucellosis or bovine tuberculosis. If all test-eligible program animals in a herd under investigation are determined to be negative for brucellosis or bovine tuberculosis, the herd would not be an affected herd. In such instances, no further action would be required and the State could remove restrictions on the movement of animals in those herds. Conversely, if any test-eligible animals in a herd under investigation are determined to be infected with brucellosis or bovine tuberculosis, the herd would be considered to be an affected herd.

Proposed paragraph (d) of § 76.7 would contain consequences for failure to conduct an epidemiological investigation in accordance with the section. If a consistent or provisionally consistent State does not follow the protocols in § 76.7 or another protocol that APHIS has authorized, the State would be redesignated as inconsistent. This is because these protocols represent generally accepted best practices for all epidemiological investigations. Thus, failure to adhere to them, or to submit an alternate protocol to us for evaluation, would necessarily lead us to consider the disease status of program animals within the State or Tribal lands uncertain or unknown, and to have concerns regarding the overall adequacy of the regulatory program for brucellosis or bovine tuberculosis in the State.

For this reason, if an inconsistent State, that is, a State about which we already have such concerns, fails to conduct epidemiological investigations in accordance with the section, the interstate movement of program animals from that State would be subject to such restrictions or prohibitions as the Administrator considers necessary to prevent the dissemination of brucellosis or bovine tuberculosis from the State. In such instances, once imposed by the Administrator, the restrictions or prohibitions would be announced through a notice in the **Federal Register**.

Proposed paragraph (e) of § 76.7 would provide requirements for management of affected herds. States would have to manage affected herds through depopulation, or through a test-and-remove protocol modeled on the protocol contained in the April 2010 Federal Order.[12] The protocol would have to demonstrate that:

- The State has implemented and is enforcing movement restrictions on the affected herd.

[12] See footnote 1.

• The States has implemented and is enforcing an affected herd management plan for the affected herd to prevent the spread of brucellosis or bovine tuberculosis.

• The State is implementing and is conducting a protocol to periodically test program animals in the affected herd for brucellosis or bovine tuberculosis and to remove and destroy those animals that do not test negative.

• The State has a protocol in place to conduct periodic assurance testing of the herd once the test-and-remove protocol is complete.

The test-and-remove protocol would have to place movement restrictions on the affected herd because, unless a program animal in an affected herd has undergone periodic testing to determine its disease status over an extended period of time and has tested negative for brucellosis or bovine tuberculosis each time, we consider the animal to present a risk of transmitting brucellosis or bovine tuberculosis to other program animals. We would require the State to implement and maintain an affected herd management plan for this same reason.

We would require removal and destruction of all animals that do not test negative to this periodic testing because such animals could be infected with brucellosis or bovine tuberculosis and thus could serve as an inoculum for the remainder of the herd if they are not removed and destroyed.

We would require assurance testing in order to monitor the herd for possible reintroduction of disease following conclusion of the test-and-remove protocol.

Proposed paragraph (f) of § 76.7 would contain consequences for failure to conduct affected herd management in accordance with the section. If a consistent or provisionally consistent State fails to do so, it would be redesignated as inconsistent. If an inconsistent State fails to do so, the interstate movement of program animals from that State would be subject to such restrictions or prohibition as the Administrator considers necessary to prevent the dissemination of brucellosis or bovine tuberculosis from the State. In such instances, the restrictions or prohibitions would be announced through a notice in the **Federal Register**.

Proposed paragraph (g) would state that the requirements in the section pertain to Tribes, provided that they have submitted a Tribal animal health plan to APHIS for review and approval in accordance with the process set forth in proposed § 76.2, and APHIS has approved the animal health plan.

Interstate Movement Requirements—General Categories of Livestock (§§ 76.8 through 76.10)

Interstate Movement of Infected Livestock Generally Prohibited (§ 76.8)

Proposed § 76.8 would state that, except as provided in paragraph (d)(7) of 9 CFR 71.3, the interstate movement of any livestock known to be infected with brucellosis or bovine tuberculosis is prohibited. Paragraph (d)(7) of § 71.3 provides that, in certain instances, the Administrator may authorize the interstate movement of livestock known to be infected with a communicable disease of livestock such as brucellosis and bovine tuberculosis, subject to such conditions as he or she may prescribe to prevent the spread of that disease. We consider such a general prohibition consistent with our mission under the AHPA to prevent the dissemination of diseases of livestock within the United States.

Interstate Movement of Program Animals from a Herd Containing a Reactor or Suspect (§ 76.9)

As we mentioned previously in this document, proposed § 76.9 would provide that, except as provided in proposed § 76.10, which would contain conditions for the interstate movement of reactor, suspect, and exposed program animals, the interstate movement of program animals from a herd containing a reactor or suspect animal for brucellosis or bovine tuberculosis is prohibited, until the disease status of all test-eligible animals in that herd is determined.

If a herd contains a reactor or suspect for brucellosis or bovine tuberculosis, there is a possibility that the herd is affected with that disease. Hence, allowing an animal to move interstate from the herd before the disease status of all animals in the herd is known could contribute to the dissemination of brucellosis or bovine tuberculosis within the United States, and would be inconsistent with our mission under the AHPA.

Interstate Movement of Reactor, Suspect, and Exposed Program Animals (§ 76.10)

This section would state that, notwithstanding the other provisions of part 76, program animals that have been classified as brucellosis or bovine tuberculosis reactors, suspects, or exposed animals could be moved interstate if:

• The animals are officially identified.

• The animals are accompanied by a permit for movement of restricted animals issued by an APHIS or State or Tribal representative.

• The permit for movement of restricted animals clearly specifies the brucellosis or bovine tuberculosis classification of the animals.

• The animals are moved for diagnostic testing, immediate slaughter, necropsy, or other use as approved by the Administrator.

• The animals are moved to a location specified as an approved location for reactor, suspect, or exposed animals. (We would include a footnote, footnote 4, stating that locations include recognized slaughtering establishments, specifically approved stockyards, official testing laboratories, research facilities, and, for exposed animals that have tested negative for brucellosis or bovine tuberculosis, quarantine feedlots and quarantine pens. Additionally, the footnote would provide that a State may request approval of alternate locations by specifying the locations within its animal health plan or proposing to amend the health plan to specify the locations.)

• The animals are moved in a means of conveyance containing only animals not susceptible to brucellosis and/or bovine tuberculosis or animals destined for immediate slaughter or necropsy.

• The means of conveyance in which the animals are moved interstate is secured with official seals applied and removed by an authorized APHIS representative, FSIS inspector, State or Tribal representative, accredited veterinarian, or other individual authorized for this purpose by an APHIS representative; or the animals are accompanied during movement by an APHIS representative, FSIS inspector, State or Tribal representative, or other individual authorized for this purpose by an APHIS representative.

• After shipment, each means of conveyance in which the animals have been transported is cleaned and disinfected by the carrier in accordance with 9 CFR part 71, under the supervision of an APHIS representative, FSIS inspector, State or Tribal representative, accredited veterinarian, or other person designated by the Administrator. (Section 71.7 provides methods for conducting cleaning and disinfection of a means of conveyance, if the means of conveyance is required within 9 CFR to be cleaned and disinfected.)

We consider reactor, suspect, and exposed program animals to potentially be infected with brucellosis or bovine tuberculosis, and thus to pose a risk of transmitting the disease to other program animals. The interstate movement requirements for reactor,

suspect, or exposed animals would be based on this consideration.

Accordingly, we would require the animals to be officially identified in order to ensure that the appropriate animals arrived at their designated destination, and to facilitate traceback and epidemiological investigations in the event that they are determined to be infected. We would require the animals to be accompanied by a permit for movement of restricted animals that specifies the animals' brucellosis or bovine tuberculosis classification so that individuals who ship, handle, transport, or receive the animals would be adequately informed that the animals pose a potential risk of transmitting brucellosis or bovine tuberculosis.

We would require the animals to be moved for diagnostic testing, immediate slaughter, or necropsy, unless the Administrator approves another use, because such uses are terminal. By terminal, we mean that they allow a final determination of the animals' disease status to be made, result in the destruction of the animal, or both.

We do envision that there may be a non-terminal use that the Administrator may approve for exposed dairy heifers in certain instances. If a dairy herd were to become affected with brucellosis or bovine tuberculosis, in order for the dairy to remain operational, it could be necessary to move exposed heifers from that herd interstate to non-terminal locations for care and feeding, and then return them to the affected dairy. However, we also recognize that allowing exposed animals to move to a non-terminal location without adequate restrictions or mitigations could result in the spread of brucellosis or bovine tuberculosis. We therefore request comment regarding whether to allow such movement of dairy heifers, and, if so, under what conditions to allow it.

We would require the animals to be moved to certain approved locations because we believe that any location that receives reactor, suspect, or exposed program animals must have structures and/or procedures in place to address the risk that the animals may pose of transmitting brucellosis or bovine tuberculosis.

We would require the animals to be moved with animals that are not susceptible to brucellosis and/or bovine tuberculosis or animals destined for immediate slaughter or necropsy, because, if a reactor, suspect, or exposed animal is, in fact, infected with brucellosis or bovine tuberculosis, prolonged contact with animals that are susceptible to the disease and are not destined to a terminal location could result in the dissemination of brucellosis or bovine tuberculosis.

We would require the means of conveyance to be sealed, or the animals to be accompanied by an APHIS representative, FSIS inspector, or State or Tribal representative, in order to prevent the diversion of the animals en route to a location that has not been approved by the Administrator, and that may not have appropriate structures and/or procedures to mitigate any risks that the animals may pose of transmitting brucellosis or bovine tuberculosis.

Finally, because surfaces can be contaminated with the bacteria that cause brucellosis and bovine tuberculosis and serve as articles that convey infection, we would require the means of conveyances in which the animals have been transported to be cleaned and disinfected after shipment.

Commuter Herds

Commuter herds are herds of cattle or bison that move interstate during the course of normal livestock operations and without change of ownership between premises that are owned or leased by the same person, as provided in a commuter herd agreement. A commuter herd agreement, in turn, is a written agreement between the owner of such a herd and the animal health officials of the State of origin and destination specifying, at a minimum, the testing, identification, and recordkeeping requirements for the interstate movement of animals in a commuter herd from one premises to another in the course of normal livestock management operations. If a commuter herd is moved interstate under a commuter herd agreement, it is not subject to the requirements of the regulations that would otherwise apply to the interstate movement of cattle and bison from that State. We allow for such an arrangement because we consider commuter herds to present a very low risk of transmitting brucellosis or bovine tuberculosis to other animals, based on the fact that a commuter herd has never tested positive for bovine tuberculosis and only one commuter herd has tested positive for brucellosis.

This arrangement was helpful to owners of commuter herds when many States did not have the highest classifications for brucellosis or bovine tuberculosis within the current State classification systems in parts 77 and 78. However, as more and more States have achieved the highest classifications for brucellosis and bovine tuberculosis, the need for such arrangements has become increasingly unnecessary.

Accordingly, in this proposed rule, we have elected not to include specific provisions for the interstate movement of commuter herds. We believe that the requirements specified in proposed §§ 76.11 through 76.15 (see immediately below) would either be less restrictive or substantially equivalent to the terms and conditions currently specified within commuter herd agreements, and would provide adequate mitigations for the interstate movement of most commuter herds. We also believe that exempting commuter herds from the requirements in proposed §§ 76.8 through 76.10 would potentially allow for the interstate movement of infected animals without appropriate mitigations.

We request public comment regarding whether to include specific conditions for the interstate movement of commuter herds within part 76, and, if so, what those conditions should be.

Interstate Movement Requirements—Cattle and Bison (§§ 76.11 through 76.15)

Interstate Movement of Cattle and Bison Generally Restricted (§ 76.11)

Section 76.11 would provide that, unless cattle or bison belong to one of the categories in §§ 76.8 through 76.10, or the Administrator has provided public notification of alternate conditions for movement of the cattle or bison, cattle or bison could only be moved interstate in accordance with §§ 76.11 through 76.15.

As we mentioned previously in this document in our discussion of proposed § 76.1, the Administrator would rarely specify such alternate conditions, and only when he or she had determined that the regulations in part 76 did not address the risk of transmission of brucellosis or bovine tuberculosis associated with the interstate movement of certain cattle or bison.

Interstate Movement of Cattle and Bison From Consistent States or Tribes for Brucellosis and Bovine Tuberculosis (§ 76.12)

Proposed § 76.12 would contain requirements for the interstate movement of cattle and bison from consistent States or Tribes for brucellosis and bovine tuberculosis. The requirements would cover three types of movements: Movement of rodeo, event, or exhibited cattle or bison; movement of all other cattle or bison from any area of the State or Tribe other than a recognized management area; and movement of all other cattle or bison from a recognized management area.

Proposed paragraph (a) of § 76.12 would contain requirements for the

interstate movement of rodeo, event, or exhibited cattle or bison. We consider such animals to be a distinct risk category because such animals tend to move frequently in interstate commerce and commingle with animals from many different regions, both domestically and internationally. Thus, the risk that rodeo, event, or exhibited cattle or bison that are moved interstate may be exposed to brucellosis or bovine tuberculosis is considerably higher than the risk that cattle or bison that are moved interstate for other purposes may be exposed to these diseases.

We would allow rodeo, event, or exhibited cattle and bison to be moved interstate from a consistent State for brucellosis or bovine tuberculosis provided that:

- The cattle or bison are tested for bovine tuberculosis using an individual official test no more than 60 days prior to initial interstate movement from the premises of origin, with negative results. (We would include a footnote, footnote 5, stating that the requirements of this and the following paragraph apply not only to rodeo, event, or exhibited cattle and bison that have been produced within the United States, but also rodeo, event, or exhibited cattle and bison of foreign origin after they have arrived at their destination within the United States.)
- If the cattle or bison are sexually intact and 6 months of age or older, they are tested for brucellosis using an individual official test no more than 60 days prior to initial interstate movement from the premises of origin, with negative results.
- The cattle or bison are tested for bovine tuberculosis using an individual official test no more than 180 days prior to any subsequent interstate movement, with negative results.
- If the cattle or bison are sexually intact and 6 months of age or older, they are tested for brucellosis using an individual official test no more than 180 days prior to any subsequent interstate movement, with negative results.
- The cattle or bison are accompanied during interstate movement by an ICVI with a statement regarding the date, location, and test results of the official tests for bovine tuberculosis and, if applicable, brucellosis administered prior to initial interstate movement, and the date, location, and test results of the last official test for bovine tuberculosis and, if applicable, brucellosis administered to the animals.
- The cattle or bison are officially identified.

We would require the cattle or bison to be tested for bovine tuberculosis, and, if they are sexually intact and 6 months of age or older, brucellosis prior to initial interstate movement from the premises of origin, with negative results, because, if cattle or bison from that premises become infected with brucellosis or bovine tuberculosis at a rodeo, event, or exhibit, and are moved back to the premises following the rodeo, event, or exhibit, they could infect animals at the premises that have not yet moved interstate. We would require this testing to take place no more than 60 days prior to movement, because 60 days has historically been the maximum amount of time that we consider negative test results for brucellosis or bovine tuberculosis to provide assurances that an animal is not infected at the time it is initially moved interstate.

We would require the cattle or bison to be tested for bovine tuberculosis, and, if they are capable of transmitting the disease, brucellosis, no more than 180 days prior to any subsequent interstate movement, with negative results, because this testing would provide assurances that the cattle or bison have not contracted brucellosis or bovine tuberculosis at a particular rodeo, event, or exhibit. The testing would be at 180-day intervals because rodeo, event, and exhibited cattle are often moved frequently over a 24 to 30-month period, starting with initial movement from their premises of origin. If they were tested more frequently during that time period, there would be a risk of anergy for bovine tuberculosis, that is, erroneous results due to a lack of sensitivity to a test.

We would require the animals to be accompanied by an ICVI with statements regarding the date, location, and test results of the official tests administered prior to initial interstate movement and the last such official tests in order to provide assurances to individuals that handle, ship, or receive the animals that they have been moved in accordance with the regulations. We would require the animals to be officially identified because official identification facilitates traceability of the animals in the event of disease outbreak at a rodeo, event, or exhibit.

Proposed paragraph (b) of § 76.12 would contain conditions for the movement of all other cattle and bison from a consistent State or Tribe. Proposed paragraph (b)(1) would contain conditions for the movement of all other cattle or bison from any area of the State or Tribe other than a recognized management area. Such animals could be moved without restriction under part 76.

Paragraph (b)(1) would contain a footnote, footnote 6, stating that the cattle and bison would still be subject to all other applicable restrictions of 9 CFR chapter 1, including those of §§ 71.3, 71.17, 86.4, and 86.5. Among other prohibitions, § 71.3 generally prohibits the interstate movement of cattle and bison infected with Johne's disease and anthrax, dangerous and communicable diseases of ruminants. Section 71.17 prohibits live cattle or bison from being moved interstate in the same car as dead cattle, bison, poultry, or other animals. Section 86.4 requires most cattle and bison that are moved interstate to be officially identified; § 86.5 requires most cattle and bison that are moved interstate to be accompanied by an ICVI.

Proposed paragraph (b)(2) of § 76.12 would contain conditions for the movement of all other cattle or bison from a recognized management area in a consistent State or Tribe. These cattle or bison would have to be moved in accordance with the conditions for movement of program animals from the recognized management area specified in the State or Tribe's animal health plan.

Interstate Movement of Cattle and Bison From a Provisionally Consistent State or Tribe (§ 76.13)

Section 76.13 would contain conditions for the interstate movement of cattle and bison from a State that is provisionally consistent for brucellosis or bovine tuberculosis.

As we mentioned previously in this document in our discussion of proposed §§ 76.2 and 76.3, whenever we redesignate a consistent State or Tribe as a provisionally consistent State or Tribe, we would publish a notice in the **Federal Register** announcing this redesignation. Proposed paragraph (a) of § 76.13 would provide that, unless this notice specifies restrictions on the interstate movement of cattle and bison arising from this redesignation, cattle or bison that are moved interstate from a provisionally consistent State or Tribe would be subject to the relevant conditions for movement in proposed § 76.12. Thus, the interstate movement of rodeo, event, or exhibited cattle and bison would be subject to the provisions of paragraph (a) of proposed § 76.12; cattle and bison that are not rodeo, event, or exhibited cattle or bison, and that are moved from any area in the State or Tribe other than a recognized management area, would be subject to the provisions of paragraph (b)(1) of that section; and cattle and bison that are not rodeo, event, or exhibited cattle or bison, and that are moved from a recognized management area, would be

subject to the provisions of paragraph (b)(2) of that section.

Proposed paragraph (b) of § 76.13 would provide that, if the notice announcing redesignation of the State or Tribe specifies restrictions on the interstate movement of cattle or bison, and these restrictions differ from the conditions for interstate movement specified in proposed § 76.12, the interstate movement of such cattle or bison would be subject to the restrictions specified in the notice.

Interstate Movement of Cattle and Bison from Inconsistent States or Tribes for Brucellosis (§ 76.14)

This section would contain conditions for the interstate movement of cattle and bison from a State or Tribe that is inconsistent for brucellosis. We would consider all cattle and bison moved interstate from an inconsistent State or Tribe to present at least an unknown risk of disseminating disease. The conditions in proposed § 76.14 would be based on this consideration.

Proposed paragraph (a) of § 76.14 would contain conditions for the interstate movement of sexually intact cattle or bison that are 6 months of age or older, that is, animals for which there is strong scientific evidence supporting their ability to transmit brucellosis.

If the animals are destined for immediate slaughter, they could be moved interstate provided that they are officially identified and accompanied by an ICVI. We do not consider additional mitigations to be necessary because slaughtering an animal at a recognized slaughtering establishment is an effective mitigation to prevent that animal from disseminating brucellosis.

If the animals are not destined for immediate slaughter, they could be moved interstate provided that they meet the following requirements:

- The herd from which the cattle or bison originate has been subjected to a herd test using an official test for brucellosis no more than 1 year and no less than 120 days prior to movement, with negative results.
- The cattle or bison are additionally tested using an individual official test no more than 60 days prior to movement, with negative results.
- Since being individually tested, the cattle or bison have not commingled with non-natural additions to the herd that are of unknown brucellosis status or animals that have had a non-negative test for brucellosis.
- The cattle or bison are officially identified.
- The cattle or bison are accompanied by an ICVI documenting the negative test results.

The initial herd test would provide assurances that the herd from which the animals originate is not affected with brucellosis. The subsequent individual test would provide assurances that the cattle or bison have not become infected with brucellosis since the time of the herd test. Isolation from non-natural additions to the herd that are of unknown brucellosis status or from animals that have had a non-negative test for brucellosis following this individual test would preclude contact with cattle or bison that are potentially infected with brucellosis. Requiring the animals to be officially identified and accompanied by an ICVI with a statement regarding their negative test results would facilitate their traceability, provide assurances to those handling, transporting, or receiving the animals that they do not present a risk of disseminating brucellosis, and help document that the appropriate animals arrived at their designated destination.

Proposed paragraph (b) of § 76.14 would provide conditions for the interstate movement of cattle that are less than 6 months of age, steers, and spayed heifers, that is, animals for which there is no scientific evidence suggesting that they are a source of transmission of brucellosis. Such animals could be moved interstate from an inconsistent State for brucellosis if they are officially identified and accompanied by an ICVI.

Interstate Movement of Cattle and Bison From Inconsistent States or Tribe for Bovine Tuberculosis (§ 76.15)

Section 76.15 would provide conditions for the interstate movement of cattle or bison from a State that is inconsistent for bovine tuberculosis. If the cattle or bison are destined for immediate slaughter, they could be moved interstate provided that they are officially identified and accompanied by an ICVI. We consider slaughtering an animal at a recognized slaughtering establishment to be an effective mitigation to prevent that animal from disseminating bovine tuberculosis.

If the cattle or bison are not destined for immediate slaughter, they could be moved interstate provided that:

- The cattle or bison originate from a herd that was subjected to a herd test using an official test for bovine tuberculosis no more than 1 year and no less than 120 days prior to the movement of the cattle or bison, with negative results.
- The cattle or bison are additionally tested for bovine tuberculosis using an individual official test no more than 60 days prior to movement, with negative results.
- Since being individually tested, the cattle or bison have not commingled with non-natural additions to the herd that are of unknown bovine tuberculosis status or animals that have had a non-negative test for bovine tuberculosis.
- The cattle or bison are officially identified.
- The cattle or bison are accompanied by an ICVI documenting the negative test results.

These conditions, which would be nearly identical to the movement from an inconsistent State for brucellosis of cattle or bison that are capable of transmitting brucellosis, would serve a purpose that is analogous to those conditions. The herd test would provide assurances that the herd from which the cattle or bison originate is not affected with bovine tuberculosis. The subsequent individual test would provide assurances that the cattle or bison have not become infected with bovine tuberculosis since the time of the herd test. Isolation from non-natural additions to the herd that are of unknown bovine tuberculosis status or animals that have had a non-negative test for bovine tuberculosis following this individual test would preclude contact with cattle or bison that are potentially infected with bovine tuberculosis. Finally, requiring the animals to be officially identified and accompanied by an ICVI with a statement regarding their negative test results would facilitate their traceability, provide assurances to those handling, transporting, or receiving the animals that they do not present a risk of disseminating bovine tuberculosis, and help document that the appropriate animals arrived at their designated destination.

Interstate Movement of Captive Cervids (§ 76.16)

Because of routine inspections conducted by FSIS inspectors or State meat inspection personnel at recognized slaughtering establishments, in conjunction with surveillance conducted pursuant to the current prevalence-based State classification systems for brucellosis and bovine tuberculosis, we have confidence in the approximate prevalence levels for brucellosis and bovine tuberculosis in the domestic cattle and bison populations within the United States.

There is, however, no routine slaughter inspection of or surveillance activities for captive cervids. Moreover, many captive cervids that are slaughtered for meat purposes are slaughtered at custom slaughter establishments that are not under Federal or State oversight. Accordingly,

APHIS does not have the same degree of certainty regarding the approximate prevalence levels of brucellosis and bovine tuberculosis in the domestic captive cervid population within the United States.

For this reason, under part 77, we currently require captive cervids that are moved interstate to be tested for bovine tuberculosis, unless the captive cervids originate directly from a herd that has undergone sufficient testing and monitoring to provide assurances that animals from the herd will not transmit bovine tuberculosis.

We currently do not regulate captive cervids for brucellosis. Because captive cervids are not regulated for brucellosis, testing of the animals for brucellosis prior to interstate movement is currently limited. Captive cervids are, however, susceptible to brucellosis, and sexually mature and intact cervids can transmit the disease. Additionally, in recent years, wild elk populations in the GYA have been determined to be infected with brucellosis. For these reasons, we believe it would be prudent to regulate the interstate movement of captive cervids for brucellosis at least until such time as we have greater knowledge of the prevalence for the disease in the domestic captive cervid population within the United States.

Proposed § 76.16 would contain conditions for the interstate movement of captive cervids. The section would generally continue our existing policy of requiring captive cervids to be tested for bovine tuberculosis prior to interstate movement, unless the cervids originate from a herd which has undergone sufficient testing and monitoring to provide assurances that cervids from the herd pose no risk of transmitting bovine tuberculosis. We would, however, also allow captive cervids to be moved interstate without testing for bovine tuberculosis if they are moved for immediate slaughter; this is because, as we mentioned previously in this document, we consider slaughtering an animal at a recognized slaughtering establishment to mitigate the risk that the animal may pose of disseminating bovine tuberculosis.

The section would also require captive cervids to be tested for brucellosis prior to interstate movement, unless we have similar assurances regarding the herd from which the cervids originate, or unless the cervids are moved for immediate slaughter.

The introductory text of the section would state that, except as provided in §§ 76.8 through 76.10, captive cervids could only be moved interstate in accordance with the section.

Proposed paragraph (a) of § 76.16 would provide conditions for the interstate movement of captive cervids that originate directly from herds that are currently accredited for both brucellosis and bovine tuberculosis. Such cervids could be moved interstate if they are officially identified and accompanied by an ICVI with a statement that the cervids originate directly from herds that are currently accredited for both brucellosis and bovine tuberculosis.

Proposed paragraph (b) would provide conditions for the interstate movement of all other cervids. Paragraph (b)(1) would provide conditions for the interstate movement of such cervids, if they are destined for immediate slaughter. Captive cervids that do not originate directly from herds that are currently accredited for brucellosis and bovine tuberculosis and that are destined for immediate slaughter could be moved interstate, provided that the cervids are officially identified and accompanied by an ICVI.

Proposed paragraph (b)(2)(i) of § 76.16 would provide general conditions for the interstate movement of captive cervids that do not originate directly from herds that are currently accredited for brucellosis and bovine tuberculosis and that are not destined for immediate slaughter. The paragraph would require that:

- The cervids originate from a herd that was subject to a herd test using an official test for brucellosis and an official test for bovine tuberculosis no more than 1 year and no less than 120 days prior to movement, with negative results.
- The cervids are additionally tested for brucellosis and bovine tuberculosis using an individual official test no more than 60 days prior to movement, with negative results.
- The cervids are officially identified.
- The cervids are accompanied by an ICVI.

Proposed paragraph (b)(2)(ii) would contain additional conditions for captive cervids moved interstate from an inconsistent State or Tribe for brucellosis and/or bovine tuberculosis. Because we would have significant concerns about an inconsistent State or Tribe's regulatory program for brucellosis and/or bovine tuberculosis, in order for a captive cervids to be moved interstate from the State or Tribe, we would require additional assurances that the cervids have not come in contact with an infected cervid after individual testing. Accordingly, we would require that, since being individually tested, the cervids do not commingle with non-natural additions to the herd that are of unknown disease status or animals that have had a non-negative test for brucellosis or bovine tuberculosis.

Finally, if we finalize this section, there is a possibility that a captive cervid will have non-negative test results to a brucellosis test administered prior to the animal's interstate movement that are such that that we must order its destruction to prevent the possible spread of brucellosis.

In such instances, under section 10407 of the AHPA, we are required to indemnify the owner of the cervid at fair market value minus salvage, with certain, limited exceptions. However, no regulations currently exist in 9 CFR regarding the payment of indemnity for such captive cervids. We therefore request public comment from all interested parties, and, in particular, captive cervid producers, regarding how an equitable appraisal process for the payment of such indemnity may be established.

If we finalize this section, we will add regulations to 9 CFR that take into consideration the comments we receive regarding how best to establish such a process.

Official Tests for Brucellosis and Bovine Tuberculosis, Official Testing Laboratories, and Official Testers (§ 76.17)

Proposed paragraph (a) of § 76.17 would require all testing for the presence or absence of brucellosis and bovine tuberculosis that is conducted in accordance with part 76 to be conducted using an official test. A list of all official tests would be found on the Internet, at *http://www.aphis.usda.gov/animal_health/animal_dis_spec/cattle.*

If this rule is finalized, the list of official tests for brucellosis would, at a minimum, be those that are currently in use within the brucellosis program: The standard card test, the manual complement-fixation test, the Rivanol test, the buffered acidified plate antigen test, the rapid automated presumptive test, the fluorescence polarization assay, the brucellosis ring test, and the heat inactivation ring test. Similarly, the list of official tests for bovine tuberculosis would, at a minimum, be those that are currently in use within the bovine tuberculosis program: The caudal fold test, the bovine interferon gamma assay, the cervical tuberculin test, the comparative cervical tuberculin test, the IDEXX Antibody serological test, the single cervical tuberculin test, and, for elk, red deer, white-tailed deer, fallow deer, and reindeer, the DPP® test.

If we determine that a test can reliably determine the presence or absence of

brucellosis or bovine tuberculosis in animals, we would add it to the list of official tests. Whenever a test is added to the list, we would publish a notice in the **Federal Register** advising the public of this addition.

If we determine at any point that an official test can no longer be considered to provide reliable results regarding the presence or absence of brucellosis or bovine tuberculosis in animals, we would remove it from the list of official tests. Whenever an official test is removed from the list, we would publish a notice in the **Federal Register** alerting the public to and setting forth the reasons for the removal.

Proposed paragraph (b) of § 76.17 would provide the process by which a laboratory could request APHIS recognition as an official testing laboratory, the conditions under which APHIS might withdraw such approval, and the appeal process for any laboratory that has had its approval withdrawn. Paragraph (b)(1) would state that, in order to be considered an official testing laboratory, a Federal, State, or university laboratory, or any other laboratory approved by the National Animal Health Laboratory Network [13], would have to submit a written application to its district APHIS VS office. A standard format for such an application would be found in the Program Standards document.

Proposed paragraph (b)(2) would describe APHIS' evaluation process for applications. First, we would review the submitted application to determine if it is complete. Then, when we determine it is complete, we would conduct formal review and evaluation of the application. Evaluation would be based on the following:

- Whether a need exists at the national level for an additional laboratory to be authorized by APHIS to conduct official tests for brucellosis and bovine tuberculosis. (This is because APHIS must exercise oversight of official testing laboratories, and has limited resources to do so.)
- Whether the laboratory has facilities, safety equipment, and standard microbiological practices appropriate for the testing specified on the application.
- Whether the personnel at the laboratory are qualified to conduct the activities specified on the application, as determined by proficiency testing.
- Whether the individual at the laboratory with oversight of serological testing or final determination of test results has adequate experience in the fields of immunology, microbiology, veterinary medicine, or a similar discipline.

Proposed paragraph (b)(3) of § 76.17 would provide that, following our evaluation, we would communicate our approval or denial of the laboratory's application to the laboratory. If this approval or denial is oral, we would subsequently communicate the approval or denial in writing.

If we approve a laboratory, it would be considered an official testing laboratory. An official testing laboratory could conduct official tests using official testers in the manner set forth in its application and approved by APHIS. A list of all official testing laboratories would be located on the APHIS Web site.

Proposed paragraph (b)(4) of § 76.17 would specify how an official testing laboratory would be required to maintain approval. In order for the laboratory to maintain approval, it would have to demonstrate, by means of annual proficiency testing, that it continually meets or exceeds the standards under which it was approved.

Proposed paragraph (b)(5) of § 76.17 would provide that, if circumstances have changed at the laboratory such that the information supplied on its application for approval is no longer accurate, the laboratory would have to provide updated information to APHIS within 30 days. In response to such notification, we could conduct another evaluation of the facility. Failure by a facility to notify us in a timely manner could result in revocation of its approval.

Proposed paragraph (b)(6) of § 76.17 would provide the conditions under which we may revoke a laboratory's approval as an official testing laboratory. It would state that we could revoke the approval of an official testing laboratory if it is determined to have falsified information on its application or to no longer meet the standards under which it was approved.

Paragraph (b)(6) would also contain the appeal process for any laboratory whose approval is revoked. Any laboratory whose approval is revoked could appeal the decision in writing to the Administrator within 14 days after receiving the written notification of the revocation. The appeal would have to state all of the reasons on which the laboratory relies to show that approval was wrongfully revoked. The Administrator would grant or deny the appeal, in writing, stating the reasons for the decision as soon as circumstances allow.

Proposed paragraph (b)(7) of § 76.17 would contain the process by which a laboratory whose approval has been revoked could seek reapproval. In order to do so, the laboratory would have to submit a written justification for reapproval to APHIS to the address specified within the Program Standards document. The justification would have to demonstrate that the issue that resulted in the revocation has been resolved.

We envision that secondary (corroboratory) testing for brucellosis or bovine tuberculosis that is conducted for purposes of the consolidated brucellosis and bovine tuberculosis program would be conducted at official testing laboratories. However, as they are today, most initial tests for the diseases would be conducted outside of a laboratory environment. Hence, paragraph (c) of § 76.17 would provide the conditions under which we would allow official testers to conduct official tests outside of such an environment. Proposed paragraph (c)(1) would continue our existing policy of allowing regulatory personnel to conduct such tests, at the discretion of a District VS office and a State or Tribal animal health official, and under the conditions specified by the office and the official.

Within the bovine tuberculosis program, we allow veterinarians that are accredited under APHIS' National Veterinary Accreditation Program (NVAP) to conduct caudal fold tests for cattle and bison and the single cervical tuberculin (SCT) test for captive cervids outside of a laboratory environment. In recent years, based on low response rates to caudal fold tests administered by certain of these veterinarians, we have begun to have concerns that those veterinarians may be incorrectly administering the caudal fold test. Because the SCT test is administered and interpreted in a similar manner to the caudal fold test, we also have similar concerns regarding consistent administration of the SCT. Accordingly, we have initiated a process to establish a ''program certification,'' that is, specialized training for accredited veterinarians, within NVAP for the correct administration of official tests for bovine tuberculosis. Proposed paragraph (c)(2) of § 76.17 would allow such certified veterinarians to operate as official testers for bovine tuberculosis outside of a laboratory environment within the State or States in which they are accredited under NVAP. If this proposed rule is finalized and an

[13] The National Animal Health Laboratory Network (NAHLN) is a network of laboratories that is overseen by APHIS and USDA's National Institute of Food and Agriculture and comprises sets of laboratories that focus on different diseases but use common testing methods and software platforms to process diagnostic requests and share information. More information regarding NAHLN may be found at the following Web site: *http://www.aphis.usda.gov/animal_health/nahln/.*

accredited veterinarian did not attain such a program certification, he or she could no longer conduct such tests.

The regulations governing program certifications under NVAP are found in 9 CFR 161.5. That section contains the process for obtaining and maintaining a program certification, but does not contain provisions regarding decertification of a program certification. However, because widespread incorrect administration of official tests for bovine tuberculosis could compromise the integrity of the bovine tuberculosis program, we believe that a qualified accredited veterinarian who consistently administers official tests for bovine tuberculosis in a manner at variance with his or her program certification should be decertified for that program certification and no longer be able to administer such tests for program purposes. We also believe that, in certain instances, deliberate or egregious misapplication of official tests should be considered grounds for suspending or revoking that veterinarian's accreditation. We would amend § 161.5 accordingly.

Miscellaneous Harmonizing Modifications to the Regulations in 9 CFR Chapter I, Subchapter C

As we mentioned at the beginning of this document, the regulations in proposed part 76 would supplant the current regulations governing the bovine tuberculosis program in 9 CFR part 77, and those governing the aspects of the brucellosis program that pertain to cattle and bison, found in 9 CFR part 78, subparts B and C. Therefore, we would remove part 77 from the regulations in its entirety, and would remove subparts B and C from part 78. We would also remove the definitions in part 78 that pertain to terms only found in subpart B or C.

As we mentioned in our discussion of the definition of *depopulate,* the regulations in 9 CFR part 50 contain conditions under which the Administrator may pay indemnity for animals destroyed because of bovine tuberculosis. Similarly, the regulations in 9 CFR part 51 contain conditions under which the Administrator may pay indemnity for animals destroyed because of brucellosis. Since these conditions are often dependent, in part, on the regulations contained in parts 77 and 78, there are, accordingly, a number of references to parts 77 and 78 within parts 50 and 51. For example, in § 51.9, paragraph (b) currently provides that the Administrator will not pay a claim for indemnity for an animal destroyed because of brucellosis, if the existence of brucellosis in the animal was determined based on the results of an official test as defined in § 78.1 and specific instructions for the administration of the test had not previously been issued to the individual performing the test by APHIS and a State animal health official. We would either modify these references to have them refer to part 76, or, if they refer to provisions in parts 77 or 78 for which no analogous provisions exist in part 76, remove the references altogether.

On a related matter, we would also modify a number of definitions in parts 50 and 51 to make them consistent with the definitions in proposed part 76. In part 50, we would amend the definitions of *Administrator, APHIS representative, approved herd plan, destroyed, herd depopulation, State, State animal health official,* and *State representative* for that reason. In part 51, we would amend the definitions of *Administrator, herd depopulation, official seal, State, State animal health official,* and *State representative* for that reason. To explain the definition of *herd depopulation,* we would also add a definition of *herd plan* to the regulations.

Part 71 of 9 CFR contains general requirements regarding the interstate movement of livestock within the United States. Several of these requirements, most notably those governing the approval of livestock facilities to receive animals that move interstate, contain multiple references to parts 77 and 78. We would modify these references to have them refer to part 76, or remove them from part 71. We would also update several of the definitions in part 71 to make them consistent with the definitions in part 76. Specifically, we would update the definitions of *Administrator, APHIS representative, State, State animal health official,* and *State representative* for that reason. (Similarly, we would revise the definition of *interstate commerce* in that part to make it consistent with the definition contained within the AHPA.)

As we mentioned previously in this document, 9 CFR part 86 contains identification and recordkeeping requirements for livestock that move in interstate commerce. Part 86 contains several references to parts 77 and 78 that would become obsolete if this proposed rule is finalized. We would modify these references to refer to part 76.

Finally, in reviewing parts 50 and 51 in developing this proposed rule, we determined that parts 50 and 51 of 9 CFR did not reference a long-standing Agency policy that APHIS does not provide indemnity for cattle, bison, or captive cervids that are publicly owned, that is, owned by the Federal Government, a State or Tribe, or any regional or local community. We would amend parts 50 and 51 to codify this policy.

Part 93 (Imports)

The regulations in 9 CFR part 93, subpart D (§§ 93.400–93.436, referred to below as part 93 or the subpart), contain requirements for the importation of ruminants into the United States to address the risk of introducing or disseminating diseases of livestock within the United States. Part 93 currently contains provisions that address the risk that imported bovines (cattle or bison) may introduce or disseminate brucellosis or bovine tuberculosis within the United States. As we mentioned in the Executive Summary at the beginning of this document, these provisions may be divided into two categories: General requirements for the importation of bovines from most countries, and country-specific requirements for Canada, Mexico, and Ireland.

The general requirements for bovines from most countries are contained in § 93.406. Bovines that are capable of transmitting brucellosis (bovines that are 6 months of age or older and sexually intact) must be tested for brucellosis within 30 days prior to the date of their exportation to the United States, unless the bovines are destined for immediate slaughter or imported from Australia or New Zealand, which we have evaluated and determined to be free of *Brucella abortus.* (We consider the results of this evaluation to still be accurate. We discuss this matter at greater length later in this document, under the section heading titled ''Brucellosis status of foreign regions (§ 93.440)''.)

Additionally, with limited exceptions, bovines that are imported into the United States must originate from a herd that tested negative to a herd test for tuberculosis within 1 year prior to the date of their exportation into the United States and must test negative to an individual test conducted within 60 days of their exportation. (In part 93, bovine tuberculosis is referred to as tuberculosis; accordingly, the remainder of this preamble will use the terms interchangeably.) Sexually intact bovines may be imported into the United States without such testing if they originate from a herd that was certified as an accredited herd within 1 year prior to export.

The regulations that are specific to bovines from Canada are contained in § 93.418. Bovines that are from an affected herd for brucellosis or bovine

tuberculosis may not be imported into the United States. Bovines that are not from an affected herd may be imported into the United States if they are destined for immediate slaughter, or if they are moved to a feedlot and then to slaughter and meet certain conditions that provide assurances that they will not transmit brucellosis or bovine tuberculosis to other animals at those feedlots.

The regulations that are specific to bovines from Mexico are contained in § 93.427. Under these regulations, bovines that are capable of transmitting brucellosis and that are not destined for immediate slaughter or movement directly to a quarantine feedlot must originate from a herd in which all test-eligible animals have been tested for brucellosis no more than 90 and no less than 30 days prior to the exportation of the bovines to the United States, with negative results, and must be subjected to an additional test for brucellosis at the port of entry into the United States, with negative results. Additionally, steers and spayed heifers that are not destined for immediate slaughter must be branded with an ''M'' or ''$M_x$'' bovine tuberculosis brand, respectively, while sexually intact bovines from Mexico must be detained at the port of entry into the United States and subjected to a test for bovine tuberculosis, with negative results.

The regulations also specify additional requirements for the importation of bovines from a herd in which animals have been determined to be reactors or suspects for brucellosis or reactors for bovine tuberculosis. Finally, based on the historically high prevalence levels of bovine tuberculosis infection in the breeds, the regulations prohibit the importation of Holstein steers and spayed heifers and Holstein cross steers and spayed heifers from Mexico.

The regulations that are specific to Ireland are contained in § 93.432. Under these regulations, bovines that are imported into the United States must originate from a herd that has been subjected to two consecutive annual whole herd tests for brucellosis, with negative results, must be subjected to an additional test for brucellosis no more than 120 and no less than 60 days prior to export, with negative results, and must be subjected to a third test for brucellosis within 30 days prior to export, with negative results.

The general requirements in part 93 predate the establishment of APHIS, and reflect what was considered at the time to be adequate mitigations for the risk of imported bovines introducing or disseminating brucellosis and bovine tuberculosis within the United States. Similarly, the country-specific requirements reflect individual assessments that we conducted at particular points in time of the risk that cattle imported from Canada, Mexico, or Ireland posed at that time of disseminating brucellosis and/or bovine tuberculosis within the United States.

The general requirements were predicated on assumptions at the time that foreign countries had regulatory programs for brucellosis and bovine tuberculosis that were comparable to our own, and the country-specific requirements were predicated on the assumption that all regions within Canada, Mexico, and Ireland have roughly equivalent bovine tuberculosis and brucellosis programs and prevalence rates for brucellosis and/or bovine tuberculosis.

We have discovered, however, that regulatory programs for brucellosis and bovine tuberculosis are not uniform throughout the world. While some of these programs are equivalent to or exceed those within the United States, others lack controls that we consider integral components of any regulatory program for brucellosis or bovine tuberculosis.

Moreover, even within a particular foreign country, we have discovered that regulatory programs for brucellosis and bovine tuberculosis can vary considerably among geopolitical regions, and that, accordingly, prevalence rates for brucellosis or bovine tuberculosis can likewise vary considerably from region to region. For example, in Mexico, herd prevalence rates for bovine tuberculosis vary significantly among exporting regions (States and zones within States), from less than 0.01 percent to as high as 14 percent.

Finally, we have discovered that regulatory programs for brucellosis and bovine tuberculosis in particular regions should not be considered static. Several regions have modified their programs in recent years in order to more aggressively pursue eradication of the diseases in their region, while other regions have had to divert resources once allocated to their regulatory programs to address the introduction or dissemination of other diseases of livestock within the region.

For these reasons, we have evaluated the risk associated with the importation of cattle and bison from foreign regions to determine whether to modify the current regulations, and, if so, how. The risk evaluation, titled ''Bovine Tuberculosis and Brucellosis: Evaluation of Import Risk and Mitigation Strategies,'' [14] finds that the existing requirements, both those that are general and those that are country-specific, sometimes provide insufficient risk mitigation for bovines from higher-prevalence regions and a barrier to trade from low-prevalence regions, and should therefore be modified. The risk evaluation examines two possible modifications: (1) Adopting international standards developed by the OIE or (2) applying the U.S. prevalence-based requirements currently delineated in the Uniform Methods and Rules for the bovine tuberculosis and brucellosis programs within the United States, to the importation of bovines from foreign regions. The risk evaluation recommends the latter approach.

Accordingly, based on the recommendations of the risk evaluation, we would establish a system to classify foreign regions [15] as a particular status level for bovine tuberculosis and a status for brucellosis. The status would be based on our assessment of the regulatory programs for tuberculosis or brucellosis within the region and the prevalence of tuberculosis or brucellosis among bovine herds within the region.

Since regulatory programs and disease status may change, we also would establish provisions for modifying the tuberculosis or brucellosis classification of a foreign region. Regions could request a higher classification for either or both of the diseases, and we would make these requests publicly available for review and comment. Based on the comments received, we would issue a follow-up notice specifying whether we were granting or denying the request for reclassification. Conversely, we would also reserve the right to downgrade a region's status based on emerging evidence.

Finally, we would establish conditions for the importation of cattle and bison from regions with the various classifications that we consider commensurate with the degree of risk of

[14] The evaluation is available on Regulations.gov (see **ADDRESSES** above) or by contacting the persons listed under **FOR FURTHER INFORMATION CONTACT**.

[15] As we mentioned earlier in this document, a region is defined in § 93.400 as ''any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following: (1) A national entity (country); (2) a part of a national entity (zone, county, department, municipality, parish, Province, State, etc.); (3) parts of several national entities combined into an area; or (4) a group of national entities (countries) combined into a single area.'' Thus a foreign country could request a classification for a particular province, State, or department within that country, or could request that a zone within a province, State, or department receive a different classification than the rest of the province, State, or department.

dissemination of bovine tuberculosis or brucellosis associated with the importation of cattle and bison imported from such regions.

Tuberculosis Status of Foreign Regions (§ 93.437)

Proposed § 93.437 would contain the classification system for the bovine tuberculosis status of foreign regions. There would be five levels of classification.

Proposed paragraph (a) of § 93.437 would describe the highest classification, Level I. Level I foreign regions would be regions of the world that have a program that meets our requirements for bovine tuberculosis classification, which would be set forth in proposed § 93.438, and a prevalence of bovine tuberculosis in their domestic bovine (cattle and bison) herds of less than 0.001 percent over at least the previous 2 years (24 consecutive months). This prevalence threshold would correspond to our highest State or zone classification level for bovine tuberculosis, accredited-free. However, while we currently require a State or zone to have a zero percent herd prevalence rate for bovine tuberculosis in the State or zone's cattle and bison herds in order to qualify for accredited-free status, we would require foreign regions to have a prevalence of bovine tuberculosis in their domestic bovine herds of less than 0.001 percent over at least the previous 2 years. We are proposing this slightly less stringent standard to reflect the overall prevalence of tuberculosis in the United States.

Proposed paragraph (b) of § 93.437 would describe the next highest classification, Level II. Level II regions would have a program that meets APHIS requirements for tuberculosis classification in accordance with proposed § 93.438, and a prevalence of tuberculosis in their domestic bovine herds equal to or greater than 0.001 percent, but less than 0.01 percent, over the previous 2 years (24 consecutive months). This prevalence threshold would correspond to the second highest State or zone classification, modified accredited advanced, in our current prevalence-based system for the domestic bovine tuberculosis program.

Proposed paragraph (c) of § 93.437 would describe the third classification, Level III. Level III regions would be regions that have a program that meets APHIS' proposed requirements for tuberculosis classification in accordance with § 93.438, and a prevalence of tuberculosis in their domestic bovine herds equal to or greater than 0.01 percent, but less than 0.1 percent, over the previous year (12 consecutive months). This would correspond to the third highest State or zone classification, modified accredited, in our current prevalence-based system for the domestic bovine tuberculosis program.

Proposed paragraph (d) of § 93.437 would describe the fourth classification, Level IV. Level IV regions would be regions that have a program that meets APHIS' requirements for tuberculosis classification in accordance with § 93.438, and a prevalence of tuberculosis in their domestic bovine herds equal to or greater than 0.1 percent, but less than 0.5 percent, over the previous year (12 consecutive months). This would correspond to the fourth highest State or zone classification, accreditation preparatory.

Proposed paragraph (e) of § 93.437 would describe the fifth and final classification, Level V. Level V regions would be regions that do not have a program that meets APHIS' requirements for tuberculosis classification, have a prevalence of tuberculosis in their domestic bovine herds equal to our greater than 0.5 percent, or are unassessed by APHIS with regard to tuberculosis prevalence.

Proposed paragraph (f) of § 93.437 would provide that lists of all Level I regions, Level II regions, Level III regions, Level IV, and Level V regions for tuberculosis are found online, at *http://www.aphis.usda.gov/import_export/animals/live_animals.shtml,* and that changes to the lists would be made in accordance with proposed § 93.438.

Process for Requesting Regional Classification for Tuberculosis (§ 93.438)

Proposed § 93.438 would set forth the process by which a region could request a classification for bovine tuberculosis.

Proposed paragraph (a) of § 93.438 would state that a representative of the competent veterinary authority of any country or countries could request that APHIS classify a region for tuberculosis. Requests for classification or reclassification would have to be submitted to APHIS electronically or through the mail to the address as provided at *http://www.aphis.usda.gov/import_export/animals/live_animals.shtml.* Guidance regarding how to complete a request in a manner that will allow APHIS to review it expeditiously would be available at *http://www.aphis.usda.gov/import_export/animals/reg_request.shtml,* and could also be obtained by contacting APHIS in writing at the address listed in the regulations. At a minimum, in order for APHIS to consider the request complete, it would have to define the boundaries of the region, specify the prevalence level for tuberculosis within the region, and demonstrate the following:

- That there is effective veterinary control and oversight within the region.
- That tuberculosis is a notifiable disease within the region.
- That the region has a program in place for tuberculosis that includes, at a minimum: Epidemiological investigations following the discovery of any infected animals or affected herds, or any animals that have had non-negative test results following a test for tuberculosis, and documentation of these investigations; management of affected herds in a manner designed to eradicate tuberculosis from those herds, and documentation regarding this management; regulatory controls on the movement of livestock into, within, and from the region that correspond to the risk of dissemination of tuberculosis associated with such movement; and access to, oversight of, and quality controls for diagnostic testing for tuberculosis within the region.
- That the region has surveillance in place that is equivalent to or exceeds federal standards for surveillance within the United States.

We recognize that the draft regulatory framework document suggested that we would require regions to submit a request in accordance with § 92.2 in order to be evaluated for bovine tuberculosis status. That section provides eight elements that must make up a region's request for evaluation of its animal health status with regard to certain disease agents.

After deliberation, we decided that directly applying the eight factors described in § 92.2 would not suffice for the evaluation of the tuberculosis or brucellosis status of a foreign region. Although many of the factors are germane, others—such as emergency preparedness and response—are more appropriate for exotic diseases rather than tuberculosis and brucellosis, which are often endemic within regions. More importantly, the eight factors do not fully reflect the specific information we require to evaluate a foreign region's regulatory programs for tuberculosis or brucellosis. We would therefore request that foreign regions provide the above information supporting a request for tuberculosis classification, which incorporates both relevant elements of § 92.2 and critical factors such as information regarding epidemiological investigations, affected herd management, and controls on diagnostic testing within the region. (The format

and content of requests for brucellosis classification, discussed below, would be similar.)

Proposed paragraph (b) of § 93.438 would provide that, if we consider a request complete, we would publish a notice in the **Federal Register** proposing to classify the region according to § 93.437, and making available to the public the information upon which this proposed classification is based. The notice would request public comment.

Proposed paragraph (c)(1) of § 93.438 would provide that, if no comments are received on the notice, or if comments are received but do not affect our proposed classification, we would publish a subsequent notice in the **Federal Register** announcing that classification to be final and adding the region to the appropriate list on the Internet.

Proposed paragraph (c)(2) of § 93.438 would provide that, if comments received on the notice suggest that the region be classified according to a different tuberculosis classification, and we agree with the comments, we would publish a subsequent notice in the **Federal Register** making the information supplied by commenters available to the public, and proposing to classify the region according to this different classification. This notice would also request public comment.

Proposed paragraph (c)(3) of § 93.438 would provide that, if comments received on the notice suggest that insufficient information was supplied on which to base a tuberculosis classification, and we agree with the comments, we would publish a subsequent notice in the **Federal Register** specifying the additional information needed before we could classify the region.

Proposed paragraph (d) of § 93.438 would provide that, if a region is classified under the provisions of the section, that region may be required to submit additional information or allow APHIS to conduct additional information collection activities in order for that region to maintain its classification. It would also provide that, if we determine that a region's classification for tuberculosis is no longer accurate, we would publish a notice in the **Federal Register** announcing the revised classification and setting forth the reasons for this reclassification.

Importation of Ruminants From Certain Regions of the World; Tuberculosis (§ 93.439)

Proposed § 93.439 would contain our revised requirements for the importation of bovines to address the risk that they could present of disseminating tuberculosis within the United States.

Proposed paragraph (a) of § 93.439 would prohibit the importation of ruminants that are known to be infected with or exposed to tuberculosis and ruminants that have had a non-negative response to any test for tuberculosis. Allowing the importation of known or potentially infected ruminants would not be in keeping with our responsibility under the AHPA to prevent the dissemination of bovine tuberculosis within the United States.

Pursuant to this paragraph, we would continue our existing prohibition on the importation of Holstein steers and spayed heifers and Holstein cross steers and spayed heifers from Mexico. Based on information obtained from veterinary authorities within Mexico, it is not uncommon for a significant percentage of the cattle in a herd of Holstein steers and spayed heifers or Holstein cross steers and spayed heifers to be infected with tuberculosis.

Proposed paragraph (b) of § 93.439 would contain conditions for the importation of bovines from Level I regions. Unless specified otherwise by the Administrator, bovines could be imported into the United States from a Level I region for tuberculosis without further restriction under the section.

Paragraph (b) would contain a footnote, footnote 11 within the subpart, stipulating that the importation of the bovines, as well as that of all other bovines covered by the section, would still be subject to all other relevant restrictions of part 93. For example, the importation of the bovines would still be subject to the restrictions of § 93.404, which requires, with limited exceptions, that a permit be issued for the importation of a ruminant before that ruminant is imported into the United States.

Proposed paragraph (c) of § 93.439 would contain conditions for the importation of bovines for immediate slaughter from Level II, III, and IV regions for tuberculosis. Such bovines could be imported into the United States provided that the bovines are officially identified and accompanied by a certificate, issued in accordance with the general requirements for issuance of certificates contained in paragraph (a) of § 93.405, with an additional statement that the bovines are officially identified. In the event that a bovine imported for immediate slaughter is determined to be infected with bovine tuberculosis, official identification would aid us in conducting traceback of the animal and could potentially trigger a review of the exporting region's classification for bovine tuberculosis.

Proposed paragraph (d) of § 93.439 would contain conditions for the importation of bovines for purposes other than immediate slaughter from a Level II region for tuberculosis. Proposed paragraph (d)(1) of § 93.439 would provide conditions for the importation of bovines directly from currently accredited herds for tuberculosis. (As we discuss below, for purposes of part 93, an accredited herd for tuberculosis would be a herd that meets APHIS' standards for accreditation for tuberculosis status, as specified in an import protocol.) Such bovines could be imported into the United States, provided that:

- The bovines are officially identified; and
- The bovines are accompanied by a certificate, issued in accordance with § 93.405, with an additional statement that the bovines are officially identified and originate directly from a currently accredited herd for tuberculosis.

These requirements would be consistent with the conditions for interstate movement of cattle from a currently accredited herd in a modified accredited advanced State or zone that are in the current Uniform Methods and Rules for the domestic bovine tuberculosis program.

Paragraph (d)(2) of § 93.439 would provide conditions for the importation of sexually intact bovines that do not originate directly from a currently accredited herd for bovine tuberculosis. Such bovines could be imported into the United States from a Level II region for tuberculosis for purposes other than immediate slaughter, provided that:

- If the bovines are 6 months of age or older, the bovines are subjected to an individual test for tuberculosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411, with negative results; and
- The bovines are officially identified; and
- The bovines are accompanied by a certificate, issued in accordance with § 93.405, with an additional statement that the animals are officially identified.

These requirements are generally consistent with the current provisions in the Uniform Methods and Rules for the interstate movement of breeding cattle from a modified accredited advanced State or zone. (The risk evaluation explains why we consider sexually intact cattle imported into the United States to be equivalent to breeding cattle produced within the United States.) However, while the Uniform Methods and Rules for the bovine tuberculosis program specifies that individual tuberculosis tests must

take place at the premises of origin prior to interstate movement, we would require them at the port of entry or during post-arrival quarantine for imported sexually intact cattle. This discrepancy is because we need assurances that tuberculosis tests of sexually intact bovines are accurately administered and interpreted; among other reasons, the life spans of sexually intact animals tend to be significantly longer than those of steers and spayed heifers, which affords a significantly longer window of opportunity for infected animals to expose other animals in their herd to the pathogen. Standardized training regarding tuberculosis testing provides such assurances for sexually intact bovines moved interstate within the United States. Testing at the port of entry or during post-arrival quarantine of the bovines would provide such assurances for imported sexually intact bovines.

Finally, we would exempt cattle less than 6 months of age from this testing requirement based on long-standing Agency policy regarding when a bovine from a foreign region becomes test-eligible for tuberculosis.

Proposed paragraph (d)(3) of § 93.439 would contain requirements for the importation of steers and spayed heifers that do not originate directly from a currently accredited herd for bovine tuberculosis. Such bovines could be imported into the United States from a Level II region for tuberculosis for purposes other than immediate slaughter, provided that:

- The steers or spayed heifers are officially identified; and
- The steers or spayed heifers are accompanied by a certificate, issued in accordance with § 93.405, with an additional statement that the bovines are officially identified.

These requirements correspond to the provisions in the Uniform Methods and Rules for the domestic bovine tuberculosis program for interstate movement of steers and spayed heifers from modified accredited advanced States and zones.

Proposed paragraph (e) of § 93.439 would contain conditions for the importation of bovines for purposes other than immediate slaughter from a Level III region for tuberculosis. Proposed paragraph (e)(1) of § 93.439 would provide conditions for the importation of bovines directly from currently accredited herds for tuberculosis. Such bovines could be imported into the United States, provided that:

- The bovines are officially identified; and
- The bovines are accompanied by a certificate, issued in accordance with § 93.405, with an additional statement that the bovines are officially identified and originate directly from a currently accredited herd for tuberculosis.

These requirements would be consistent with the conditions for interstate movement of cattle from a currently accredited herd in a modified accredited State or zone that are in the current Uniform Methods and Rules for the domestic bovine tuberculosis program.

Proposed paragraph (e)(2) of § 93.439 would provide conditions for the importation of sexually intact bovines that do not originate directly from a currently accredited herd for bovine tuberculosis. Such bovines could be imported into the United States from a Level III region for tuberculosis for purposes other than immediate slaughter, provided that:

- The bovines originate from a herd that was subjected to a whole herd test for tuberculosis on its premises of origin no more than 1 year prior to export of the bovines to the United States, with negative results; and
- If the bovines are 2 months of age or older, the bovines are subjected to an additional individual test for tuberculosis on the premises of origin no more than 60 days prior to export of the bovines to the United States, with negative results, except that this test is not required if the bovines are exported within 60 days of the whole herd test and were included in that test; and
- The bovines are officially identified; and
- The bovines are accompanied by a certificate, issued in accordance with § 93.405, with an additional statement that the animals meet the conditions for importation in the section.

These requirements would be consistent with the provisions for interstate movement of breeding cattle and bison from a modified accredited State or zone that are currently in the Uniform Methods and Rules for the domestic bovine tuberculosis program.

Proposed paragraph (e)(3) of § 93.439 would contain requirements for the importation of steers and spayed heifers that do not originate directly from a currently accredited herd for tuberculosis. Such bovines could be imported into the United States from a Level III region for tuberculosis for purposes other than immediate slaughter, provided that:

- If the steers or spayed heifers are 6 months of age or older, the steers or spayed heifers are subjected to an individual test for tuberculosis on the premises of origin no more than 60 days prior to export of the bovines to the United States, with negative results; and
- The steers or spayed heifers are officially identified; and
- The steers or spayed heifers are accompanied by a certificate, issued in accordance with § 93.405, with an additional statement that the animals meet the conditions for importation in paragraph (e)(3) of § 93.439.

These requirements would be consistent with the conditions for interstate movement of steers and spayed heifers from a modified accredited State or zone that are currently in the Uniform Methods and Rules for the domestic bovine tuberculosis program.

Proposed paragraph (f) of § 93.439 would contain conditions for the importation of bovines for purposes other than immediate slaughter from a Level IV region for tuberculosis. Proposed paragraph (f)(1) of § 93.439 would provide conditions for the importation of bovines directly from currently accredited herds for tuberculosis. Such bovines could be imported into the United States, provided that:

- The bovines are subjected to an individual test for tuberculosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411, with negative results; and
- The bovines are officially identified; and
- The bovines are accompanied by a certificate, issued in accordance with § 93.405, with an additional statement that the bovines are officially identified and originate directly from a currently accredited herd for tuberculosis.

These requirements would be generally consistent with the requirements for interstate movement of cattle from a currently accredited herd in an accreditation preparatory State or zone that are currently in the Uniform Methods and Rules. However, while the Uniform Methods and Rules requires an individual tuberculosis test to take place on the premises of origin, we would require it to take place at the port of entry or during post-arrival quarantine. This would be in order to have assurances that the test was reliably administered and interpreted.

Proposed paragraph (f)(2) of § 93.439 would provide conditions for the importation of sexually intact bovines that do not originate directly from a currently accredited herd for bovine tuberculosis. Such bovines could be imported into the United States from a Level IV region for tuberculosis for purposes other than immediate slaughter, provided that:

• The bovines originate from a herd that was subjected to two whole herd tests for tuberculosis on its premises of origin conducted no less than 9 months and no more than 15 months apart, with the second test conducted no less than 60 days prior to the export of the bovines to the United States, with negative results; and

• If the bovines are 2 months of age or older, the bovines are subjected to an additional individual test for tuberculosis at the port of entry into the United State or during post-arrival quarantine in accordance with § 93.411, with negative results; and

• The bovines are officially identified; and

• The bovines are accompanied by a certificate, issued in accordance with § 93.405, with an additional statement that the bovines meet the requirements in this paragraph.

The testing requirements in part 77 for the interstate movement of sexually intact cattle and bison from non-accredited herds in accreditation preparatory States and zones require a herd test followed by two individual tuberculosis tests. However, the Uniform Methods and Rules for the bovine tuberculosis program currently limit the interstate movement of breeding cattle from accreditation preparatory States and zones to cattle that originate directly from currently accredited herds, and the herd testing protocol for accreditation in the Uniform Methods and Rules requires whole herd tests administered at no less than 9 and no more than 15 months apart, with negative test results. The Uniform Methods and Rules also specify that the cattle must be subsequently individually tested for tuberculosis prior to movement, with negative results. These proposed import requirements would be consistent with that testing protocol.

Proposed paragraph (f)(3) of § 93.439 would contain requirements for the importation of steers and spayed heifers that do not originate directly from a currently accredited herd for bovine tuberculosis. Such bovines could be imported into the United States from a Level IV region for tuberculosis for purposes other than immediate slaughter, provided that:

• The bovines originate from a herd that was subjected to a whole herd test for tuberculosis on its premises of origin no more than 1 year prior to the export of the bovines to the United States, with negative results; and

• If the bovines are 2 months of age or older, the bovines are subjected to an additional individual test for tuberculosis on the premises of origin no more than 60 days prior to export of the bovines to the United States, with negative results, except that this additional test is not required if the bovines are exported within 60 days of the whole herd test and were included in that test; and

• The bovines are officially identified; and

• The bovines are accompanied by a certificate, issued in accordance with § 93.405, with an additional statement that the bovines meet the requirements in paragraph (f)(3) of § 93.439.

These proposed requirements would be consistent with the current conditions in the Uniform Methods and Rules for the interstate movement of steers and spayed heifers from an accreditation preparatory State or zone.

Currently, the Uniform Methods and Rules for the bovine tuberculosis program prohibit the movement of cattle from a nonaccredited State or zone to an accredited free State or zone. If we were to apply this principle to the importation of bovines, based on the prevalence of bovine tuberculosis within the United States, the importation of cattle from Level V regions for tuberculosis would be prohibited. However, as the risk evaluation points out, there could be reasons why an importer would want to import cattle from such a region, such as in order to improve the genetic diversity of his or her domestic herd. We are therefore proposing the following requirements for the importation of bovines for any purpose from a Level V region for tuberculosis; these requirements would be contained in paragraph (g) of § 93.439:

• APHIS and the importer have entered into a Cooperative and Trust Fund Agreement, and the importer has deposited funds with APHIS in an amount determined by APHIS to cover all costs incurred by APHIS in providing services in accordance with the Cooperative and Trust Fund Agreement; and

• The bovines originate from a herd that was subjected to two whole herd tests for tuberculosis on its premises of origin and conducted no less than 9 months and no more than 15 months apart, with at least the second whole herd test administered by an APHIS veterinarian and conducted no less than 60 days prior to export, with negative results; and

• The bovines are subjected to an additional individual test for tuberculosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411, with negative results; and

• The bovines are officially identified; and

• The bovines are accompanied by a certificate, issued in accordance with § 93.405, with an additional statement that the bovines meet the requirements in paragraphs (g)(1), (g)(2), and (g)(4) of § 93.439.

We would require at least one of the whole herd tests to be administered by an APHIS veterinarian because foreign regions with a Level V classification for tuberculosis may either not have a control program for bovine tuberculosis, may have a control program for tuberculosis that APHIS has determined not to be equivalent to that within the United States, or may have a bovine tuberculosis prevalence rate that is an order of magnitude higher than that of the United States.

Brucellosis Status of Foreign Regions (§ 93.440)

Proposed § 93.440 would contain our classification system for the brucellosis status of foreign regions. There would be the three levels of classification.

Proposed paragraph (a) of § 93.440 would describe the higher classification, Level I. A Level I region for brucellosis would be a region that has a program that meets APHIS requirements for brucellosis classification in accordance with proposed § 93.441, and a prevalence of brucellosis in their domestic bovine herds of less than 0.001 percent over at least the previous two years (24 consecutive months). This prevalence threshold would correspond to the highest State classification level for brucellosis in the Uniform Methods and rules for that program, Class Free, which requires a zero prevalence rate for brucellosis within a State. However, as we do not believe that we can hold foreign regions to a standard for bovine tuberculosis prevalence that is more stringent than the actual prevalence of bovine tuberculosis within the United States, so we similarly believe that we cannot hold foreign regions to a higher standard for brucellosis than the actual prevalence of brucellosis within the United States.

Proposed paragraph (b) of § 93.440 would describe the second classification, Level II. A Level II region for brucellosis would be a region that has a program that meets APHIS requirements for brucellosis classification in accordance with § 93.441, and that has a prevalence of brucellosis in their domestic bovine herds equal to or greater than 0.001 percent, but less than 0.01 percent, over the previous 2 years. This corresponds to the second highest State classification for brucellosis in the Uniform Methods

and Rules for the domestic brucellosis program, Class A.

Proposed paragraph (c) of § 93.440 would describe the third classification, Level III. A Level III region would be a region that has a program that does not meet APHIS requirements for brucellosis classification in accordance with § 93.441, that has a herd prevalence equal to or greater than .01 percent, or that is unassessed by APHIS with regard to brucellosis prevalence. This would correspond to the third and lowest State classification for brucellosis in the Uniform Methods and Rules for the domestic brucellosis program, Class B.

Proposed paragraph (d) of § 93.440 would state that lists of all Level I, Level II, and Level III regions for brucellosis are found online, at *http://www.aphis.usda.gov/import_export/animals/live_animals.shtml.* It would further state that changes to the lists would be made in accordance with proposed § 93.441.

As we mentioned previously in this document, the general requirements for importation of bovines to address the risk of introducing and disseminating brucellosis within the United States currently exempt Australia and New Zealand from having to follow the requirements; this is because we have evaluated both Australia and New Zealand and determined them to be free of *Brucella abortus.* For that reason, if this rule is finalized, both Australia and New Zealand would be categorized as Level I regions for brucellosis.

Process for Requesting Regional Classification for Brucellosis (§ 93.441)

Proposed § 93.441 would set forth the process by which a region could request a classification for brucellosis. This process would be very similar to the process described in proposed § 93.438 for requesting a classification for bovine tuberculosis.

Proposed paragraph (a) of § 93.441 would state that a representative of the competent veterinary authority of any country or countries could request that APHIS classify for brucellosis. Requests for classification would have to be submitted to APHIS electronically or through the mail as provided at *http://www.aphis.usda.gov/import_export/animals/live_animals.shtml.* Guidance regarding how to complete a request in a manner that will allow APHIS to review it expeditiously would be available at *http://www.aphis.usda.gov/import_export/animals/reg_request.shtml,* and could also be obtained by contacting APHIS in writing at the address listed in the regulations. At a minimum, in order for APHIS to consider the request complete, it would have to define the boundaries of the region, specify the prevalence level for brucellosis within the region, and demonstrate the following:

- That there is effective veterinary control and oversight within the region.
- That brucellosis is a notifiable disease within the region.
- That the region has a program for brucellosis in place that includes, at a minimum: Epidemiological investigations following the discovery of any infected animals or affected herds, or any animals or herds that have had non-negative test results following a test for brucellosis, and documentation of these investigations; management of affected herds in a manner designed to eradicate brucellosis from those herds, and documentation regarding this management; regulatory controls on the movement of livestock into, within, and from the region that correspond to the risk of dissemination of brucellosis associated with such movement; and access to, oversight of, and quality controls on diagnostic testing for brucellosis within the region.
- That the region has surveillance in place that is equivalent to or exceeds Federal standards for brucellosis surveillance within the United States.
- That, if the region vaccinates for brucellosis, it is in a manner that has been approved by APHIS.

Like the proposed information requirements for a regional classification for tuberculosis, these requirements would be aimed at obtaining specific information from a foreign region sufficient to evaluate the regulatory program for brucellosis within the region.

Proposed paragraph (b) of § 93.441 would provide that, if we consider the request complete, APHIS would publish a notice in the **Federal Register** proposing to classify the region for brucellosis, and making available to the public the information upon which this proposed classification is based. The notice would request public comment.

Proposed paragraph (c) of § 93.441 would set out our process for notifying the public of our determination. If no comments are received on the initial notice, or if comments are received but do not affect our proposed classification, we would publish a subsequent notice in the **Federal Register** announcing the classification to be final and adding the region to the list of such regions on the Internet.

If comments received on the initial notice suggest that the region be classified according to a different brucellosis classification, and we agree with the comments, we would publish a subsequent notice in the **Federal Register** making the information supplied by the commenters available to the public, and proposing to classify the region according to this different classification. This notice would also request public comment.

Finally, if comments received on the notice suggest that insufficient information was supplied on which to base brucellosis classification, and we agree with the comments, we would publish a subsequent notice in the **Federal Register** specifying the additional information needed before we could classify the region.

Proposed paragraph (d) would provide that, if a region is classified under the provisions of the section, that region may be required to submit additional information or allow APHIS to conduct additional information collection activities in order for that region to maintain its classification. It would also provide that if APHIS determines that a region's classification for brucellosis is no longer accurate, we will publish a notice in the **Federal Register** announcing that revised classification, as well as the reasons for it.

Importation of Ruminants From Certain Regions of the World; Brucellosis (§ 93.442)

Proposed § 93.442 would contain our revised requirements for the importation of bovines to address the risk that they could present of disseminating brucellosis within the United States.

Proposed paragraph (a) of § 93.442 would prohibit the importation of ruminants that are known to be infected with or exposed to brucellosis and ruminants that have had a non-negative response to any test for *Brucella* spp. Allowing the importation of known or potentially infected ruminants would not be in keeping with our responsibility under the AHPA to prevent the dissemination of brucellosis within the United States.

Proposed paragraph (b) of § 93.442 would provide that, unless specified otherwise by the Administrator, bovines could be imported into the United States from a Level I region for brucellosis without further restriction under the section. Paragraph (b) would contain a footnote, footnote 12 within the subpart, stipulating that the importation of such bovines would still be subject to all other relevant restrictions within 9 CFR.

Proposed paragraph (c) of § 93.442 would contain conditions for the importation of bovines for immediate slaughter from Level II or Level III regions. Such bovines could be

imported into the United States, provided that they are officially identified and accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines are officially identified.

Proposed paragraph (d) of § 93.442 would contain conditions for the importation of sexually intact bovines from a Level II region for brucellosis for purposes other than immediate slaughter. Proposed paragraph (d)(1) of § 93.442 would contain conditions for the importation of bovines that originate directly from currently accredited herds for brucellosis. Such bovines could be imported into the United States from a Level II region for brucellosis, provided that:

- The bovines are officially identified; and
- The bovines are accompanied by a certificate, in accordance with § 93.405, with an additional statement that the bovines are officially identified and originate directly from a currently accredited herd for brucellosis.

These requirements would consistent with the conditions for the interstate movement of cattle directly from currently certified brucellosis-free herds in Class A States that are contained in the current Uniform Methods and Rules for the domestic brucellosis program.

Proposed paragraph (d)(2) of § 93.442 would contain conditions for the importation of sexually intact bovines that do not originate directly from a currently accredited herd for brucellosis. Such bovines could be imported into the United States from a Level II region for brucellosis for purposes other than immediate slaughter, provided that:

- The bovines originate from a herd that was subjected to a whole herd test for brucellosis on its premises of origin no more than 90 days and no less than 30 days prior to the export of the bovines to the United States, with negative results; and
- If the bovines are 6 months of age or older, the bovines are subjected to an additional individual test for brucellosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411, with negative results; and
- The bovines are officially identified; and
- The bovines are accompanied by a certificate, issued in accordance with § 93.406, with an additional statement that the bovines meet the relevant requirements in the paragraph.

These requirements would be consistent with the conditions for the importation of breeding bovines from Mexico that are currently contained in part 93. We have evaluated those requirements and determined that they are appropriate mitigations, provided that a foreign region has a brucellosis prevalence of less than 0.01 percent.

Proposed paragraph (d)(3) of § 93.442 would contain provisions for the importation of steers and spayed heifers from Level II regions for brucellosis. Steers and spayed heifers could be imported to the United States from such regions, provided that:

- The steers or spayed heifers are officially identified; and
- The steers or spayed heifers are accompanied by a certificate, issued in accordance with § 93.405, with an additional statement that the steers or spayed heifers are officially identified.

We would not require the steers or spayed heifers to be tested for brucellosis because there is no evidence that steers or spayed heifers can transmit brucellosis. However, we would require them to be identified. In the event that a shipment of bovines destined to the United States is determined to contain infected animals, knowing the origin of each of the bovines in that shipment would facilitate a timely epidemiological investigation.

Proposed paragraph (e) of § 93.442 would contain conditions for the importation of cattle from Level III regions for brucellosis. Paragraph (e)(1) § 93.442 would contain standards for the importation of bovines directly from currently accredited herds for brucellosis in a Level III region for brucellosis:

- If sexually intact, the bovines are subjected to an individual test for brucellosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411, with negative results; and
- The bovines are officially identified; and
- The bovines are accompanied by a certificate, issued in accordance with § 93.405, with an additional statement that the bovines are officially identified and originate directly from a currently accredited herd for brucellosis.

It is important to note that these cattle would have to come from herds that are accredited according to our standards for accreditation, as these are specified in an import protocol with the foreign region. In order for us to enter into such an import protocol with a Level III region for brucellosis, we would have to evaluate their veterinary infrastructure and determine it to be sufficient to have assurances that it can implement the standards that would be specified in the protocol document. It is therefore possible that the conditions in this paragraph will not be applicable for certain Level III regions for brucellosis.

Proposed paragraph (e)(2) of § 93.442 would contain conditions for the importation of sexually intact bovines from a Level III region for brucellosis for purposes other than immediate slaughter. Such bovines could be imported into the United States, provided that:

- The bovines originate from a herd that was subjected to two whole herd tests for brucellosis on its premises of origin, with the second test taking place no more than 90 days and no less than 30 days prior to the export of the bovines to the United States, with negative results each time; and
- If the bovines are 6 months of age or older, the bovines are subjected to an additional individual test for brucellosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411; and
- The bovines are officially identified; and
- The bovines are accompanied by a certificate, issued in accordance with § 93.405, with an additional statement that the bovines meet the relevant requirements of the paragraph.

These requirements would be consistent with the conditions for the movement of breeding cattle from Class B States that are specified in the current Uniform Methods and Rules for the domestic brucellosis program.

Proposed paragraph (e)(3) of § 93.442 would set forth conditions for the importation of steers and spayed heifers from a Level III region for purposes other than immediate slaughter. Because there is no scientific evidence suggesting that they are a source of transmission of brucellosis, steers or spayed heifers would not have to be tested for the disease in order to be imported into the United States. They would, however, need to be officially identified and accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that they are officially identified.

Existing General Requirements

We would remove paragraphs (a), (c), and (d) of § 93.406, which contain the existing brucellosis and bovine tuberculosis testing requirements for bovines imported from all countries other than Canada, Mexico, and Ireland.

Existing Country-Specific Requirements

As we mentioned previously in this document, the regulations in part 93 that address the risk that bovines from Canada may present of disseminating

bovine tuberculosis or brucellosis within the United States are contained in § 93.418. We are proposing to remove paragraphs (b) and (c) of § 93.418, which contain the tuberculosis and brucellosis testing or certification requirements for such bovines.

As we also mentioned previously in this document, § 93.427 contains regulations that address the risk that bovines from Mexico may present of disseminating bovine tuberculosis or brucellosis within the United States. We would remove paragraphs (c) and (d) of § 93.427, which contain the bovine tuberculosis- and brucellosis-specific requirements for the importation of cattle from Mexico.

We would, however, retain one of the existing provisions in paragraph (c)(1) of that section, which requires steers and spayed heifers that are not destined for immediate slaughter to be branded with an ''M'' or ''$M_x$'' bovine tuberculosis brand, by incorporating this provision into the general requirements for the importation of bovines from Mexico in paragraph (a) of the section. We are retaining this branding requirement because steers and spayed heifers from Mexico constitute a large portion of the total cattle imported into the United States, because tracing such animals using solely their official identification is commensurately harder, and because we believe it is therefore necessary to have additional identification of such animals regarding their country of origin in the unlikely event that steers or spayed heifers of Mexican origin that have been imported into the United States are determined to be infected with bovine tuberculosis.

Section 93.424 requires an import permit to be issued for most ruminants that are imported into the United States from Mexico. Paragraph (b) of § 93.424 requires, for most cattle imported from Mexico, an official record of brucellosis testing conducted pursuant to § 93.427 to be presented at inspection at the port of entry. We are amending paragraph (b) to reflect the fact that § 93.427 no longer has such testing requirements.

Section 93.429 contains conditions for the importation of ruminants from Mexico for immediate slaughter. Since cattle imported from Mexico for immediate slaughter would now be subject to the relevant importation requirements in §§ 93.439 and 93.442, we are removing references to cattle from § 93.429.

As we mentioned previously in this document, § 93.432 contains conditions for the importation of cattle from Ireland. We are removing this section in its entirety.

We are not proposing at this time to assign a tuberculosis or brucellosis classification to Canada, Mexico, or Ireland, or any portion of those countries. Rather, if this proposed rule is finalized, we would stagger the effective dates of various sections. Sections 93.438 and 93.441, which contain the process by which to request a regional classification for brucellosis or bovine tuberculosis, and §§ 93.437 and 93.442, which contain the classification systems themselves, would be effective before the importation requirements for bovines from regions with those classifications or the removal of the existing country-specific import requirements. Before the new importation requirements go into effect, we would evaluate the information that we currently have regarding Mexico, Canada, and Ireland, then gather any additional information that we would need in order to propose tuberculosis or brucellosis statuses for these countries, or portions thereof.

Definitions

Section 93.400 contains definitions of terms used with the following sections of subpart D of part 93. We would amend this section by adding several definitions, removing several definitions, and modifying one definition.

We would add definitions of the following terms: *Accredited herd for brucellosis, accredited herd for tuberculosis, import protocol, individual test, non-negative test results, notifiable disease, spayed heifer, steer, tuberculosis, whole herd test for brucellosis,* and *whole herd test for tuberculosis.*

We would define *import protocol* as a document issued by APHIS and provided to officials of the competent veterinary authority of an exporting region that specifies in detail the mitigation measures that will comply with APHIS' regulations regarding the import of certain animals or commodities. We have long used such import protocols to assist exporting countries in complying with our regulations; in this manner import protocols serve an analogous function for exporting countries that the Program Standards document would serve for States and Tribes.

On a related matter, we would define an *accredited herd for tuberculosis* as a herd that meets APHIS' standards for accreditation for tuberculosis status, and *accredited herd for brucellosis* as a herd that meets APHIS' standards for accreditation for brucellosis status. Both definitions would specify that standards for accreditation are specified in import protocols.

We would define *brucellosis* as infection with or disease caused by *Brucella abortus.*

We would define *individual test* as a test for brucellosis or tuberculosis that is approved by the Administrator and that is administered individually in accordance with part 93 to ruminants that are susceptible to brucellosis or tuberculosis. The definition would specify that, for purposes of part 93, testing of individual animals as part of a whole herd test does not constitute an individual test.

We would define *non-negative test results* as any test results for tuberculosis or brucellosis within the suspect or positive range parameters of a pathogen assay that has been approved by the Administrator.

We would define *notifiable disease* as a disease for which confirmed or suspected occurrences within a region must be reported to the competent veterinary authority or other competent authority of that region. This would be consistent with the meaning of the term *notifiable disease* as it is used within various OIE standards.

We would define *spayed heifer* as a female bovine that has been neutered in a manner approved by the Administrator and specified in an import protocol. The definition would require the female bovine to be neutered in a specific manner because, on occasion, bovines that have been imported into the United States under the conditions reserved for spayed heifers have given birth.

We would define *steer* as a sexually neutered male bovine.

We would define *tuberculosis* as infection with or disease caused by *Mycobacterium bovis.*

We would define *whole herd test for brucellosis* as a brucellosis test that has been approved by APHIS of all bovines in a herd of origin that are 6 months of age or older, and of all bovines in the herd of origin that are less than 6 months of age and were not born into the herd of origin, except those bovines that are less than 6 months of age and originate directly from a currently accredited herd for brucellosis.

Likewise, *whole herd test for tuberculosis* would mean a tuberculosis test that has been approved by APHIS of all bovines in a herd of origin that are 6 months of age or older, and of all bovines in the herd of origin that are less than 6 months of age and were not born into the herd of origin, except those bovines that are less than 6 months of age and originate directly

from a currently accredited herd for tuberculosis.

The scope of these definitions would be generally consistent with the definition of *test-eligible animal* within proposed part 76. However, we would set the minimum age for whole herd testing for tuberculosis at 6 months, rather than 12, as it would be in part 76, because this reflects long-standing agency policy regarding the minimum testing age for tuberculosis for foreign regions with prevalence levels that are greater than our own.

We would remove the definitions of *brucellosis certified-free province or territory of Canada, official tuberculin test, tuberculosis-free herd,* and *whole herd test.* These definitions would either no longer be found in part 93, or would be superseded by the definitions that we are proposing to add.

Finally, the definition of *herd of origin* in § 93.400 currently is written in a manner that conflates two distinct understandings of that term: The herd in which an animal was born, and any herd in which the animal was continually maintained for at least 4 months. Both of these understandings are correct, therefore we would retain them within the definition. We would, however, modify the definition to make it clearer that there are two distinct understandings of the term.

Miscellaneous Provisions

Section 93.401 contains general prohibitions regarding the importation of ruminants. We have long required that a means of conveyance be cleaned and disinfected prior to use to transport a ruminant for importation; if it is not, we consider the means of conveyance to present an unknown risk of harboring diseases of ruminants, and prohibit the entry of animals into the United States in that means of conveyance. However, § 93.401 does not currently contain that prohibition. We would amend the section to add it.

Section 93.423 contains conditions for the importation of ruminants from Central America and the West Indies. As written, the section could be construed to exempt ruminants from those regions from the requirements in proposed §§ 93.439 and 93.442. We would amend § 93.423 accordingly.

Finally, in reviewing part 93 during the preparation of this proposed rule, we noted an erroneous citation in § 93.408. We would remove the citation.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This proposed rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides an initial regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Bovine tuberculosis and brucellosis are contagious diseases affecting cattle as well as other livestock species. Cooperative State-Federal-Industry programs to eliminate bovine tuberculosis and brucellosis have been administered by APHIS, State animal health agencies, and U.S. livestock producers. The United States has made great strides in recent years toward eradication of brucellosis and bovine tuberculosis. As a result, occurrences of these diseases within the United States have become increasingly rare.

However, in recent years, several factors have arisen that make changes to the programs necessary. These factors include the identification of reservoirs of brucellosis and bovine tuberculosis in wildlife populations in certain areas of the country, significant changes to the cattle industry within the United States, and the establishment of bison and captive cervid industries.

This rule would consolidate the regulations governing bovine tuberculosis, and those governing brucellosis. Under these changes, States and/or Tribes would implement animal health plans that identify sources of the diseases within the State or Tribe and specify mitigations to address the risk posed by these sources. The consolidated regulations would also set forth standards for surveillance, epidemiological investigations, and affected herd management that must be incorporated into each animal health plan, with certain limited exceptions; would provide revised conditions for the interstate movement of cattle, bison, and captive cervids; and would provide revised conditions for APHIS approval of tests, testing laboratories, and testers for bovine tuberculosis and/or brucellosis. Finally, the proposal would also revise the import requirements for cattle and bison that pertain to the risk the cattle or bison may present of transmitting bovine tuberculosis or brucellosis, to make these conditions clearer and assure that they more effectively mitigate the risk of introduction of the diseases into the United States.

Economic effects of the proposed rule are not expected to be significant. Bovine tuberculosis affects less than 0.001 percent of domestic program herds, and brucellosis also less than 0.001 percent. There would be few on-the-ground operational changes for States or producers. Most reporting requirements in areas where bovine tuberculosis and brucellosis are not found, as well as surveillance, movement limitations, testing, and reporting in areas where either disease is present, would continue with little alteration. Additionally, we do not expect requirements for the importation of cattle and bison from foreign regions to change significantly as a direct result of this proposed rule, and where they do change they will affect very few producers or importers.

Specific costs associated with this rule are discussed in the Executive Summary at the beginning of this document, under the heading ''Costs and Benefits.''

We expect that the economic effects of this rule on foreign producers of cattle and bison would be minimal. With regard to domestic production, we expect that the benefits would justify the costs. While direct effects of this proposed rule for producers should be small, whether the entity affected is small or large, consolidation of the brucellosis and bovine tuberculosis regulations would benefit the affected livestock industries. The use of animal health plans would require States to identify and monitor potential sources of disease transmission in their State, leading to more focused, flexible and responsive disease management and reducing the number of producers that incur costs when disease concerns arise in an area. Under these circumstances, the APHIS Administrator has determined that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

The provisions of this proposed rule concerning the importation of ruminants have been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with those provisions will be preempted; (2) no retroactive effect will be given to the provisions; and (3) administrative proceedings will not be required before parties may file suit in court challenging the provisions.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2011–0044. Please send a copy of your comments to: (1) Docket No. APHIS–2011–0044, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, Room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This rule would require States, and if they so choose, Tribes, to submit animal health plans to APHIS that identify sources of the diseases within the State or Tribal lands and specify mitigations to address the risk posed by these sources. It would also require States to submit certain reports.

In certain instances, foreign governments could have to enter into trust fund agreements with APHIS so that cattle may be exported to the United States from their region as a result of this rule.

Additionally, there may be instances in which producers would request alternate affected herd management protocols from those specified within the rule.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.,* permitting electronic submission of responses).

*Estimate of burden:* Public reporting burden for this collection of information is estimated to average 163.45 hours per response.

*Respondents:* States, Tribes, foreign governments, producers of cattle, bison, and captive cervids.

*Estimated annual number of respondents:* 68.

*Estimated annual number of responses per respondent:* 3.514.

*Estimated annual number of responses:* 239.

*Estimated total annual burden on respondents:* 39,063 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the EGovernment Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2727.

**List of Subjects**

*9 CFR Part 50*

Animal diseases, Bison, Cattle, Hogs, Indemnity payments, Reporting and recordkeeping requirements, Tuberculosis.

*9 CFR Part 51*

Animal diseases, Cattle, Hogs, Indemnity payments, Reporting and recordkeeping requirements.

*9 CFR Part 71*

Animal diseases, Cattle, Quarantine, Transportation.

*9 CFR Part 76*

Bison, Bovine tuberculosis, Brucellosis, Captive cervids, Cattle, Quarantine, Reporting and recordkeeping requirements, Transportation.

*9 CFR Part 77*

Animal diseases, Bison, Cattle, Reporting and recordkeeping requirements, Transportation, Tuberculosis.

*9 CFR Part 78*

Animal diseases, Bison, Cattle, Hogs, Quarantine, Reporting and recordkeeping requirements, Transportation.

*9 CFR Part 86*

Animal diseases, Bison, Cattle, Interstate movement, Livestock, Official identification, Reporting and recordkeeping requirements, Traceability.

*9 CFR Part 93*

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

*9 CFR Part 161*

Reporting and recordkeeping requirements, Veterinarians.

Accordingly, under the authority of 7 U.S.C. 8301 *et seq.,* we propose to amend 9 CFR chapter I as follows:

## PART 50—ANIMALS DESTROYED BECAUSE OF TUBERCULOSIS

■ 1. The authority citation for part 50 continues to read as follows:

**Authority:** 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 50.1 is amended as follows:

■ a. By revising the definitions for *Administrator, APHIS representative, approved herd plan, destroyed,* and *herd depopulation.*

■ b. By adding, in alphabetical order, a definition for *publicly owned.*

■ c. By revising the definitions for *quarantined feedlot, reactor cattle, bison, and captive cervids, State, State animal health official,* and *State representative.*

The addition and revisions read as follows:

**§ 50.1 Definitions.**

* * * * *

*Administrator.* The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

* * * * *

*APHIS representative.* An individual employed by APHIS who is authorized to perform that function involved.

*Approved herd plan.* An affected herd management plan designed by the herd owner, the owner's veterinarian if so requested, and a State, Tribal, or APHIS representative to control and eradicate tuberculosis within the herd. The herd plan must be approved by the State or Tribal animal health official and the Administrator.

* * * * *

*Destroyed.* Condemned under State authority and either destroyed by slaughter or otherwise euthanized.

* * * * *

*Herd depopulation.* Destruction of animals within a herd at a location, in a manner, and within a timeframe as specified within an approved herd plan.

* * * * *

*Publicly owned.* Owned by the Federal government, a State or Tribe, or any regional or local community.

*Quarantined feedlot.* A facility that is approved by APHIS and/or a State or Tribal animal health official as meeting the standards for such feedlots as these are specified by the Administrator, and that accordingly is authorized to assemble and feed reactor, suspect, or exposed program animals prior to their movement to a recognized slaughtering establishment, another quarantine feedlot, or a quarantine pen.

*Reactor cattle, bison, and captive cervids.* Cattle, bison, or captive cervids that, for tuberculosis, fall within the scope of the definition of *reactor,* as this is set forth in § 76.0 of this chapter.

* * * * *

*State.* Any of the States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, the U.S. Virgin Islands, or any territory or possession of the United States.

*State animal health official.* The State official responsible for livestock and poultry disease control and eradication programs in a State.

*State representative.* An individual employed in animal health work by a State or a political subdivision of a State and authorized by that State to perform the function involved.

* * * * *

■ 3. In § 50.3, paragraph (c) is added to read as follows:

**§ 50.3 Payment to owners for animals destroyed.**

* * * * *

(c) The Department will not pay indemnity for publicly owned cattle, bison, or captive cervids.

■ 4. In § 50.4, paragraphs (b) and (c) are revised to read as follows:

**§ 50.4 Classification of cattle, bison, captive cervids, and other livestock as infected, exposed, or suspect.**

* * * * *

(b) Cattle, bison, and captive cervids are considered to be exposed to tuberculosis when, for tuberculosis, they fall within the scope of the definition of *exposed,* as this is set forth in § 76.0 of this chapter.

(c) Cattle, bison, and captive cervids are considered to be suspects for tuberculosis when, for tuberculosis, they fall within the scope of the definition of *suspect,* as this is set forth in § 76.0 of this chapter.

* * * * *

**§ 50.14 [Amended]**

■ 5. Section 50.14 is amended as follows:

■ a. In paragraph (e)(1), by removing the citation ''§ 77.1'' and adding the citation ''§ 76.0'' in its place.

■ b. In paragraphs (e)(2)(i) and (e)(2)(ii), by removing the words ''an official tuberculin test, as defined in § 77.1'' and adding the words ''an official test, as defined in § 76.0'' in their place.

■ c. By removing and reserving paragraph (f).

## PART 51—ANIMALS DESTROYED BECAUSE OF BRUCELLOSIS

■ 6. The authority citation for part 51 continues to read as follows:

**Authority:** 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 7. Section 51.1 is amended as follows:

■ a. By revising the definitions for *Administrator, brucellosis exposed animal,* and *brucellosis reactor animal.*

■ b. By removing the definition of *complete herd test.*

■ c. By revising the definitions for *destroyed* and *herd depopulation.*

■ d. By adding, in alphabetical order, a definition for *herd plan.*

■ e. By revising the definition of *official seal.*

■ f. By adding, in alphabetical order, the definition for *publicly owned.*

■ g. By revising the definitions for *State, State animal health official,* and *State representative.*

■ h. By removing the definition of *unofficial vaccinate.*

The additions and revisions read as follows:

**§ 51.1 Definitions.**

* * * * *

*Administrator.* The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

* * * * *

*Brucellosis exposed animal.* An animal that, for brucellosis, falls within the scope of the definition of *exposed,* as this is set forth in § 76.0 of this chapter.

*Brucellosis reactor animal.* An animal that, for brucellosis, falls within the scope of the definition of *reactor,* as this is set forth in § 76.0 of this chapter.

* * * * *

*Destroyed.* Condemned under State authority and either destroyed by slaughter or otherwise euthanized.

* * * * *

*Herd depopulation.* Destruction of animals within a herd at a location, in a manner, and within a timeframe as specified within a herd plan.

* * * * *

*Herd plan.* An affected herd management plan designed by the herd owner, the owner's veterinarian if so requested, and a State, Tribal, or APHIS representative to control and eradicate brucellosis within the herd. The herd plan must be approved by the State animal health official and the Administrator.

* * * * *

*Official seal.* A serially numbered, metal or plastic strip, consisting of a self-locking device on one end and a slot on the other end, which forms a loop when the ends are engaged and which cannot be reused if opened, or a serially numbered, self-locking button.

* * * * *

*Publicly owned.* Owned by the Federal Government, a State or Tribe, or any regional or local community.

* * * * *

*State.* Any of the States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, the U.S. Virgin Islands, or any territory or possession of the United States.

*State animal health official.* The State official responsible for livestock and poultry disease control and eradication programs in a State.

*State representative.* An individual employed in animal health work by a State or a political subdivision of a State and authorized by that State to perform the function involved.

* * * * *

■ 8. In § 51.3, paragraphs (a)(1) introductory text and (a)(1)(i) are revised to read as follows:

**§ 51.3 Payment to owners for animals destroyed.**

(a) * * *

(1) Owners of the following types of animals destroyed because of brucellosis are eligible to receive Federal indemnity for their animals; except that, indemnity will not be paid for the animals if they are publicly owned.

(i) Cattle and bison classified as reactors for brucellosis;

* * * * *

**§ 51.4 [Amended]**

■ 9. Section 51.4 is amended by removing the words ‘‘, including the reactor tag number of each brucellosis reactor animals and the registration name and number of each brucellosis reactor registered animal’’.

**§ 51.5 [Amended]**

■ 10. In § 51.5, paragraph (b) is removed and reserved.

**§ 51.9 [Amended]**

■ 11. Section 51.9 is amended as follows:

■ a. In paragraph (b), by removing the citation ‘‘§ 78.1’’ and adding the citation ‘‘§ 76.0’’ in its place.

■ b. In paragraph (i)(2), by removing the words ‘‘(as defined in § 78.1 of this chapter)’’.

**§ 51.20 [Amended]**

■ 12. In § 51.20, in the definition of *brucellosis reactor animal,* paragraph (3) is amended by removing the words ‘‘as provided in the definition of official test in § 78.1 of this chapter’’ and adding the words ‘‘by APHIS’’ in their place.

## PART 71—GENERAL PROVISIONS

■ 13. The authority citation for part 71 continues to read as follows:

**Authority:** 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 14. Section 71.1 is amended by revising the definitions of *Administrator, APHIS representative, interstate commerce, State, State animal health official,* and *State representative* to read as follows:

**§ 71.1 Definitions.**

* * * * *

*Administrator.* The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

* * * * *

*APHIS representative.* An individual employed by APHIS who is authorized to perform that function involved.

* * * * *

*Interstate commerce.* Trade, traffic, or other commerce in animals between a place in a State and a place in another State or between places in the same State but through any place outside that State; or trade, traffic, or other commerce in animals within the District of Columbia or any territory or possession of the United States.

* * * * *

*State.* Any of the States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, the U.S. Virgin Islands, or any territory or possession of the United States.

*State animal health official.* The State official responsible for livestock and poultry disease control and eradication programs in a State.

*State representative.* An individual employed in animal health work by a State or a political subdivision of a State and authorized by that State to perform the function involved.

* * * * *

**§ 71.3 [Amended]**

■ 15. Section 71.3 is amended as follows:

■ a. In paragraph (c)(1), by removing the words ‘‘part 78’’ and adding the words ‘‘part 76’’ in their place.

■ b. In paragraph (c)(3), by removing the words ‘‘the tuberculin test’’ and adding the words ‘‘an official test for tuberculosis’’ in their place, and by removing the words ‘‘the provisions of § 77.17’’ and adding the words ‘‘part 76’’ in their place.

**§ 71.20 [Amended]**

■ 16. Section 71.20 is amended as follows:

■ a. In paragraph (a)(3), by removing the words ‘‘9 CFR parts 71, 75, 78, 79, and 85’’ and adding the words ‘‘9 CFR parts 71, 75, 76, 79, and 85’’ in their place.

■ b. In paragraph (a)(6), by removing the words ‘‘9 CFR parts 71, 75, 78, 79, and 85’’ and adding the words ‘‘9 CFR parts 71, 75, 76, 79, and 85’’ in their place.

■ c. In paragraph (a)(8), by removing the words ‘‘9 CFR parts 71, 75, 78, 79, 85, and 86’’ and adding the words ‘‘9 CFR parts 71, 75, 76, 79, 85, and 86’’ in their place.

■ d. In paragraph (a)(14)(i), by removing the words ‘‘parts 71 and 78’’ and adding the words ‘‘parts 71 and 76’’ in their place.

■ e. In paragraphs (a)(14)(ii),(iii), and (iv), by removing the words ‘‘part 78’’ each time they appear, and adding the words ‘‘part 76’’ in their place.

■ f. By removing and reserving paragraphs (a)(14)(v) through (a)(14)(ix).

■ g. In paragraph (a)(18), by removing the words ‘‘9 CFR parts 71, 75, 78, 79, and 85’’ each time they appear, and adding the words ‘‘9 CFR parts 71, 75, 76, 79, 85, and 86’’ in their place.

■ 17. Part 76 is added to subchapter C to read as follows:

## PART 76—BRUCELLOSIS AND BOVINE TUBERCULOSIS

Sec.
76.0 Definitions.
76.1 Authority of the Administrator.
76.2 Animal health plan requirements.
76.3 State or Tribal classifications.
76.4 Reporting requirements.
76.5 Recognized management areas.
76.6 Surveillance requirements.
76.7 Epidemiological investigations and affected herd management.

**Subpart A—General Categories of Livestock**

76.8 Interstate movement of infected livestock generally prohibited.
76.9 Interstate movement of program animals from a herd containing a reactor or suspect.
76.10 Interstate movement of reactor, suspect, and exposed program animals.

**Subpart B—Cattle and Bison**

76.11 Interstate movement of cattle and bison generally restricted.
76.12 Interstate movement of cattle and bison from consistent States or Tribes for brucellosis and bovine tuberculosis.
76.13 Interstate movement of cattle and bison from a provisionally consistent State or Tribe.
76.14 Interstate movement of cattle and bison from inconsistent States or Tribes for brucellosis.
76.15 Interstate movement of cattle and bison from inconsistent States or Tribes for bovine tuberculosis.

**Subpart C—Interstate Movement of Captive Cervids**

76.16 Interstate movement of captive cervids.
76.17 Official tests for brucellosis and bovine tuberculosis, official testing laboratories, and official testers.

**Authority:** 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

**§ 76.0 Definitions.**

The following definitions apply to this part:

*Accredited herd for bovine tuberculosis.* A herd that, in accordance with APHIS' standards for accreditation, has tested negative for bovine tuberculosis using an official test and is subject to measures that lower the risk of bovine tuberculosis introduction into the herd through the addition of animals to the herd. APHIS' standards for accreditation are described in the Program Standards document. States may submit an alternate accreditation standard to the Administrator for evaluation and approval by sending a written request to the address provided in the Program Standards document.

This standard must be at least equally stringent to that within the Program Standards document.

*Accredited herd for brucellosis.* A herd that, in accordance with APHIS' standards for accreditation, has tested negative for brucellosis using an official test and is subject to measures that lower the risk of brucellosis introduction into the herd through the addition of animals to the herd. APHIS' standards for accreditation are described in the Program Standards document. States may submit an alternate accreditation standard to the Administrator for evaluation and approval by sending a written request to the address provided in the Program Standards document. This standard must be at least equally stringent to that within the Program Standards document.

*Accredited veterinarian.* A veterinarian approved by the Administrator in accordance with the provisions of part 161 of this title to perform functions specified in parts 1, 2, 3, and 11 of this chapter, and to perform functions required by cooperative State-Federal disease control and eradication programs.

*Administrator.* The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

*Affected herd management plan.* An affected herd management plan designed by the herd owner, the owner's veterinarian if so requested, and a State, Tribal, or APHIS representative to control and eradicate bovine tuberculosis and/or brucellosis within the herd. The affected herd management plan must be approved by a State or Tribal animal health official and the Administrator.

*Animal identification number (AIN).* A numbering system for the official identification of individual animals in the United States that provides a nationally unique identification number for each animal. The AIN consists of 15 digits, with the first 3 being the country code (840 for the United States or a unique country code for any U.S. territory that has such a code and elects to use it in place of the 840 code). The alpha characters USA or the numeric code assigned to the manufacturer of the identification device by the International Committee on Animal Recording may be used as an alternative to the 840 or other prefix representing a U.S. territory; however, only the AIN beginning with the 840 or other prefix representing a U.S. territory will be recognized as official for use on AIN tags applied to animals on or after March 11, 2015. The AIN beginning with the 840 prefix may not be applied to animals known to have been born outside the United States.

*Annual report form.* The annual report form authorized by the Administrator for State and Tribal use to fulfill the requirements of this part. The report form is located on the Web at [*address to be added in final rule*].

*APHIS.* The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

*APHIS representative.* An individual employed by APHIS who is authorized to perform the function involved.

*Bison.* Domestically produced or captive bison.

*Bovine tuberculosis.* The contagious, infectious, and communicable disease caused by *Mycobacterium bovis.* It is also referred to as tuberculosis.

*Brucellosis.* The contagious, infectious, and communicable disease caused by *Brucella abortus.* It is also known as Bangs disease, undulant fever, and contagious abortion.

*Calf raiser.* A cattle production operation in which calves, yearlings, and other sexually immature cattle are brought together and maintained until they are of sufficient size or sexual maturity to move to their next stage of production.

*Captive cervid.* All species of deer, elk, moose, and all other members of the family Cervidae raised or maintained in captivity for the production of meat and other agricultural products, for sport, or for exhibition, including time such animals are moved interstate; or any wild cervid that is moved interstate, during the period of time from capture until release into the wild. A captive cervid that escapes continues to be considered a captive cervid as long as it bears an official eartag or other official identification approved by the Administrator as unique and traceable with which to trace the animal back to its herd of origin.

*Depopulate.* To destroy program animals in a herd at a location, in a manner, and within a timeframe as specified within an affected herd management plan.

*Epidemiologist designated by the District Director.* An epidemiologist selected by the APHIS District Director, in consultation with State or Tribal animal health officials, to perform the function required.

*Exposed.* An animal that has had association with infected program animals, livestock, or other sources of brucellosis or bovine tuberculosis such that an epidemiologist designated by the District Director determines the animal may be infected.

*Feedlot.* A facility for assembling and feeding program animals.

*Herd.* All livestock under common ownership or supervision that are grouped on one or more parts of any single premises (lot, farm, or ranch) for at least 4 months; or all livestock under common ownership for at least 4 months on two or more premises which are geographically separated but on which animals from the different premises have been interchanged or had contact with each other.

*Herd test.*

(1) For brucellosis:

(i) In any area of a consistent State other than a recognized management area, testing of all sexually intact animals within a herd that are 18 months of age or older, as well as all sexually intact animals in the herd that are less than 18 months of age and were not born into the herd, except those sexually intact animals that are less than 18 months of age and originate directly from a currently accredited herd for brucellosis.

(ii) In any area of a provisionally consistent State other than a recognized management area, testing of all sexually intact animals within a herd that are 12 months of age or older, as well as all sexually intact animals in the herd that are less than 12 months of age and were not born into the herd, except those sexually intact animals that are less than 12 months of age and originate directly from a currently accredited herd for brucellosis.

(iii) In any area of an inconsistent State, or in a recognized management area for brucellosis, testing of all sexually intact animals within a herd that are 6 months of age or older, as well as all sexually intact animals in the herd that are less than 6 months of age and were not born into the herd, except those sexually intact animals that are less than 6 months of age and originate directly from a currently accredited herd for brucellosis.

(2) For bovine tuberculosis:

(i) In any area of a consistent State other than a recognized management area, testing of all animals within a herd that are 18 months of age or older, as well as all animals in the herd that are less than 18 months of age and were not born into the herd, except those animals that are less than 18 months of age and originate directly from a currently accredited herd for bovine tuberculosis.

(ii) In any area of a provisionally consistent State other than a recognized management area, testing of all animals within a herd that are 12 months of age or older, as well as all animals in the herd that are less than 12 months of age and were not born into the herd, except

those animals that are less than 12 months of age and originate directly from a currently accredited herd for bovine tuberculosis.

(iii) In any area of an inconsistent State and in a recognized management area for bovine tuberculosis, testing of all animals within a herd that are 6 months of age or older, as well as all animals in the herd that are less than 6 months of age and were not born into the herd, except those animals that are less than 6 months of age and originate directly from a currently accredited herd for bovine tuberculosis.

*Immediate slaughter.* Consignment directly to a recognized slaughtering establishment.

*Interstate certificate of veterinary inspection (ICVI).* An official document issued by a Federal, State, Tribal, or accredited veterinarian certifying the inspection of animals in preparation for interstate movement.

(1) The ICVI must show the species of animals covered by the ICVI; the number of animals covered by the ICVI; the purpose for which the animals are to be moved; the address at which the animals were loaded for interstate movement; the address to which the animals are destined; and the names of the consignor and the consignee and their addresses if different from the address at which the animals were loaded or the address to which the animals are destined. Additionally, the ICVI must list the official identification number of each animal or group of animals moved that is required to be officially identified, or, if an alternative form of identification has been agreed upon by the sending and receiving States or Tribes, the ICVI must include a record of that identification. If the animals are not required by the regulations to be officially identified, the ICVI must state the exemption that applies (*e.g.,* the cattle and bison belong to one of the classes of cattle and bison exempted under § 86.4 of this chapter from the official identification requirements of 9 CFR part 86 during the initial stage of the phase-in of those requirements). If the animals are required to be officially identified but the identification number does not have to be recorded on the ICVI, the ICVI must state that all animals to be moved under the ICVI are officially identified. An ICVI may not be issued for any animal that is not officially identified if official identification is required.

(2) As an alternative to an ICVI, another document may be used to provide this information, but only under the following conditions:

(i) The document is agreed upon by the shipping and receiving States or Tribes as an acceptable alternative to an ICVI; and

(ii) The document is a State or Tribal form or APHIS form that requires individual identification of animals; and

(iii) Each copy of the document identifies each animal to be moved, but any information pertaining to other animals, and any unused space on the document for recording animal identification, is crossed out in ink; and

(iv) The following information is written in ink in the identification column on the original and each copy and is circled or boxed, also in ink, so that no additional information can be added:

(A) The name of the document; and

(B) Either the unique serial number on the document or, if the document is not imprinted with a serial number, both the name of the person who prepared the document and the date the document was signed.

(v) A copy of the document accompanies the program animals during interstate movement.

*Livestock.* All farm-raised animals.

*Location-based numbering system.* The location-based number system combines a State or Tribal issued location identification (LID) number or a premises identification number (PIN) with a producer's unique livestock production numbering system to provide a nationally unique and herd-unique identification number for an animal.

*Location identification (LID) number.* A nationally unique number issued by a State, Tribal, and/or Federal animal health authority to a location as determined by the State or Tribe in which it is issued. The LID number may be used in conjunction with a producer's own unique livestock production numbering system to provide a nationally unique and herd-unique identification number for an animal.

*Management area.* A clearly delineated geographical area in which a State or Tribe has detected brucellosis or bovine tuberculosis, has determined that there is a risk of transmission of brucellosis or bovine tuberculosis to program animals, and has taken or proposes to take measures to control the spread of the brucellosis or bovine tuberculosis within and from the area and/or to eradicate the disease within the area.

*National Uniform Eartagging System (NUES).* A numbering system for the official identification of individual animals in the United States that provides a nationally unique identification number for each animal.

*Official Brucella vaccine.* A vaccine for brucellosis that has been approved by the Administrator and produced under license of the United States Department of Agriculture.

*Official brucellosis vaccination program.* A brucellosis vaccination program that consists of, at a minimum:

(1) Vaccination of program animals with an official *Brucella* vaccine.

(2) Tattooing to specify the animals' vaccination status.

(3) Identification of the animals with an official eartag designed to specify the animals' vaccination status.

*Official eartag.* An identification tag approved by APHIS that bears an official identification number for individual animals. Beginning March 11, 2014, all official eartags manufactured must bear an official eartag shield. Beginning March 11, 2015, all official eartags applied to animals must bear an official eartag shield. The design, size, shape, color, and other characteristics of the official eartag will depend on the needs of the users, subject to the approval of the Administrator. The official eartag must be tamper-evident and have a high retention rate in the animal.

*Official eartag shield.* The shield-shaped graphic of the U.S. Route Shield with ''U.S.'' or the State postal abbreviation or Tribal alpha code imprinted within the shield.

*Official identification number.* A nationally unique number that is permanently associated with an animal or group of animals and that adheres to one of the following systems:

(1) National Uniform Eartagging System (NUES).

(2) Animal identification number (AIN).

(3) Flock-based number system.

(4) Location-based numbering system.

(5) Any other numbering system approved by the Administrator for the official identification of animals.

*Officially identified.*

(1) *For cattle and bison:* Identified by means of an official eartag.

(2) *For captive cervids:* Identified by means of an official eartag, by a tattoo containing an official identification number, or by other identification devices acceptable to APHIS and the shipping and receiving States or Tribes.

*Official seal.* A serially numbered, metal or plastic strip, consisting of a self-locking device on one end and a slot on the other end, which forms a loop when the ends are engaged and which cannot be reused if opened, or a serially numbered, self-locking button.

*Official test.* Any test that is approved by the Administrator for determining the presence or absence of brucellosis or

bovine tuberculosis in program animals and that is conducted and reported by an official tester. If an official test is applied to a program animal, it must be identified by means of an official eartag. If this eartag uses the NUES system, the eartag must indicate the State or Tribe in which it was applied; if the AIN system, the identification number of the premises on which it was applied. If an animal that is tested already has such an eartag, the information on this eartag must be recorded by the tester.

*Official tester.* Any person associated with the conducting and reporting of official tests within an official testing laboratory, or any person authorized by the Administrator to conduct and report official tests outside of a laboratory environment.

*Official testing laboratory.* A laboratory approved by the Administrator in accordance with part 76 of this chapter to conduct official tests.

*Owner.* Any person who has legal or rightful title to program animals whether or not the animals are subject to a mortgage.

*Permit for movement of restricted animals.* A document that is issued by an APHIS representative, State or Tribal representative, or accredited veterinarian and that authorizes the restricted interstate movement of livestock to certain specified destinations.

*Premises identification number (PIN).* A nationally unique number assigned by a State, Tribal, and/or Federal animal health authority to a premises that is, in the judgment of the State, Tribal, and/or Federal animal health authority, a geographically distinct location from other premises. The PIN may be used in conjunction with a producer's own livestock production numbering system to provide a nationally unique and herd-unique identification number for an animal.

*Program animals.* Cattle, bison, and captive cervids.

*Program Standards document.* A document providing guidance related to the regulations contained in this part. The Program Standards document is available on the Internet at *http://www.aphis.usda.gov/animal_health/animal_dis_spec/cattle,* or at district VS offices, the addresses for which are located in local telephone directories. Substantive changes to the Program Standards document are announced through notices published in the **Federal Register**. These notices request public comment on the changes.

*Qualified accredited veterinarian.* An accredited veterinarian who has been granted a program certification by the Administrator pursuant to § 161.5 of this chapter based on completion of an APHIS-approved orientation or training program.

*Quarantine feedlot.* A facility that is approved by APHIS as having sufficient biosecurity measures in place to assemble and feed exposed program animals, without risk of spread of brucellosis or bovine tuberculosis to other susceptible animals at the facility. Program animals may only be moved interstate from a quarantine feedlot if their movement is to a recognized slaughtering establishment, another quarantine feedlot, or a quarantine pen.

*Quarantine pen.* An area within a feedlot that is approved by APHIS as having sufficient biosecurity measures in place to assemble and feed exposed program animals, without risk of spread of brucellosis or bovine tuberculosis to other susceptible animals at the facility. Program animals may only be moved interstate from a quarantine feedlot if their movement is to a recognized slaughtering establishment, another quarantine pen, or a quarantine feedlot.

*Reactor.*

(1) *For brucellosis:* A program animal that has had non-negative test results to an official test such that an epidemiologist designated by the District Director has determined that there is a high likelihood that the animal is infected with brucellosis, and a low likelihood of false positive test results.

(2) *For bovine tuberculosis:* A program animal that has had non-negative test results to an official test such that an epidemiologist designated by the District Director has determined that further action is warranted to make a final determination regarding the animal's disease status.

*Recognized slaughtering establishment.* Any slaughtering facility operating under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or State meat or poultry inspection acts that is approved in accordance with 9 CFR 71.21.

*Reporting period.* October 1 of one year through September 30 of the following year.

*Responsible person.* The individual who is immediately responsible for implementation and maintenance of an animal health plan within a State or Tribe, who is authorized to amend the plan as circumstances warrant, and who will assume responsibility for the State or Tribe's compliance with all provisions of the plan and all requirements in this part.

*Spayed heifers.* Sexually neutered female cattle or bison.

*Specifically approved stockyard.* Premises where program animals are assembled for sale purposes and which meet the standards set forth in § 71.20 of this subchapter and are approved by APHIS.

*State.* Any of the States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, the U.S. Virgin Islands, or any territory or possession of the United States.

*State or Tribal animal health official.* The State or Tribal official responsible for livestock and poultry disease control and eradication programs in a State or Tribe.

*State or Tribal representative.* An individual employed in animal health work by a State or Tribe, or a political subdivision of a State or Tribe, and authorized by that State or Tribe to perform the function involved.

*Steers.* Sexually neutered male cattle or bison.

*Suspect.* A program animal that has had non-negative test results to an official test for brucellosis or bovine tuberculosis that lead an epidemiologist designated by the District Director to determine that the animal should not be classified as a reactor, but cannot be classified as free of brucellosis or bovine tuberculosis.

*Test-eligible animal.* Unless the Administrator specifies or approves an alternate testing age, *test-eligible animal* means:

(1) For brucellosis, all sexually intact program animals in a herd that are 6 months of age or older, and all program animals in the herd that are less than 6 months of age and were not born into the herd, except those program animals that are less than 6 months of age and originate directly from an accredited herd for brucellosis.

(2) For bovine tuberculosis, all program animals in a herd that are 12 months of age or older, and all program animals in the herd that are less than 12 months of age and were not born into the herd, except those program animals that are less than 12 months of age and originate directly from an accredited herd for bovine tuberculosis; except that, if the herd is located on a calf raiser's premises, all program animals in the herd that are 2 months of age or older are considered test-eligible for bovine tuberculosis.

*Tribe.* Any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 *et seq.*], that is recognized as eligible for the special

programs and services provided by the United States to Indians because of their status as Indians.

*United States.* All of the States.

**§ 76.1 Authority of the Administrator.**

Notwithstanding the provisions of this part, the Administrator is authorized pursuant to the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*) to prohibit or restrict the movement in commerce of any animals, if the Administrator considers that prohibition or restriction to be necessary to prevent the dissemination of brucellosis or bovine tuberculosis within the United States. Moreover, pursuant to the Act, the Administrator may also hold, seize, quarantine, treat, destroy, dispose of, or take other remedial action with respect to any animal, article, or means of conveyance that is moving or has moved in interstate commerce, if the Administrator has reason to believe that animal, article, or means of conveyance may carry, have carried, or have been affected with or exposed to brucellosis or bovine tuberculosis at the time of interstate movement.

**§ 76.2 Animal health plan requirements.**

(a) In order to be considered a consistent or provisionally consistent State or Tribe, a State or Tribe must submit an animal health plan to APHIS via the mail as provided within the Program Standards document, or submit the plan electronically as specified within the Program Standards document. At a minimum, in order to be considered complete, each animal health plan must contain the following categories of information:

(1) Confirmation that the State or Tribe has a legal and regulatory basis for the activities and measures specified within the animal health plan.

(2) A description of the organization and infrastructure of the animal health and wildlife authorities within the State or Tribe. The description must include the animal health and wildlife work force within the State or Tribe that is available to implement or perform activities and maintain and enforce measures specified within the animal health plan, and must demonstrate that the State or Tribe has sufficient resources to implement, maintain, and enforce its animal health plan.

(3) The name and contact information for the responsible person that the State or Tribe has designated to oversee implementation, performance, and enforcement of activities and measures carried out under the plan within the State or Tribe, and the name and contact information for the person that the State has designated to oversee implementation, performance, and enforcement of wildlife activities and measures carried out under the plan. States or Tribes may designate a single individual to serve in multiple roles.

(4) A description of program animal demographics within the State or Tribal lands. The description must include:

(i) The approximate number and types of program animal herds within the State or Tribal lands, and the approximate number of animals in those herds; and

(ii) The approximate number and geographic distribution of any animal concentration points within the State or Tribal lands.

(5) A description of the surveillance activities for brucellosis or bovine tuberculosis in animals within the State or Tribal lands that are being conducted or would be conducted under the animal health plan.[1]

(6) A description of the known sources of brucellosis or bovine tuberculosis that pose a risk of disease introduction into program animals within the State or Tribal lands, and an assessment of the likelihood of transmission of brucellosis or bovine tuberculosis from these sources to program animals within the State or Tribal lands. The description must include:

(i) The approximate number of herds or wildlife populations within the State or Tribal lands that are known sources of brucellosis or bovine tuberculosis, and the approximate number of animals in these herds or populations; and

(ii) The approximate prevalence of brucellosis or bovine tuberculosis infection in those populations, the geographic distribution of the populations within the State or Tribal lands, and any other factors that make the populations a potential source of brucellosis or bovine tuberculosis transmission to program animals within the State or Tribal lands; and

(iii) The potential for exposure of program animals within the State or Tribal lands to these known source populations; and

(iv) Factors, other than mitigation measures that are or would be implemented by the State or Tribe, that may influence this potential for exposure; and

(v) An assessment of the likelihood of transmission of brucellosis or bovine tuberculosis from known source populations to program animals within the State or Tribal lands.

(7) If the State or Tribe has identified known source populations of brucellosis or bovine tuberculosis that pose a risk of disease introduction into program animals within the State or Tribal lands, a description of the measures that the State or Tribe has implemented or would implement to mitigate the risk that program animals within the State or Tribal lands will become infected with brucellosis or bovine tuberculosis.

(8) A description of the epidemiological investigation and affected herd management activities that the State or Tribe has taken or would take in response to occurrences of brucellosis and bovine tuberculosis within program animals in the State or Tribal lands.[2]

(b) *Review.* APHIS will review the plan submitted by the State or Tribe for completeness. When APHIS determines that the plan is complete, it will conduct review and evaluation of the plan. This may include sharing a copy of the plan with persons for technical review and comment. If, based on its review, APHIS determines not to propose to approve the plan, APHIS will contact the State or Tribe that submitted the plan and set forth the deficiencies identified in the plan that preclude APHIS from proposing to approve the plan.

(c) *Proposal of approval; public notification.* Based on its review, APHIS may propose to approve a State or Tribal animal health plan unconditionally, or on the condition that the State or Tribe implement certain provisions of its plan within a specified period of time that it cannot implement immediately upon approval of the plan. In either instance, APHIS will publish a notice in the **Federal Register** announcing proposed approval of the plan and making the plan available for public review and comment. Prior to issuance of this notice, APHIS will ensure that the State or Tribe is prepared for APHIS to make the plan, proposed amendments to the plan, and all reports required by this part publicly available.

(d) *APHIS determination*—(1) *Following a notice proposing unconditional approval of an animal health plan.* (i) If no comments are received on the notice, or if the comments received do not affect APHIS' conclusion that the plan may be approved unconditionally, APHIS will publish a subsequent notice in the **Federal Register** announcing that the plan has been approved

[1] Minimum requirements for surveillance activities conducted under an animal health plan are set forth in § 76.6.

[2] Minimum requirements for epidemiological investigation and affected herd management activities conducted under an animal health plan are set forth in § 76.7.

unconditionally, and designating the State or Tribe as a consistent State or Tribe.

(ii) If the comments received on the notice suggest that the plan should be approved, but that the State or Tribe cannot implement certain provisions of its animal health plan immediately upon approval of the plan, and, after reviewing the information, APHIS agrees, APHIS will publish a subsequent notice in the **Federal Register** announcing that the plan has been approved conditionally, and designating the State or Tribe as a provisionally consistent State or Tribe. The notice will also specify the provisions of the plan that APHIS has determined cannot be implemented immediately and the time period in which they must be implemented. The notice may also specify restrictions on the interstate movement of program animals or other program requirements that apply to the State or Tribe while it is in provisionally consistent status.

(iii) If the comments received suggest that the plan should not be approved, and, after reviewing the information, APHIS agrees, APHIS will publish a subsequent notice in the **Federal Register** describing the comments that it received, its reevaluation of the plan in light of those comments, and its reasons why it cannot approve the plan.

(2) *Following a notice proposing conditional approval of an animal health plan.* (i) If no comments are received on the notice, or if the comments received do not affect APHIS' conclusion that the plan may be approved on the condition that the State or Tribe implement certain provisions of its plan within a specified period of time that it cannot implement immediately upon approval of the plan, APHIS will publish a subsequent notice in the **Federal Register** announcing that the plan has been approved conditionally, and designating the State or Tribe as a provisionally consistent State or Tribe. The notice will also specify the provisions of the plan that APHIS has determined cannot be implemented immediately and the time period in which they must be implemented. The notice may also specify restrictions on the interstate movement of program animals or other program requirements that apply to the State or Tribe while it is in provisionally consistent status.

(ii) If the comments received suggest that the plan should not be approved, and, after reviewing the information, APHIS agrees, APHIS will publish a subsequent notice in the **Federal Register** describing the comments that it received, its reevaluation of the plan in light of those comments, and its reasons why it cannot approve the plan.

(e) *Subsequent notification regarding conditionally approved plans.* If APHIS approves a State or Tribal animal health plan on the condition that the State or Tribe implement certain provisions of its plan within a specified period of time that it cannot implement immediately upon approval of the plan, APHIS will publish a subsequent notice in the **Federal Register** announcing whether the State or Tribe has implemented all provisions of its plan within that period of time.

(1) If the State or Tribe has implemented the provisions, the notice will also announce that APHIS now considers the plan unconditionally approved, and has redesignated the State or Tribe as a consistent State or Tribe.

(2) If the State or Tribe has not implemented all the provisions, the notice will also announce that APHIS has withdrawn approval of the plan, and has redesignated the State or Tribe as an inconsistent State or Tribe.

(f) *Amendments*—(1) *Amendments initiated by APHIS.* If APHIS determines that the activities or measures specified in an approved animal health plan no longer correspond to the risk of spread of brucellosis or bovine tuberculosis, APHIS will make ongoing approval of the plan contingent on the State or Tribe amending the plan in a manner that APHIS approves of. The amended plan must be submitted to APHIS via the mail as provided within the Program Standards document, or electronically as provided within the Programs Standards document.

(2) *Amendments initiated by a State or Tribe.* If a State or Tribe wishes to amend its animal health plan, the State or Tribe must submit proposed amendments to the plan to APHIS via the mail as provided within the Program Standards document, or submit the proposed amendments electronically as provided within the Programs Standards document. Amendments will be subject to the review process specified in paragraphs (b) through (d) of this section.

(g) *Compliance reviews.* APHIS reserves the right to conduct a review of States or Tribes at any point for compliance with their approved animal health plan. Such a compliance review may include site visits and/or documentation review.

**§ 76.3 State or Tribal classifications.**

(a) Each State within the United States is classified according to one of the classifications for brucellosis and bovine tuberculosis listed below. Tribes will be classified according to these classifications, provided that they have submitted a Tribal animal health plan to APHIS for review and approval in accordance with the process set forth in § 76.2, and APHIS has approved the animal health plan. A State or Tribal classification for brucellosis and bovine tuberculosis may differ.

(1) Consistent.

(2) Provisionally consistent.

(3) Inconsistent.

(b) *Initial designation of status*—(1) *Consistent.* APHIS will initially designate a State or Tribe as a consistent State or Tribe if APHIS approves the State's or Tribe's animal health plan unconditionally, in accordance with the process set forth in § 76.2.

(2) *Provisionally consistent.* APHIS will initially designate a State or Tribe as a provisionally consistent State or Tribe if APHIS approves the State or Tribe's animal health plan on the condition that it implement certain provisions of its plan within a specified period of time that it cannot implement immediately upon approval of the plan, in accordance with the process set forth in § 76.2.

(3) *Inconsistent*—(i) *States.* If a State does not have an animal health plan that has been approved by APHIS by [*Date of publication of notice in the Federal Register*], the State will be considered an inconsistent State.

(ii) *Tribes.* Tribes will not initially be designated as inconsistent.

(c) *Conditions for redesignation to a lower classification*—(1) *From consistent to provisionally consistent.* If any of the following occurs, APHIS may redesignate a consistent State or Tribe as a provisionally consistent State or Tribe:

(i) The State or Tribe fails to implement or perform an activity or maintain a measure specified within its animal health plan, and APHIS has determined that this failure may result in the spread of brucellosis or bovine tuberculosis.

(ii) The State or Tribe fails to submit an annual report as specified in § 76.4(a).

(iii) The State or Tribe fails to submit an initial epidemiological investigation situation report within 14 days of the period of time specified in § 76.4(c) for submitting such a report.

(iv) The State or Tribe fails to submit an updated epidemiological investigation situation report as specified in § 76.4(d).

(v) On more than one occasion, the State or Tribe fails to submit a closing report as specified in § 76.4(e).

(vi) The State or Tribe fails to meet national surveillance levels as these are specified within the National

Surveillance Plans for brucellosis or bovine tuberculosis or as these are specified within an alternate State or Tribal plan that has been approved by APHIS.[3]

(vii) The State or Tribe fails to conduct targeted surveillance of wildlife source populations as specified in § 76.6(b)(1).

(viii) The State or Tribe fails to conduct targeted surveillance of at-risk program animals as specified in § 76.6(b)(2).

(ix) The State or Tribe has failed to conduct an investigation of a program animal with non-negative test results for brucellosis in accordance with § 76.7(a), or to send a report regarding those activities as specified in § 76.4(b).

(2) *From consistent to inconsistent.* If any of the following occurs, APHIS may redesignate a consistent State or Tribe as an inconsistent State or Tribe:

(i) The State or Tribe fails to implement or perform an activity or maintain a measure specified within its animal health plan, or fails to amend the plan in response to a request from APHIS, and APHIS determines that this failure has resulted or may result in the spread of brucellosis or bovine tuberculosis.

(ii) On more than one occasion, the State or Tribe fails to submit an annual report as specified in § 76.4(a).

(iii) On more than one occasion, the State or Tribe fails to submit an initial epidemiological investigation situation report within 14 days of the period of time specified in § 76.4(c) for submitting such a report.

(iv) On more than one occasion, the State or Tribe fails to submit an updated epidemiological investigation situation report as specified in § 76.4(d).

(v) APHIS has terminated recognition of the State or Tribe's management area.

(vi) The State or Tribe refuses to participate in or otherwise conduct surveillance as specified in § 76.6(a).

(vii) On more than one occasion, the State or Tribe has failed to conduct an investigation of a program animal with non-negative test results for brucellosis in accordance with § 76.7(a), or to send a report regarding those activities as specified in § 76.4(b).

(viii) The State or Tribe fails to conduct epidemiological investigations as specified in § 76.7(b).

(ix) The State or Tribe fails to conduct affected herd management as specified in § 76.7(e).

(3) *From provisionally consistent to inconsistent.* A provisionally consistent State or Tribe may be redesignated to inconsistent for any of the reasons specified in paragraph (c)(2) of this section. Additionally, if a provisionally consistent State or Tribe fails to implement provisions of its animal health plan or take required remedial measures within the period of time specified by APHIS for implementing these provisions or taking these measures, APHIS will redesignate the State or Tribe as an inconsistent State or Tribe.

(d) *Notification of redesignation*—(1)(i) *Notice regarding redesignation from consistent to provisionally consistent status.* Whenever APHIS redesignates a consistent State or Tribe as a provisionally consistent State or Tribe, APHIS will publish a notice in the **Federal Register** announcing this redesignation. The notice will also state the reason or reasons that led to the redesignation and the remedial measures APHIS considers necessary for the State or Tribe to complete in order to regain consistent status. The notice may also specify restrictions on the interstate movement of program animals or other program requirements that apply to the State or Tribe while it is in provisionally consistent status. While a State or Tribe is in provisionally consistent status, APHIS may publish an additional notice in the **Federal Register** announcing additional remedial measures, as circumstances warrant.

(ii) *Notice regarding termination of provisionally consistent status.* (A) If the State or Tribe completes the required remedial measures, APHIS will publish a notice in the **Federal Register** announcing that it has redesignated the State or Tribe as a consistent State or Tribe.

(B) If the State or Tribe fails to take the required remedial measures, APHIS will publish a notice in the **Federal Register** announcing that it has redesignated the State or Tribe as an inconsistent State or Tribe.

(2) *Notice regarding immediate redesignation from consistent or provisionally consistent to inconsistent status.* Whenever APHIS immediately redesignates a consistent or provisionally consistent State or Tribe as an inconsistent State or Tribe, APHIS will publish a notice in the **Federal Register** announcing this redesignation.

(e) *Inconsistent status; conditions for regaining consistent status.* If a State or Tribe has been redesignated to inconsistent status, in order to regain consistent status, the State or Tribe must:

(1) Take appropriate remedial measures, as determined by APHIS, to address the issue or issues that led to redesignation to inconsistent status;

(2) Submit amendments to its animal health plan to APHIS for review and approval in accordance with the process set forth in § 76.2; and

(3) Submit any additional outstanding annual reports, initial investigation reports, initial or updated epidemiological investigation situation reports, and closing reports.

(f) *Listing.* Lists of all consistent, provisionally consistent, and inconsistent States and Tribes are located on the Internet, at [*address to be added in final rule*]. The lists are also available at district APHIS Veterinary Services (VS) offices, addresses for which are located in local telephone directories. The lists specify a State or Tribe's classification for brucellosis, and its classification for bovine tuberculosis.

**§ 76.4 Reporting requirements.**

States must submit the following reports:

(a) *Annual reports.* Within 60 days of the end of the reporting period, a State must submit a completed annual report form to APHIS as provided in the Program Standards document. Additionally:

(1) If the State has submitted an initial epidemiological investigation situation report to APHIS, but has not yet submitted a corresponding closing report, the State must submit additional information regarding epidemiological activities related to that incident undertaken during the reporting period within the annual report form.

(2) If the State has an animal health plan that has been approved by APHIS, the State must submit a summary of any changes to the categories of information in that plan that have occurred during the reporting period along with the annual report form, unless the State has already submitted amendment requests to APHIS that incorporate these changes to its plan.

(b) *Initial investigation reports.* Whenever a State initiates an investigation of an animal with non-negative test results for brucellosis or an animal determined to be infected with brucellosis or bovine tuberculosis in accordance with § 76.7, the State must provide a report regarding the investigation within 15 days of initiation of the investigation.

(c) *Initial epidemiological investigation situation reports.* Whenever a State initiates an epidemiological investigation of an affected herd in accordance with § 76.7, the State must provide a report of that epidemiological investigation to APHIS within 15 days of the date when the State is notified that an animal from the herd has been determined to be infected

[3] See § 76.6(a).

with brucellosis or bovine tuberculosis. The report must be sent to APHIS as provided within the Program Standards document.

(d) *Updated epidemiological investigation situation reports.* Every 4 weeks following submission of an initial situation report or initial epidemiological situation report, and more frequently at the Administrator's request, a State must submit subsequent reports updating information in the initial situation report or initial epidemiological investigation situation report. The reports must be sent to APHIS as provided within the Program Standards document.

(e) *Closing reports.* Within 60 days following the conclusion of an epidemiological investigation of an affected herd, a State must submit a closing report to APHIS. The report must be sent to APHIS as provided within the Program Standards document.

(f) *Additional reporting requirements for States with recognized management areas.* Additional reporting requirements for States with recognized management areas are specified in § 76.5(f).

(g) *Additional reporting requirements as part of redesignation to provisionally consistent status.* If a consistent State is redesignated as provisionally consistent, additional reporting requirements for the State may be specified in the notice in the **Federal Register** that announces such redesignation.

(h) *Reporting requirements; applicability to Tribes.* The requirements in this section pertain to Tribes, provided that they have submitted a Tribal animal health plan to APHIS for review and approval in accordance with the process set forth in § 76.2, and APHIS has approved the animal health plan.

**§ 76.5 Recognized management areas.**

(a) A State or Tribe may request APHIS recognition of a management area within the State or Tribal lands.

(b) *Process for requesting recognition of a management area*—(1) *States or Tribes without an approved animal health plan.* If a State or Tribe does not have an animal health plan that has been approved by APHIS and wishes to request APHIS recognition of a management area, the State or Tribe must submit a request for recognition of the management area when it submits an animal health plan to APHIS in accordance with the process set forth in § 76.2.

(2) *States or Tribes with an approved animal health plan.* If a State or Tribe has an animal health plan that has been approved by APHIS and wishes to request APHIS recognition of a management area, the State or Tribe must submit a request for recognition of the management area by submitting an amendment to its animal health plan in accordance with the process set forth in § 76.2.

(c) *Requirements for a request to recognize a management area.* (1) Except as provided in paragraph (c)(2) of this section, any request to recognize a management area must contain the following categories of information.

(i) A description of the geographical area that the State or Tribe requests to be recognized as a management area. The description must specify continuous and uninterrupted boundaries for the management area.

(ii) A description of the assessments and activities that the State or Tribe has conducted or plans to conduct to support the specified boundaries for the management area and a timeline of implementation of these activities. At a minimum, the activities specified must provide assurances that the boundaries for the management area continually reflect current epidemiological knowledge about the extent of disease and risk of transmission of disease within and from the area, and must include:

(A) Epidemiological investigations.

(B) Surveillance activities within the management area to determine or further delineate sources of brucellosis and/or bovine tuberculosis.

(C) Surveillance activities outside of the boundaries of the management area sufficient to detect brucellosis or bovine tuberculosis infection in program animals that originate from or are otherwise related to the management area.

(iii) A description of the known sources of brucellosis or bovine tuberculosis that pose a risk of disease introduction into program animals within and surrounding the management area, and an assessment of the likelihood of spread of brucellosis or bovine tuberculosis from these sources to program animals. This description must include:

(A) The approximate number of herds, individual program animals, and susceptible wildlife populations within the management area and in the area surrounding the management area as this surrounding area is determined in consultation with an epidemiologist designated by the District Director; and

(B) The number of affected herds or wildlife populations detected within the management area since the first investigation or surveillance activity specified by the State or Tribe in order to fulfill the requirements of paragraph (c)(1)(ii) of this section was conducted, the approximate number of animals in these herds or source populations, and the approximate prevalence of brucellosis or bovine tuberculosis infection in these herds or populations during that time period; and

(C) The potential for exposure of program animals to these known affected herds or wildlife populations; and

(D) Any factors, other than mitigation measures maintained by the State or Tribe, that may influence this potential for exposure; and

(E) An assessment of the likelihood of transmission of brucellosis or bovine tuberculosis from known affected herds or wildlife populations to program animals within and surrounding the management area.

(iv) A description of the measures that the State or Tribe has implemented or would implement to mitigate the risk that program animals within the State or Tribal lands will become infected with brucellosis or bovine tuberculosis, a timeline for implementation of these measures, and the means by which the State or Tribe has monitored and enforced or plans to monitor and enforce these measures. For all management areas, measures must include conditions for the movement of program animals from the management area, herd testing of at least a targeted representative sample of herds of program animals within the area, and change-of-ownership testing of all test-eligible program animals that reside within the area. For management areas for brucellosis, the measures must also include an official brucellosis vaccination program.

(v) A citation of or hyperlink to the laws and regulations that authorize the State or Tribe's establishment of the management area.

(vi) A description of the personnel that the State or Tribe has used or plans to use in order to implement or perform activities or maintain measures associated with the management area. This description must demonstrate that the State or Tribe has sufficient personnel to implement and perform these activities and maintain these measures, and must include:

(A) The name, contact information, and affiliation of the person within the State or Tribe who will assume responsibility for implementation and performance of activities and maintenance and enforcement of measures associated with the management area; and

(B) The name, contact information, and affiliation of all personnel assigned

to the implementation and performance of activities and maintenance and enforcement of measures associated with the management area; and

(C) The role or roles assigned to these personnel.

(vii) Information demonstrating that all program animals that are moved from the management area are or will be required to be officially identified prior to movement.

(2) If a State had a geographical area designated as a zone for bovine tuberculosis or covered by a brucellosis management plan prior to (*Effective date of final rule*), and the State wishes the geographical area to continue to be recognized as a management area, the State's request for recognition of that area as a management area only needs to contain those categories of information that the State has not already submitted to APHIS.

(d) *APHIS review.* APHIS will review each proposal for recognition of a management area in accordance with the process set forth in § 76.2 for review of an animal health plan or amendment to an animal health plan.

(e) *APHIS determination.* In communicating its determination to approve or not approve an animal health plan or amendment to an animal health plan in accordance with the process set forth in § 76.2, APHIS will also communicate its determination to recognize or not recognize the requested management area. If APHIS recognizes the requested management area, the request for recognition of the area will be considered part of the State or Tribe's animal health plan. APHIS will not recognize a management area in a State or on Tribal lands if it determines not to approve that State or Tribe's animal health plan.

(f) *Annual reporting.* In addition to the annual reporting requirements contained in § 76.4(a), States or Tribes with recognized management areas must submit a separate annual report form for each recognized management area in the State or Tribe.

(g) *Amendments to recognized management areas.* If a State or Tribe with a recognized management area wishes to expand or contract the geographical boundaries of the management area, or determines that any information in its request for recognition of the management area has substantively changed, the State or Tribe must submit amendments to its animal health plan that reflect these changes to APHIS in accordance with the process set forth in § 76.2.

(h) *Termination of management areas*—(1) *Termination initiated by the State or Tribe.* In order for APHIS to recognize termination of a management area, a State or Tribe must submit amendments to its animal health plan that reflect this termination in accordance with the process set forth in § 76.2. Additionally, the State or Tribe must provide an explanation of the reasons for the termination.

(2) *Termination initiated by APHIS.* (i) If APHIS determines that a State or Tribe has failed to implement or maintain measures specified within its proposal for recognition of a management area for brucellosis or bovine tuberculosis, APHIS will terminate recognition of all management areas for the disease or diseases within the State or Tribal lands, and will redesignate the State or Tribe an inconsistent State or Tribe for the disease or diseases.

(ii) If APHIS redesignates a State or Tribe as an inconsistent State or Tribe for brucellosis or bovine tuberculosis, APHIS will also terminate recognition of all management areas for that disease within the State or Tribal lands as part of this redesignation.

(3) *APHIS review of State or Tribal requests.* If a State or Tribe requests recognition of termination of a management area, APHIS will review the request in accordance with the process set forth in § 76.2 for review of an amendment to an animal health plan.

(4) *APHIS determination.* APHIS will communicate its determination regarding termination of a recognized management area in accordance with the process set forth in § 76.2 for communication of a determination regarding amendments to an animal health plan.

**§ 76.6 Surveillance requirements.**

(a) *National surveillance.* All States must agree to participate in the National Surveillance Plans for Brucellosis and Bovine Tuberculosis, found online at [*address to be added in final rule*], or must conduct equivalent surveillance in a manner approved by APHIS.

(1) *Failure to meet surveillance levels.* If a State fails to meet the surveillance levels set forth in the National Surveillance Plans or otherwise approved by APHIS, the State may be redesignated to a lower State classification.

(2)(i) *Refusal to participate in or otherwise conduct such surveillance.* If a consistent or provisionally consistent State refuses to participate in or otherwise conduct such surveillance, the State will be redesignated as an inconsistent State.

(ii) If an inconsistent State refuses to participate in or otherwise conduct such surveillance, the interstate movement of program animals from that State will be subject to such restrictions or prohibitions as the Administrator considers necessary to prevent the dissemination of brucellosis or bovine tuberculosis from the State. In such instances, the restrictions or prohibitions will be announced through a notice in the **Federal Register**.

(b) *Targeted surveillance within a State.* (1) *Surveillance of source populations.* If a consistent or provisionally consistent State has identified a known source of brucellosis or bovine tuberculosis transmission within wildlife in the State in its animal health plan and determined that this source population presents a risk of transmitting brucellosis or bovine tuberculosis to program animals, in order to maintain consistent or provisionally consistent status, the State must conduct surveillance of that source population in a manner approved by APHIS as sufficient to detect brucellosis or tuberculosis in an animal within the source population. A consistent State that fails to conduct such surveillance will be redesignated as provisionally consistent. A provisionally consistent State that fails to conduct such surveillance may be redesignated as inconsistent.

(2) *Surveillance of at-risk populations.* If a consistent or provisionally consistent State has identified a known source of brucellosis or bovine tuberculosis transmission in the State in its animal health plan and has determined that this source population presents a risk of transmitting brucellosis or bovine tuberculosis to program animals, in order to maintain consistent or provisionally consistent status, the State must conduct annual herd testing of all herds of at-risk program animals, or alternatively, a statistically representative sample of those herds, as determined by APHIS. A consistent State that fails to conduct such surveillance will be redesignated as provisionally consistent. A provisionally consistent State that fails to conduct such surveillance will be redesignated as inconsistent.

(c) *Surveillance within recognized management areas.* States must conduct surveillance within a recognized management area in the manner specified within that section of the State's animal health plan that pertains to the management area. Failure to conduct such surveillance will result in termination of recognition of the management area and redesignation of the State as an inconsistent State.

(d) *Additional surveillance as part of redesignation to provisionally consistent status.* If a consistent State is

redesignated as provisionally consistent, additional surveillance requirements for the State may be specified in the notice in the **Federal Register** that announces such redesignation.

(e) *Surveillance requirements; applicability to Tribes.* The requirements in this section pertain to Tribes, provided that they have submitted a Tribal animal health plan to APHIS for review and approval in accordance with the process set forth in § 76.2, and APHIS has approved the animal health plan.

**§ 76.7 Epidemiological investigations and affected herd management.**

(a) *Investigations of animals with non-negative test results for brucellosis.* If a program animal has a non-negative test result for brucellosis, within 15 days of receiving notification of these results, the State in which the animal was detected must initiate an investigation to determine the herd from which the animal originated and all herds in which it has resided. A consistent State that fails to conduct such an investigation on one occasion may be redesignated as provisionally consistent. A consistent or provisionally consistent State that fails to conduct such an investigation on multiple occasions may be redesignated as inconsistent.

(b) *Epidemiological investigations.* Unless a State has submitted an alternate protocol to APHIS by submitting a written request to the address provided in the Program Standards document, and the Administrator has authorized this alternate protocol:

(1) If a program animal is determined to be infected with brucellosis or bovine tuberculosis, within 15 days of this determination, the State in which the infected animal was detected must identify the herd from which the infected animal originated and all herds in which it has resided, impose the restrictions specified in §§ 76.9 and 76.10 on the interstate movement of animals from those herds, impose substantially similar restrictions on intrastate movement, and begin determining the disease status of all test-eligible animals in those herds.

(2) If a herd of program animals is determined to be affected with brucellosis or bovine tuberculosis, within 15 days of this determination, the State in which the herd resides must identify and impose the restrictions specified in §§ 76.9 and 76.10 on the interstate movement of animals from the following herds, impose substantially similar restrictions on intrastate movement, and begin determining the disease status of all test-eligible animals in those herds.

(i) Any herd into which program animals from the affected herd may have been moved; and

(ii) Any herd from which program animals in the affected herd may have originated or in which they may have resided; and

(iii) Any herd, individual program animals, or other animals that are susceptible to brucellosis or bovine tuberculosis that may have commingled with or otherwise been exposed to the affected herd, as determined by the Administrator and communicated to the State.

(3) If the State in which an infected animal or affected herd was detected determines that any of these herds or animals are located in a different State than the infected animal or affected herd, the State in which the infected animal or affected herd was detected must notify both that State and APHIS, in writing, within 3 days. APHIS notification must be submitted to the address specified in the Program Standards document.

(4) If a non-program animal within a State is determined to be infected with brucellosis or bovine tuberculosis and the Administrator determines that this animal presents a risk of transmitting brucellosis or bovine tuberculosis to program animals, the State or States surrounding the detection must identify all herds that may have been exposed to brucellosis or bovine tuberculosis because of this detection, as determined by the Administrator and communicated to the States, impose the restrictions specified in §§ 76.9 and 76.10 on the interstate movement of animals from those herds, impose substantially similar restrictions on intrastate movement, and must determine the disease status of all test-eligible animals in those herds.

(5) If an animal infected with brucellosis or bovine tuberculosis is discovered on or has been determined to have originated from a calf raiser's premises or feedlot, the State in which the calf raiser's premises or feedlot is located must conduct an epidemiological investigation of that premises or feedlot according to a method that has been approved by the Administrator. An approved method for conducting such an investigation is set forth in the Program Standards document.

(c) *Conditions for determining whether a herd is affected with brucellosis or bovine tuberculosis.* (1) If all test-eligible program animals in a herd under investigation are determined to be negative for brucellosis or bovine tuberculosis, the herd is not an affected herd. No further action is required and the State may remove the restrictions on the movement of those animals.

(2) If any test-eligible animals in a herd under investigation are determined to be infected with brucellosis or bovine tuberculosis, the herd is considered an affected herd.

(d) *Failure to conduct an epidemiological investigation in accordance with this section.* (1) If a consistent or provisionally consistent State fails to conduct an epidemiological investigation in accordance with this section, that State will be redesignated as inconsistent.

(2) If an inconsistent State fails to conduct an epidemiological investigation in accordance with this section, the interstate movement of program animals from that State will be subject to such restrictions or prohibitions as the Administrator considers necessary to prevent the dissemination of brucellosis or bovine tuberculosis from the State. In such instances, the restrictions or prohibitions will be announced through a notice in the **Federal Register**.

(e) *Affected herd management.* States must manage affected herds through one of the following methods:

(1) Depopulation.

(2) A test-and-remove protocol approved by the Administrator. In order to be approved by the Administrator, the protocol must demonstrate that:

(i) The State has implemented and is enforcing movement restrictions on the affected herd.

(ii) The State has implemented and is enforcing an affected herd management plan for the affected herd to prevent the spread of brucellosis or bovine tuberculosis.

(iii) The State has implemented and is conducting a protocol to periodically test program animals in the affected herd for brucellosis or bovine tuberculosis and to remove and destroy those animals that do not test negative.

(iv) The State has a protocol in place to conduct periodic assurance testing of the herd once the test-and-remove protocol is complete.

(f) *Failure to conduct affected herd management in accordance with this section.* (1) If a consistent or provisionally consistent State fails to manage an affected herd through one of the methods specified in paragraph (e) of this section, the State will be redesignated as inconsistent.

(2) If an inconsistent State fails to manage an affected herd through one of the methods specified in paragraph (e) of this section, the interstate movement of program animals from that State will

be subject to such restrictions or prohibitions as the Administrator considers necessary to prevent the dissemination of brucellosis or bovine tuberculosis from the State. In such instances, the restrictions or prohibitions will be announced through a notice in the **Federal Register**.

(g) *Epidemiological investigation and affected herd management requirements; applicability to Tribes.* The requirements in this section pertain to Tribes, provided that they have submitted a Tribal animal health plan to APHIS for review and approval in accordance with the process set forth in § 76.2, and APHIS has approved the animal health plan.

## Subpart A—General Categories of Livestock

### § 76.8 Interstate movement of infected livestock generally prohibited.

Except as provided for in § 71.3(d)(7) of this subchapter, the interstate movement of any livestock known to be infected with brucellosis or bovine tuberculosis is prohibited.

### § 76.9 Interstate movement of program animals from a herd containing a reactor or suspect.

Except as provided in § 76.10, the interstate movement of program animals from a herd containing a reactor or suspect for brucellosis or bovine tuberculosis is prohibited, until the disease status of all test-eligible animals in that herd is determined.

### § 76.10 Interstate movement of reactor, suspect, and exposed program animals.

Notwithstanding the other provisions of this part, program animals that have been classified as brucellosis or bovine tuberculosis reactors, suspects, or exposed animals may be moved interstate if:

(a) The animals are officially identified; and

(b) The animals are accompanied by a permit for movement of restricted animals issued by an APHIS or State or Tribal representative; and

(c) The permit for movement of restricted animals clearly specifies the brucellosis or bovine tuberculosis classification of the animals; and

(d) The animals are moved for diagnostic testing, immediate slaughter, necropsy, or other use as approved by the Administrator; and

(e) The animals are moved to a location specified by the Administrator as an approved location for reactor, suspect, or exposed animals; [4] and

(f) The animals are moved in a means of conveyance containing only animals not susceptible to brucellosis and/or bovine tuberculosis or animals destined for immediate slaughter or necropsy; and

(g)(1) The means of conveyance in which the animals are moved interstate is secured with official seals applied and removed by an authorized APHIS representative, Food Safety and Inspection Service inspector, State or Tribal representative, accredited veterinarian, or other individual authorized for this purpose by an APHIS representative; or

(2) The animals are accompanied during movement by an APHIS representative, Food Safety and Inspection Service inspector, State or Tribal representative, or other individual authorized for this purpose by an APHIS representative; and

(h) After shipment, each means of conveyance in which the animals have been transported is cleaned and disinfected by the carrier in accordance with part 71 of this subchapter, under the supervision of an APHIS representative, Food Safety and Inspection Service inspector, State or Tribal representative, accredited veterinarian, or other person designated by the Administrator.

## Subpart B—Cattle and Bison

### § 76.11 Interstate movement of cattle and bison generally restricted.

Except as provided in §§ 76.8 through 76.10, unless the Administrator has provided public notification of alternate conditions for movement, cattle and bison may only be moved interstate in accordance with this subpart.

### § 76.12 Interstate movement of cattle and bison from consistent States or Tribes for brucellosis and bovine tuberculosis.

(a) *Rodeo, event, or exhibited cattle or bison.* Rodeo, event, or exhibited cattle or bison may be moved interstate from a consistent State or Tribe for brucellosis and bovine tuberculosis provided that:

(1) The cattle or bison are tested for bovine tuberculosis using an individual official test no more than 60 days prior to initial interstate movement from the premises of origin, with negative results; [5] and

(2) If the cattle or bison are sexually intact and 6 months of age or older, they are tested for brucellosis using an individual official test no more than 60 days prior to initial interstate movement from the premises of origin, with negative results; and

(3) The cattle or bison are tested for bovine tuberculosis using an individual official test no more than 180 days prior to any subsequent interstate movement, with negative results; and

(4) If the cattle or bison are sexually intact and 6 months of age or older, they are tested for brucellosis using an individual official test no more than 180 days prior to any subsequent interstate movement, with negative results; and

(5) The cattle or bison are accompanied during interstate movement by an ICVI with a statement regarding the date, location, and test results of the official tests for bovine tuberculosis and, if applicable, brucellosis administered prior to initial interstate movement, and the date, location, and test results of the last official test for bovine tuberculosis and, if applicable, brucellosis administered to the animals; and

(6) The cattle or bison are officially identified.

(b) *Movement of all other cattle or bison*—(1) *Movement from all areas of a consistent State or Tribe other than a recognized management area.* Cattle or bison that are not rodeo, event, or exhibited cattle or bison may be moved from any area of a consistent State or Tribe for brucellosis and bovine tuberculosis, other than from a recognized management area in the State or Tribe, without further restriction under this part.[6]

(2) *Movement from a recognized management area within a consistent State or Tribe.* Cattle or bison that are not rodeo, event, or exhibited cattle or bison may be moved interstate from a recognized management area within a consistent State or Tribe for brucellosis and bovine tuberculosis if the cattle or bison are moved in accordance with the conditions for movement of program animals from the recognized management area specified in the State or Tribe's animal health plan.

[4] Approved locations include recognized slaughtering establishments, specifically approved stockyards, official testing laboratories, research facilities, and, for exposed animals that have tested negative for brucellosis or bovine tuberculosis, quarantine feedlots and quarantine pens. A State may request approval of alternate locations by specifying the locations within its animal health plan or proposing to amend the health plan to specify the locations.

[5] The requirements of this and the following paragraph apply not only to rodeo, event, or exhibited cattle or bison that have been produced within the United States, but also rodeo, event, or exhibited cattle and bison of foreign origin after they have arrived at their destination within the United States.

[6] The cattle or bison are still subject to all other applicable restrictions of 9 CFR chapter I, including those of §§ 71.3, 71.17, 86.4, and 86.5.

**§ 76.13 Interstate movement of cattle and bison from a provisionally consistent State or Tribe.**

(a) Unless specified otherwise in the notice in the **Federal Register** designating the State or Tribe as a provisionally consistent State or Tribe, cattle or bison that are moved interstate from a provisionally consistent State or Tribe are subject to the relevant conditions for movement in § 76.12.

(b) If the notice in the **Federal Register** designating the State or Tribe as a provisionally consistent State or Tribe specifies restrictions on the interstate movement of cattle or bison from the State or Tribe, and these restrictions differ from the conditions for interstate movement specified in § 76.12, the interstate movement of such cattle or bison is subject to the restrictions specified in the notice in the **Federal Register.**

**§ 76.14 Interstate movement of cattle and bison from inconsistent States or Tribes for brucellosis.**

(a) *Sexually intact cattle or bison that are 6 months of age or older*—(1) *Cattle or bison destined for immediate slaughter.* Sexually intact cattle or bison that are 6 months of age or older and are destined for immediate slaughter may be moved interstate from an inconsistent State or Tribe for brucellosis, if:

(i) The cattle or bison are officially identified; and

(ii) The cattle or bison are accompanied by an ICVI.

(2) *Cattle or bison not destined for immediate slaughter.* Sexually intact cattle or bison that are 6 months of age or older and that are not destined for immediate slaughter may be moved interstate from an inconsistent State or Tribe for brucellosis if:

(i) The herd from which the cattle or bison originate has been subjected to a herd test using an official test for brucellosis no more than 1 year and no less than 120 days prior to movement, with negative results;

(ii) The cattle or bison are additionally tested using an individual official test no more than 60 days prior to movement, with negative results;

(iii) Since being individually tested, the cattle or bison have not commingled with non-natural additions to the herd that are of unknown brucellosis status or animals that have had a non-negative test for brucellosis;

(iv) The cattle or bison are officially identified; and

(v) The cattle or bison are accompanied by an ICVI documenting the negative test results.

(b) *Cattle or bison that are less than 6 months of age, steers, and spayed heifers.* Sexually intact cattle or bison that are less than 6 months of age, steers, and spayed heifers may be moved interstate from an inconsistent State or Tribe for brucellosis if:

(1) The cattle or bison are officially identified; and

(2) The cattle or bison are accompanied by an ICVI.

**§ 76.15 Interstate movement of cattle and bison from inconsistent States or Tribes for bovine tuberculosis.**

(a)(1) *Cattle or bison destined for immediate slaughter.* Cattle or bison that are destined for immediate slaughter may only be moved interstate from an inconsistent State or Tribe for bovine tuberculosis, if:

(i) The cattle or bison are officially identified; and

(ii) The cattle or bison are accompanied by an ICVI.

(2) *Cattle or bison not destined for immediate slaughter.* Cattle or bison that are not destined for immediate slaughter may only be moved interstate from an inconsistent State or Tribe for bovine tuberculosis, if:

(i) The cattle or bison originate from a herd that was subjected to a herd test using an official test for bovine tuberculosis no more than 1 year and no less than 120 days prior to the movement of the cattle or bison, with negative results.

(ii) The cattle or bison are additionally tested for bovine tuberculosis using an individual official test no more than 60 days prior to movement, with negative results.

(iii) Since being individually tested, the cattle or bison have not commingled with non-natural additions to the herd that are of unknown bovine tuberculosis status or animals that have had a non-negative test for bovine tuberculosis.

(iv) The cattle or bison are officially identified.

(v) The cattle or bison are accompanied by an ICVI documenting the negative test results.

(b) [Reserved]

## Subpart C—Interstate Movement of Captive Cervids

**§ 76.16 Interstate movement of captive cervids**

Except as provided in §§ 76.8 through 76.10, captive cervids may only be moved interstate in accordance with this section.

(a) *Captive cervids that originate directly from accredited herds.* Captive cervids that originate directly from herds that are currently accredited for both brucellosis and bovine tuberculosis may be moved interstate if:

(1) The cervids are officially identified; and

(2) The cervids are accompanied by an ICVI with a statement that the cervids originate directly from herds that are currently accredited for both brucellosis and bovine tuberculosis.

(b) *All other captive cervids*—(1) *Captive cervids destined for immediate slaughter.* Captive cervids that are destined for immediate slaughter may be moved interstate, provided that:

(i) The cervids are officially identified; and

(ii) The cervids are accompanied by an ICVI.

(2) *Captive cervids not destined for immediate slaughter*—(i) *General conditions.* Captive cervids that are not destined for immediate slaughter may be moved interstate provided that:

(A) The cervids originate from a herd that was subjected to a herd test using an official test for brucellosis and an official test for bovine tuberculosis no more than 1 year and no less than 120 days prior to movement, with negative results; and

(B) The cervids are additionally tested for brucellosis and bovine tuberculosis using an individual official test no more than 60 days prior to movement, with negative results; and

(C) The cervids are officially identified; and

(D) The cervids are accompanied by an ICVI.

(ii) *Additional conditions for captive cervids moved from an inconsistent State or Tribe for brucellosis and/or bovine tuberculosis.* In addition to all general conditions for the interstate movement of captive cervids specified in paragraph (a)(2)(i) of this section, captive cervids that are not destined for immediate slaughter may only be moved interstate from an inconsistent State or Tribe for brucellosis or bovine tuberculosis if, since being individually tested for brucellosis and bovine tuberculosis, the cervids have not commingled with non-natural additions to the herd that are of unknown disease status or animals that have had a non-negative test for brucellosis or bovine tuberculosis.

**§ 76.17 Official tests for brucellosis and bovine tuberculosis, official testing laboratories, and official testers.**

(a) *Official tests.* All testing for the presence or absence of brucellosis and bovine tuberculosis in animals that is conducted in accordance with this part must be conducted using an official test. A list of all official tests is found on the Internet, at *http://www.aphis.usda.gov/animal_health/animal_dis_spec/cattle.*

(1) If APHIS determines that a test can reliably determine the presence or

absence of brucellosis or bovine tuberculosis in animals, APHIS will add it to the list of official tests. Whenever a test is added to the list, APHIS will publish a notice in the **Federal Register** advising the public of this addition.

(2) If APHIS determines at any point that an official test can no longer be considered to provide reliable results regarding the presence or absence of brucellosis or bovine tuberculosis in animals, APHIS will remove it from the list of official tests. Whenever an official test is removed from the list, APHIS will publish a notice in the **Federal Register** alerting the public to and setting forth the reasons for the removal.

(b) *Official testing laboratories*—(1) *Application for approval.* In order to be considered an official testing laboratory, a Federal, State, or university laboratory, or any other laboratory approved by the National Animal Health Laboratory Network, must submit a written application to its district APHIS Veterinary Services office. A standard format for such an application is found in the Program Standards document.

(2) *Evaluation process.* APHIS will review the submitted application to determine if it is complete. When APHIS determines that the application is complete, it will conduct formal review and evaluation of the application. Evaluation will be based on the following considerations:

(i) Whether a need exists at the national level for an additional laboratory to be authorized by APHIS to conduct official tests for brucellosis and bovine tuberculosis;

(ii) Whether the laboratory has facilities, safety equipment, and standard microbiological practices appropriate for the testing specified on the application;

(iii) Whether the personnel at the laboratory are qualified to conduct the activities specified on the application, as determined by proficiency testing; and

(iv) Whether the individual at the laboratory with oversight of serological testing or final determination of test results has adequate experience in the fields of immunology, microbiology, veterinary medicine, or a similar discipline.

(3) *Approval or denial.* APHIS will communicate its approval or denial of the laboratory's application to the laboratory. If this approval or denial is oral, APHIS will subsequently communicate the approval or denial in writing. If APHIS approves a laboratory, it will be considered an official testing laboratory. An official testing laboratory may conduct official tests using official testers in the manner set forth in its application and approved by APHIS. A list of all official testing laboratories is found on the Internet at [*address to be added in final rule*].

(4) *Maintaining approval.* In order for a laboratory to maintain approval as an official testing laboratory, it must demonstrate, by means of annual proficiency testing, that it continually meets or exceeds the standards under which it was approved.

(5) *Changes to approval.* (i) If circumstances have changed at the laboratory such that the information supplied on its application for approval is no longer accurate, the laboratory must provide updated information to APHIS within 30 days. In response to such notification, APHIS may conduct another evaluation of the facility. Failure by a facility to notify APHIS in a timely manner may result in revocation of its approval.

(ii) A facility may provide additional information to APHIS for evaluation and approval at any point.

(6) *Revocation of approval.* APHIS may revoke the approval of an official testing laboratory if it is determined to have falsified information on its application or to no longer meet the standards under which it was approved. Any laboratory whose approval is revoked may appeal the decision in writing to the Administrator within 14 days after receiving the written notification of the revocation. The appeal must state all of the reasons on which the laboratory relies to show that approval was wrongfully revoked. The Administrator shall grant or deny the appeal, in writing, stating the reasons for the decision as soon as circumstances allow.

(7) *Reapproval.* In order to be reapproved, any laboratory whose approval has been revoked must submit a written justification for reapproval to APHIS to the address specified within the Program Standards document. The justification must demonstrate that the issue that resulted in the revocation has been resolved.

(c) *Official testers outside of a laboratory environment*—(1) *State, Federal, and Tribal animal health and wildlife officials.* At the discretion of a district APHIS Veterinary Services office and a State or Tribal animal health official, regulatory personnel may conduct official tests outside of a laboratory environment and under the conditions specified by the VS office and State or Tribal official.

(2) *Qualified accredited veterinarians.* A qualified accredited veterinarian with a program certification for bovine tuberculosis is authorized to operate as an official tester for bovine tuberculosis outside of a laboratory environment within the State or States in which he or she is accredited.

## PART 77—[REMOVED AND RESERVED]

■ 18. Part 77 is removed and reserved.

## PART 78—BRUCELLOSIS

■ 19. The authority citation for part 78 continues to read as follows:

**Authority:** 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 20. Section 78.1 is amended as follows:

■ a. By removing the definitions for *animal identification number, approved brucella vaccine, approved individual herd plan, approved intermediate handling facility, area, ''B'' branded, brucellosis, brucellosis exposed, brucellosis reactor, brucellosis ring test, brucellosis suspect, certified brucellosis-free herd, Class A State or area, Class B State or area, Class C State or area, Class Free State or area, dairy cattle, farm of origin, finished fed cattle, herd blood test, market cattle identification test cattle, official adult vaccinate, official brand inspection certificate, official brand recording agency, official calfhood vaccinate, official eartag, official vaccinate, official vaccination eartag, permit for entry, qualified herd, quarantined area, quarantined feedlot, quarantined pasture, ''S'' branded, ''S'' brand permit, specifically approved stockyard, successfully closed case, test-eligible cattle and bison, United States Department of Agriculture backtag,* and *whole herd vaccination.*

■ b. In the definition of *official test,* by removing and reserving paragraph (a).

■ c. By revising the definitions of *animals, originate,* and *permit.*

The revisions read as follows:

### § 78.1 Definitions.

* * * * *

*Animals.* Swine.

* * * * *

*Originate.* (1) Animals will have the status of the herd from which they were moved if:

(i) They were born and maintained in that herd since birth; or

(ii) They have been in the herd for at least 120 days.

(2) Animals will have the status of the State from which they were moved if:

(i) They were born and maintained in the State since birth; or

(ii) They were previously moved from a State of equal or higher class to the State; or

(iii) They were previously moved from a State of lower class to the State

where they are now located and have been in the new State for at least 120 days.

* * * * *

*Permit.* A document issued by an APHIS representative, State representative, or accredited veterinarian and authorizing the restricted interstate movement of livestock to certain specified destinations.

* * * * *

**§ 78.2 [Amended]**

■ 21. Section 78.2 is amended as follows:

■ a. In paragraph (a), in the first sentence, by removing the words ''ICVI, permit, or 'S' brand permit'' and adding the words ''ICVI or permit'' in their place.

■ b. In paragraph (b), by removing the words '', except for permits for entry and 'S' brand permits,''.

**§ 78.3 [Removed and reserved]**

■ 22. Section 78.3 is removed and reserved.

## Subpart B—[Removed and reserved]

■ 23. Subpart B, consisting of §§ 78.5 through 78.14, is removed and reserved.

## Subpart C—[Removed and reserved]

■ 24. Subpart C, consisting of §§ 78.20 through 78.25, is removed and reserved.

## PART 86—ANIMAL DISEASE TRACEABILITY

■ 25. The authority citation for part 86 continues to read as follows:

**Authority:** 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

**§ 86.4 [Amended]**

■ 26. Section 86.4 is amended as follows:

■ a. In paragraph (a)(6), by removing the words ''part 77'' and adding the words ''part 76'' in their place.

■ b. In paragraph (b)(6), by removing the words ''part 77'' and adding the words ''part 76'' in their place.

■ c. In paragraph (c)(4), by removing the words ''part 78'' and adding the words ''part 76'' in their place.

**§ 86.5 [Amended]**

■ 27. In § 86.5, paragraph (h) is amended as by removing the words ''part 77'' and adding the words ''part 76'' in their place.

## PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, FISH, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

■ 28. The authority citation for part 93 continues to read as follows:

**Authority:** 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 29. Section 93.400 is amended as follows:

■ a. By removing the definitions of *brucellosis certified-free province or territory of Canada, official tuberculin test, tuberculosis-free herd,* and *whole herd test.*

■ b. By revising the definition of *herd of origin.*

■ c. By adding, in alphabetical order, definitions for *accredited herd for brucellosis, accredited herd for tuberculosis, brucellosis, import protocol, individual test, non-negative test results, notifiable disease, spayed heifer, steer, tuberculosis, whole herd test for brucellosis,* and *whole herd test for tuberculosis.*

The additions and revision read as follows:

**§ 93.400 Definitions.**

* * * * *

*Accredited herd for brucellosis.* A herd that meets APHIS' standards for accreditation for brucellosis status. Standards for accreditation are specified in import protocols.

*Accredited herd for tuberculosis.* A herd that meets APHIS' standards for accreditation for bovine tuberculosis status. Standards for accreditation are specified in import protocols.

* * * * *

*Brucellosis.* Infection with or disease caused by *Brucella abortus.*

* * * * *

Herd of origin.

(1) The herd within which an individual animal was born and raised; or

(2) Any herd in which an individual animal has been continually maintained for at least 4 months prior to shipment to the United States.

* * * * *

*Import protocol.* A document issued by APHIS and provided to officials of the competent veterinary authority of an exporting region that specifies in detail the mitigation measures that will comply with the regulations in 9 CFR part 93 regarding the import of certain animals or commodities.

*Individual test.* A test for brucellosis or tuberculosis that is approved by the Administrator and that is administered individually in accordance with this part to ruminants that are susceptible to brucellosis or tuberculosis. For purposes of this part, testing of individual animals as part of a whole herd test does not constitute an individual test.

* * * * *

*Non-negative test results.* Any test results for tuberculosis or brucellosis within the suspect or positive range parameters of a pathogen assay that has been approved by the Administrator.

* * * * *

*Notifiable disease.* A disease for which confirmed or suspected occurrences within a region must be reported to the competent veterinary authority or other competent authority of that region.

* * * * *

*Spayed heifer.* A female bovine that has been neutered in a manner otherwise approved by the Administrator and specified in an import protocol.

* * * * *

*Steer.* A sexually neutered male bovine.

* * * * *

*Tuberculosis.* Infection with or disease caused by *Mycobacterium bovis.*

* * * * *

*Whole herd test for brucellosis.* A brucellosis test that has been approved by APHIS of all bovines in a herd of origin that are 6 months of age or older, and of all bovines in the herd of origin that are less than 6 months of age and were not born into the herd of origin, except those bovines that are less than 6 months of age and originate directly from a currently accredited herd for brucellosis.

*Whole herd test for tuberculosis.* A tuberculosis test that has been approved by APHIS of all bovines in a herd of origin that are 6 months of age or older, and of all bovines in the herd of origin that are less than 6 months of age and were not born into the herd of origin, except those bovines that are less than 6 months of age and originate directly from a currently accredited herd for tuberculosis.

* * * * *

■ 30. Section 93.401 is amended by adding paragraph (d) to read as follows:

**§ 93.401 General prohibitions; exceptions.**

* * * * *

(d) *Cleaning and disinfection prior to shipment.* Unless a means of conveyance was cleaned and disinfected in a manner specified within an import protocol prior to being used to transport an animal for importation in accordance

with this subpart, or unless an exemption has been granted by the Administrator, the transport of the animal to the United States in that means of conveyance is prohibited.

**§ 93.406 [Amended]**

■ 31. Section 93.406 is amended by removing and reserving paragraphs (a), (c), and (d).

**§ 93.408 [Amended]**

■ 32. In § 93.408, the first sentence is amended by removing the words ''§§ 93.421 and 93.426'' and adding in their place ''§ 93.421''.

**§ 93.418 [Amended]**

■ 33. Section 93.418 is amended as follows:

■ a. By removing and reserving paragraphs (b) and (c).

■ b. In paragraph (d), introductory text, by removing the words ''the requirements of paragraphs (a) through (c)'' and adding the words ''the other requirements'' in their place.

**§ 93.423 [Amended]**

■ 34. In § 93.423, the first sentence in paragraph (a) is amended by removing the words ''Ruminants intended for'' and adding the words ''In addition to all other applicable requirements of the regulations in this part, ruminants intended for'' in their place.

■ 35. In § 93.424, paragraph (b) is revised to read as follows:

**§ 93.424 Import permits and applications for inspection of ruminants.**

* * * * *

(b) For ruminants intended for importation into the United States from Mexico, the importer or his or her agent shall deliver to the veterinary inspector at the port of entry an application, in writing, for inspection, so that the veterinary inspector and customs representatives may make mutual satisfactory arrangements for the orderly inspection of the animals. The veterinary inspector at the port of entry will provide the importer or his or her agent with a written statement assigning a date when the animals may be presented for import inspection.

■ 36. Section 93.427 is amended as follows:

■ a. By revising paragraph (a).

■ b. By removing and reserving paragraphs (c) and (d).

The revision reads as follows:

**§ 93.427 Cattle from Mexico.**

(a) Cattle from Mexico, except animals being transported in bond for immediate return to Mexico or animals imported for immediate slaughter, may be detained at the port of entry, and there subjected to such disinfection, blood tests, other tests, and dipping as required in this part to determine their freedom from any communicable disease or infection of such disease. The importer shall be responsible for the care, feed, and handling of the animals during the period of detention. In addition, all steers from Mexico that arrive at a port of entry into the United States, except animals being transported in bond for immediate return to Mexico or animals imported for immediate slaughter, must be identified on the right hip with a distinct, permanent, and legible ''M'' mark applied with a freeze brand, hot iron, or other method approved by APHIS, and all spayed heifers from Mexico that arrive at a port of entry into the United States, except animals being transported in bond for immediate return to Mexico or animals imported for immediate slaughter, must be identified on the right hip with a distinct, permanent, and legible ''$M_X$'' mark applied with a freeze brand, hot iron, or other method approved by APHIS.

* * * * *

■ 37. Section 93.429 is revised to read as follows:

**§ 93.429 Ruminants for immediate slaughter.**

Ruminants, other than bovines, sheep, and goats, may be imported from Mexico subject to the applicable provisions of §§ 93.424, 93.425, and 93.426 for immediate slaughter if accompanied by a certificate issued in accordance with § 93.405(a) and stating that the veterinarian who issued the certificate has inspected the animals in the herd from which the ruminants will be imported and found them free of evidence of communicable disease, and that, so far as it has been possible to determine, they have not been exposed to any such disease common to animals of their kind during the preceding 60 days, and if the ruminants are shipped by rail or truck, the certificate shall further specify that the ruminants were loaded into cleaned and disinfected cars or trucks for transportation directly to the port of entry. Such ruminants shall be moved from the port of entry in conveyances sealed with seals of the United States Government. Bovines, sheep, and goats, may be imported only in compliance with other applicable sections in this part.

**§ 93.432 [Removed and reserved]**

■ 38. Section 93.432 is removed and reserved.

■ 39. Section 93.437 is added to subpart D to read as follows:

**§ 93.437 Tuberculosis status of foreign regions.**

(a) *Level I regions.* APHIS considers certain regions of the world to have a program that meets APHIS requirements for tuberculosis classification in accordance with § 93.438, and a prevalence of tuberculosis in their domestic bovine herds of less than 0.001 percent over at least the previous 2 years (24 consecutive months).

(b) *Level II regions.* APHIS considers certain regions of the world to have a program that meets APHIS requirements for tuberculosis classification in accordance with § 93.438, and a prevalence of tuberculosis in their domestic bovine herds equal to or greater than 0.001 percent, but less than 0.01 percent, over the previous 2 years (24 consecutive months).

(c) *Level III regions.* APHIS considers certain regions of the world to have a program that meets APHIS requirements for tuberculosis classification in accordance with § 93.438, and a prevalence of tuberculosis in their domestic bovine herds equal to or greater than 0.01 percent, but less than 0.1 percent, over the previous year (12 consecutive months).

(d) *Level IV regions.* APHIS considers certain regions of the world to have a program that meets APHIS requirements for tuberculosis classification in accordance with § 93.438, and a prevalence of tuberculosis in their domestic bovine herds equal to or greater than 0.1 percent, but less than 0.5 percent, over the previous year (12 consecutive months).

(e) *Level V regions.* APHIS considers certain regions of the world not to have a program that meets APHIS requirements for tuberculosis classification in accordance with § 93.438, to have a prevalence of tuberculosis in their domestic bovine herds equal to or greater than 0.5 percent, or to be unassessed by APHIS with regard to tuberculosis prevalence.

(f) *Listing of regions.* Lists of all Level I regions, Level II regions, Level III regions, Level IV, and Level V regions for tuberculosis are found online, at *http://www.aphis.usda.gov/import_export/animals/live_animals.shtml.* Changes to the lists will be made in accordance with § 93.438.

■ 40. Section 93.438 is added to subpart D to read as follows:

**§ 93.438 Process for requesting regional classification for tuberculosis.**

(a) *Request for regional classification; requirements.* A representative of the competent veterinary authority of any country or countries may request that APHIS classify a region for tuberculosis.

Requests for classification or reclassification must be submitted to APHIS electronically or through the mail as provided at *http://www.aphis.usda.gov/import_export/animals/live_animals.shtml.* Guidance regarding how to complete a request in a manner that will allow APHIS to review it expeditiously is available at *http://www.aphis.usda.gov/import_export/animals/reg_request.shtml,* and may also be obtained by contacting the National Director, Regionalization Evaluation Services, National Import Export Services, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737. At a minimum, in order for APHIS to consider the request complete, it must define the boundaries of the region, specify the prevalence level for tuberculosis within the region, and demonstrate the following:

(1) That there is effective veterinary control and oversight within the region;

(2) That tuberculosis is a notifiable disease within the region; and

(3) That the region has a program in place for tuberculosis that includes, at a minimum:

(i) Epidemiological investigations following the discovery of any infected animals or affected herds, or any animals or herds that have had non-negative test results following a test for tuberculosis, and documentation of these investigations;

(ii) Management of affected herds in a manner designed to eradicate tuberculosis from those herds, and documentation regarding this management;

(iii) Regulatory controls on the movement of livestock into, within, and from the region that correspond to the risk of dissemination of tuberculosis associated with such movement; and

(iv) Access to, oversight of, and quality controls for diagnostic testing for tuberculosis within the region.

(4) That the region has surveillance in place that is equivalent to or exceeds Federal standards for surveillance within the United States.

(b) *APHIS evaluation.* If APHIS considers the request complete, APHIS will publish a notice in the **Federal Register** proposing to classify the region according to § 93.437, and making available to the public the information upon which this proposed classification is based. The notice will request public comment.

(c) *APHIS determination.* (1) If no comments are received on the notice, or if comments are received but do not affect APHIS' proposed classification, APHIS will publish a subsequent notice in the **Federal Register** announcing that classification to be final and adding the region to the appropriate list on the Internet.

(2) If comments received on the notice suggest that the region be classified according to a different tuberculosis classification, and APHIS agrees with the comments, APHIS will publish a subsequent notice in the **Federal Register** making the information supplied by commenters available to the public, and proposing to classify the region according to this different classification. The notice will request public comment.

(3) If comments received on the notice suggest that insufficient information was supplied on which to base a tuberculosis classification, and APHIS agrees with the comments, APHIS will publish a subsequent notice in the **Federal Register** specifying the additional information needed before APHIS can classify the region.

(d) *Maintaining classification and reclassification initiated by APHIS.* If a region is classified under the provisions of this section, that region may be required to submit additional information or allow APHIS to conduct additional information collection activities in order for that region to maintain its classification. Moreover, if APHIS determines that a region's classification for tuberculosis is no longer accurate, APHIS will publish a notice in the **Federal Register** announcing the revised classification and setting forth the reasons for this reclassification.

■ 41. Section 93.439 is added to subpart D to read as follows:

**§ 93.439 Importation of ruminants from certain regions of the world; tuberculosis.**

(a) *Importation of certain ruminants prohibited.* Notwithstanding any other provisions of this section, ruminants that are known to be infected with or exposed to tuberculosis and ruminants that have had a non-negative response to any test for tuberculosis are prohibited importation into the United States.

(b) *Importation of bovines from Level I regions.* Unless specified otherwise by the Administrator, bovines may be imported into the United States from a Level I region for tuberculosis without further restriction under this section.[11]

(c) *Importation of bovines for immediate slaughter from Level II, III, or IV regions.* Bovines may be imported into the United States for immediate slaughter from a Level II, III, or IV region for tuberculosis provided that:

(1) The bovines are officially identified; and

(2) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines are officially identified.

(d) *Importation of other bovines from a Level II region*—(1) *Bovines directly from currently accredited herds for tuberculosis.* Bovines may be imported into the United States for purposes other than immediate slaughter directly from a currently accredited herd for tuberculosis in a Level II region for tuberculosis, provided that:

(i) The bovines are officially identified; and

(ii) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines are officially identified and originate directly from a currently accredited herd for tuberculosis.

(2) *Sexually intact bovines that do not originate directly from a currently accredited herd for tuberculosis.* Sexually intact bovines that do not originate directly from a currently accredited herd for tuberculosis may be imported into the United States from a Level II region for tuberculosis for purposes other than immediate slaughter provided that:

(i) If the bovines are 6 months of age or older, the bovines are subjected to an individual test for tuberculosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411, with negative results; and

(ii) The bovines are officially identified; and

(iii) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the animals are officially identified.

(3) *Steers or spayed heifers that do not originate directly from a currently accredited herd for tuberculosis.* Steers or spayed heifers that do not originate directly from a currently accredited herd for tuberculosis may be imported into the United States from a Level II region for tuberculosis for purposes other than immediate slaughter provided that:

(i) The steers or spayed heifers are officially identified; and

(ii) The steers or spayed heifers are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the steers or spayed heifers are officially identified.

(e) *Importation of other bovines from a Level III region*—(1) *Bovines directly from currently accredited herds for*

[11] The importation of such bovines, as well as that of all other bovines covered by this section, is still subject to all other relevant restrictions of this part.

*tuberculosis.* Bovines may be imported into the United States for purposes other than immediate slaughter directly from a currently accredited herd for tuberculosis in a Level III region for tuberculosis, provided that:

(i) The bovines are officially identified; and

(ii) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines are officially identified and originate directly from a currently accredited herd for tuberculosis.

(2) *Sexually intact bovines that do not originate directly from a currently accredited herd for tuberculosis.* Sexually intact bovines that do not originate directly from a currently accredited herd for tuberculosis may be imported into the United States from a Level III region for tuberculosis for purposes other than immediate slaughter, provided that:

(i) The bovines originate from a herd that was subjected to a whole herd test for tuberculosis on its premises of origin no more than 1 year prior to the export of the bovines to the United States, with negative results; and

(ii) If the bovines are 2 months of age or older, the bovines are subjected to an additional individual test for tuberculosis on the premises of origin no more than 60 days prior to export of the bovines to the United States, with negative results, except that this additional test is not required if the bovines are exported within 60 days of the whole herd test and were included in that test; and

(iii) The bovines are officially identified; and

(iv) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the animals meet the conditions for importation in paragraphs (e)(2)(i) through (iii) of this section.

(3) *Steers or spayed heifers that do not originate directly from a currently accredited herd for tuberculosis.* Steers or spayed heifers that do not originate directly from a currently accredited herd for tuberculosis may be imported into the United States from a Level III region for tuberculosis for purposes other than immediate slaughter provided that:

(i) If the steers or spayed heifers are 6 months of age or older, the steers or spayed heifers are subjected to an individual test for tuberculosis on the premises of origin no more than 60 days prior to export of the bovines to the United States, with negative results; and

(ii) The steers or spayed heifers are officially identified; and

(iii) The steers or spayed heifers are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the animals meet the conditions for importation in this paragraph (e)(3).

(f) *Importation of other bovines from a Level IV region*—(1) *Bovines directly from currently accredited herds for tuberculosis.* Bovines may be imported into the United States for purposes other than immediate slaughter directly from a currently accredited herd for tuberculosis in a Level IV region for tuberculosis, provided that:

(i) The bovines are subjected to an individual test for tuberculosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411, with negative results; and

(ii) The bovines are officially identified; and

(iii) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines are officially identified and originate directly from a currently accredited herd for tuberculosis.

(2) *Sexually intact bovines that do not originate directly from a currently accredited herd for tuberculosis.* Sexually intact bovines that do not originate directly from a currently accredited herd for tuberculosis may be imported into the United States from a Level IV region for tuberculosis for purposes other than immediate slaughter, provided that:

(i) The bovines originate from a herd that was subjected to two whole herd tests for tuberculosis on its premises of origin and conducted no less than 9 months and no more than 15 months apart, with the second whole herd test conducted no less than 60 days prior the export of the bovines to the United States, with negative results each time; and

(ii) If the bovines are 2 months of age or older, the bovines are subjected to an additional individual test for tuberculosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411, with negative results; and

(iii) The bovines are officially identified; and

(iv) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines meet the requirements in paragraphs (f)(2)(i) and (iii) of this section.

(3) *Steers or spayed heifers that do not originate directly from a currently accredited herd for tuberculosis.* Steers or spayed heifers that do not originate directly from a currently accredited herd for tuberculosis may be imported into the United States from a Level IV region for tuberculosis for purposes other than immediate slaughter provided that:

(i) The bovines originate from a herd that was subjected to a whole herd test for tuberculosis on its premises of origin no more than 1 year prior to the export of the bovines, with negative results; and

(ii) If the bovines are 2 months of age or older, the bovines are subjected to an additional individual test for tuberculosis on the premises of origin no more than 60 days prior to export of the bovines to the United States, with negative results, except that this additional test is not required if the bovines are exported within 60 days of the whole herd test and were included in that test; and

(iii) The bovines are officially identified; and

(iv) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines meet the requirements in this paragraph (f)(3).

(g) *Importation of bovines from a Level V region.* Bovines may be imported from a Level V region for tuberculosis, provided that:

(1) APHIS and the importer have entered into a Cooperative and Trust Fund Agreement, and the importer has deposited funds with APHIS in an amount determined by APHIS to cover all costs incurred by APHIS in providing services in accordance with the Cooperative and Trust Fund Agreement; and

(2) The bovines originate from a herd that was subjected to two whole herd tests for tuberculosis on its premises of origin and conducted no less than 9 months and no more than 15 months apart, with at least the second whole herd test administered by an APHIS veterinarian and conducted no less than 60 days prior to export, with negative results; and

(3) The bovines are subjected to an additional individual test for tuberculosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411, with negative results; and

(4) The bovines are officially identified; and

(5) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that bovines meet the requirements in paragraphs (g)(1), (2), and (4) of this section.

■ 42. Section 93.440 is added to subpart D to read as follows:

**§ 93.440 Brucellosis status of foreign regions.**

(a) *Level I regions.* APHIS considers certain regions of the world to have a program that meets APHIS requirements for brucellosis classification in accordance with § 93.441, and a prevalence of brucellosis in their domestic bovine herds of less than 0.001 percent over at least the previous 2 years (24 consecutive months).

(b) *Level II regions.* APHIS considers certain regions of the world to have a program that meets APHIS requirements for brucellosis classification in accordance with § 93.441, and a prevalence of brucellosis in their domestic bovine herds equal to or greater than 0.001 percent, but less than 0.01 percent over at least the previous 2 years (24 consecutive months).

(c) *Level III regions.* APHIS considers certain regions of the world not to have a program that meets APHIS requirements for brucellosis classification in accordance with § 93.441, to have a herd prevalence equal to or greater than 0.01 percent, or to be unassessed by APHIS with regard to brucellosis prevalence.

(d) *Listing of regions.* Lists of all Level I, Level II, and Level III regions for brucellosis are found online, at *http://www.aphis.usda.gov/import_export/animals/live_animals.shtml.* Changes to the lists will be made in accordance with § 93.441.

■ 43. Section 93.441 is added to subpart D to read as follows:

**§ 93.441 Process for requesting regional classification for brucellosis.**

(a) *Request for regional classification; requirements.* A representative of the competent veterinary authority of any country or countries may request that APHIS classify a region for brucellosis. Requests for classification or reclassification must be submitted to APHIS electronically or through the mail as provided at *http://www.aphis.usda.gov/import_export/animals/live_animals.shtml.* Guidance regarding how to complete a request in a manner that will allow APHIS to review it expeditiously is available at *http://www.aphis.usda.gov/import_export/animals/reg_request.shtml,* and may also be obtained by contacting the National Director, Regionalization Evaluation Services, National Import Export Services, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD, 20737. At a minimum, in order for APHIS to consider the request complete, it must define the boundaries of the region, specify the prevalence level for brucellosis within the region, and demonstrate the following:

(1) That there is effective veterinary control and oversight within the region;

(2) That brucellosis is a notifiable disease within the region; and

(3) That the region has a program for brucellosis in place that includes, at a minimum:

(i) Epidemiological investigations following the discovery of any infected animals or affected herds, or any animals or herds that have had non-negative test results following a test for brucellosis, and documentation of these investigations;

(ii) Management of affected herds in a manner designed to eradicate brucellosis from those herds, and documentation regarding this management;

(iii) Regulatory controls on the movement of livestock into, within, and from the region that correspond to the risk of dissemination of brucellosis associated with such movement; and

(iv) Access to, oversight of, and quality controls on diagnostic testing for brucellosis within the region.

(4) That the region has surveillance in place that is equivalent to or exceeds Federal standards for brucellosis surveillance within the United States; and

(5) That, if the region vaccinates for brucellosis, it is in a manner that has been approved by APHIS.

(b) *APHIS evaluation.* If APHIS considers the request complete, APHIS will publish a notice in the **Federal Register** proposing to classify the region according to § 93.440, and making available to the public the information upon which this proposed classification is based. The notice will request public comment.

(c) *APHIS determination.* (1) If no comments are received on the notice, or if comments are received but do not affect APHIS' proposed classification, APHIS will publish a subsequent notice in the **Federal Register** announcing that classification to be final and adding the region to the appropriate list on the Internet.

(2) If comments received on the notice suggest that the region be classified according to a different brucellosis classification, and APHIS agrees with the comments, APHIS will publish a subsequent notice in the **Federal Register** making the information supplied by commenters available to the public, and proposing to classify the region according to this different classification. The notice will request public comment.

(3) If comments received on the notice suggest that insufficient information was supplied on which to base a brucellosis classification, and APHIS agrees with the comments, APHIS will publish a subsequent notice in the **Federal Register** specifying the additional information needed before APHIS can classify the region.

(d) *Maintaining classification and reclassification initiated by APHIS.* If a region is classified under the provisions of this section, that region may be required to submit additional information or allow APHIS to conduct additional information collection activities in order for that region to maintain its classification. Moreover, if APHIS determines that a region's classification for brucellosis is no longer accurate, APHIS will publish a notice in the **Federal Register** announcing the revised classification and setting forth the reasons for this reclassification.

■ 44. Section 93.442 is added to subpart D to read as follows:

**§ 93.442 Importation of ruminants from certain regions of the world; brucellosis.**

(a) *Importation of certain ruminants prohibited.* Notwithstanding any other provisions of this section, ruminants that are known to be infected with or exposed to brucellosis and ruminants that have had a non-negative response to any test for *Brucella* spp. are prohibited importation into the United States.

(b) *Importation of bovines from Level I regions.* Unless specified otherwise by the Administrator, bovines may be imported into the United States from a Level I region for brucellosis without further restriction under this section.[12]

(c) *Bovines for slaughter.* Bovines may be imported for slaughter from a Level II or Level III region for brucellosis provided that:

(1) The bovines are officially identified; and

(2) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines are officially identified.

(d) *Importation of other bovines from a Level II region for purposes other than immediate slaughter*—(1) *Bovines directly from currently accredited herds for brucellosis.* Bovines may be imported into the United States for purposes other than immediate slaughter from a currently accredited herd for brucellosis in a Level II region for brucellosis, provided that:

[12] The importation of such bovines, as well as that of all other bovines covered by this section, is still subject to all other relevant restrictions of this chapter.

(i) The bovines are officially identified; and

(ii) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines are officially identified and originate directly from a currently accredited herd for brucellosis.

(2) *Sexually intact bovines that do not originate directly from a currently accredited herd for brucellosis.* Sexually intact bovines that do not originate directly from a currently accredited herd for brucellosis may be imported into the United States from a Level II region for brucellosis for purposes other than immediate slaughter, provided that:

(i) The bovines originate from a herd that was subjected to a whole herd test for brucellosis on its premises of origin no more than 90 days and no less than 30 days prior to the export of the bovines to the United States, with negative results; and

(ii) If the bovines are 6 months of age or older, the bovines are subjected to an additional individual test for brucellosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411, with negative results; and

(iii) The bovines are officially identified; and

(iv) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines meet the requirements in paragraphs (d)(2)(i) and (iii) of this section.

(3) *Steers and spayed heifers that do not originate directly from a currently accredited herd for brucellosis.* Steers or spayed heifers that do not originate directly from a currently accredited herd for brucellosis may be imported into the United States from a Level II region for brucellosis for purposes other than immediate slaughter, provided that:

(i) The steers or spayed heifers are officially identified; and

(ii) The steers or spayed heifers are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the steers or spayed heifers are officially identified.

(e) *Importation of other bovines from a Level III region for purposes other than immediate slaughter*—(1) *Bovines directly from currently accredited herds for brucellosis.* Bovines may be imported into the United States for purposes other than immediate slaughter from a currently accredited herd for brucellosis in a Level III region for brucellosis, provided that:

(i) If sexually intact, the bovines are subjected to an individual test for brucellosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411, with negative results; and

(ii) The bovines are officially identified; and

(iii) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines are officially identified and originate directly from a currently accredited herd for brucellosis.

(2) *Sexually intact bovines that do not originate directly from a currently accredited herd for brucellosis.* Sexually intact bovines that do not originate directly from a currently accredited herd for brucellosis may be imported into the United States from a Level III region for brucellosis for purposes other than immediate slaughter, provided that:

(i) The bovines originate from a herd that was subjected to two whole herd tests for brucellosis on its premises of origin, with the second test taking place no more than 90 days and no less than 30 days prior to the export of the bovines to the United States, with negative results each time; and

(ii) If the bovines are 6 months of age or older, the bovines are subjected to an additional individual test for brucellosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411; and

(iii) The bovines are officially identified; and

(iv) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines meet the requirements in paragraphs (e)(2)(i) and (iii) of this section.

(3) *Steers and spayed heifers that do not originate directly from a currently accredited herd for brucellosis.* Steers or spayed heifers that do not originate directly from a currently accredited herd for brucellosis may be imported into the United States from a Level III region for brucellosis for purposes other than immediate slaughter, provided that:

(i) The steers or spayed heifers are officially identified; and

(ii) The steers or spayed heifers are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the steers or spayed heifers are officially identified.

## PART 161—REQUIREMENTS AND STANDARDS FOR ACCREDITED VETERINARIANS AND SUSPENSION OR REVOCATION OF SUCH ACCREDITATION

■ 45. The authority citation for part 161 continues to read as follows:

**Authority:** 7 U.S.C. 8301–8317; 15 U.S.C. 1828; 7 CFR 2.22, 2.80, and 371.4.

■ 46. Section 161.5 is amended by removing the last two sentences of the section and adding five new sentences in their place to read as follows:

### § 161.5 Program certifications.

* * * A QAV will be accredited to perform those specific accredited duties related to the program certification he or she has been granted; accredited veterinarians not granted a program certification will not be permitted to perform accredited duties related to that particular program certification. In order to retain a program certification, a QAV must meet standards set forth by APHIS regarding performance of accredited duties identified for that certification. APHIS may decertify a QAV for a specific program certification if that QAV does not perform accredited duties in accordance with that program certification standard. APHIS may also suspend or revoke the accreditation of the QAV, if warranted. Finally, if a QAV allows his or her Category II accreditation to expire, the QAV's program certification expires as well, and the QAV must be qualified for the program certification again in accordance with this section.

Done in Washington, DC, this 9th day of December 2015.

**Edward Avalos,**

*Under Secretary for Marketing and Regulatory Programs.*

[FR Doc. 2015–31510 Filed 12–15–15; 8:45 am]

BILLING CODE 3410–34–P