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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 78

[Docket No. APHIS-2009-0083]
RIN 0579-AD22

Brucellosis Class Free States and Certified Brucellosis-Free Herds; Revisions to Testing and Certification Requirements

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the brucellosis regulations to reduce the amount of testing required to maintain Class Free status for States that have been Class Free for 5 or more years and have no Brucella abortus in wildlife. We are also removing the provision for automatic reclassification of any Class Free State or area to a lower status if two or more herds are found to have brucellosis within a 2-year period or if a single brucellosis-affected herd is not depopulated within 60 days. Further, we are reducing the age at which cattle are included in herd blood tests. We are also adding a requirement that any Class Free State or area with Brucella abortus in wildlife must develop and implement a brucellosis management plan approved by the Administrator in order to maintain Class Free status. Finally, we are providing an alternative testing protocol for maintaining the certified brucellosis-free status of dairy herds, which will give producers more flexibility for the herd certification process. These changes are necessary to refocus resources to control and prevent the spread of brucellosis and to protect and maintain the economic viability of the domestic livestock industry.

DATES: This interim rule is effective December 27, 2010. We will consider all comments that we receive on or before February 25, 2011.

ADDRESSES: You may submit comments by either of the following methods:
Federal eRulemaking Portal: Go to
http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-

2009-0083 to submit or view comments and to view supporting and related materials available electronically.

Postal Mail/Commercial Delivery: Please send one copy of your comment to Docket No. APHIS-2009-0083, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. APHIS-2009-0083.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room 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) 690-2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at http://www.aphis.usda.gov.

FOR FURTHER INFORMATION CONTACT: Dr. Debbi Donch, National Brucellosis Epidemiologist and Program Manager, National Center for Animal Health Programs, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1231; (301) 734-6954.

SUPPLEMENTARY INFORMATION:

Background

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.

The brucellosis regulations, contained in 9 CFR part 78 (referred to below as the regulations), provide a system for classifying States or portions of States according to the rate of Brucella abortus (B. abortus) infection present and the general effectiveness of a brucellosis control and eradication program. The classifications are Class Free, Class A, Class B, and Class C. States or areas that do not meet the minimum standards for Class C status are required to be placed under Federal quarantine. Restrictions on moving cattle and bison interstate become less stringent as a State or area approaches or achieves Class Free status.

APHIS' regulations support a cooperative Federal-State-industry program that has made considerable progress in eradicating brucellosis from the United States. By 2007, the national brucellosis program had achieved an all-time low national herd prevalence of 0.0001 percent (one affected herd in approximately 1 million cattle herds). In February 2008, every State, along with Puerto Rico and the U.S. Virgin Islands, achieved Class Free status for the first time in the program's 74-year history. Currently, all States, including Puerto Rico and the U.S. Virgin Islands, are Class Free for brucellosis. In addition, every State except Montana, Idaho, Wyoming, and Texas has been classified as free from brucellosis for at least 5 consecutive years. Each of the three States in the Greater Yellowstone Area, Idaho, Montana and

Wyoming, experienced a temporary loss of Class Free status for a period of time during the past 7 years. The source of disease in these three States is attributable to exposure to brucellosis-affected wildlife in the Greater Yellowstone Area.

The brucellosis Class Free classification is based on a finding of no known brucellosis in cattle for the 12 months preceding classification as Class Free. In order to maintain Class Free classification, the regulations have required Class Free States or areas to conduct surveillance by carrying out as many brucellosis ring tests per year as are necessary to ensure that all cattle herds producing milk for sale are tested at least twice per year at approximately 6-month intervals. In addition, the regulations have required Class Free States or areas to collect blood samples from at least 95 percent of all cows and bulls 2 years of age or over at each recognized slaughtering establishment and subject the samples to an official brucellosis test. The regulations have further provided that a Class Free State or area may have no more than one herd determined to be affected with brucellosis within a 2-year period, and if a herd is found to be affected with brucellosis, the herd must be depopulated within 60 days of an infected animal being detected. If two or more herds are found to be affected with brucellosis within a 2-year period or if an affected herd is not depopulated within 60 days, the State or area loses its Class Free status. The regulations have provided no exceptions to these requirements for reclassification.

These requirements have encouraged producers to depopulate brucellosis-affected herds to prevent a reclassification of State status. Cattle and bison from States or areas reclassified to a lower status--usually Class A--are subject to testing requirements for interstate movement. Furthermore, the regulations in 9 CFR

[[Page 81091]]

part 51 authorize APHIS to pay indemnity to owners of animals destroyed because of brucellosis. These payments provide a financial incentive for owners to elect depopulation instead of maintaining a herd under quarantine.

APHIS has reevaluated this approach and no longer uniformly recommends whole herd depopulation for disease management. The number of brucellosis-infected animals found in a herd is often small and test and removal of the infected animals will often mitigate transmission of brucellosis within and from the herd. In such circumstances, it is difficult to justify depopulation. Limited indemnity funds also make herd depopulation a less viable option, especially as herd sizes continue to increase. In addition, the public perceives whole-herd depopulation as a less acceptable approach for disease management. Changing social values concerning the care and well-being of livestock, the recognition of the environmental consequences of animal disposal, and the value of proteins derived from livestock also drive the need to develop new approaches to disease control.

APHIS has announced its intention to take a new approach to managing the bovine brucellosis eradication program that will allow APHIS and States to apply limited resources effectively and efficiently and focus on current program disease-risk issues. The new approach for the program, which includes strategies for surveillance and depopulation and would involve revisions to the brucellosis regulations, is described in the brucellosis concept paper that was made available for public comment on October 5, 2009. (See ``A Concept

Paper for a New Direction for the Bovine Brucellosis Program,'' 74 FR 51115-51116; Docket No. APHIS-2009-0006). In the meantime, the requirements for maintaining Class Free status give APHIS little flexibility in reclassifying States or areas based on risk. This lack of flexibility is an obstacle to effectively addressing the current challenges of the brucellosis program. When a Class Free State is reclassified to a lower status, APHIS and the State expend scarce resources to enable the State to regain its status or to establish split-State status. These resources could be applied more effectively to program activities that would have a greater impact on disease management and elimination. Additionally, many producers in Class Free States that are reclassified incur additional costs to meet testing and other interstate movement requirements associated with the reclassification, regardless of the risk associated with their particular herd.

As we proceed to develop this new approach, APHIS intends to continue making decisions regarding the disposition of each brucellosis-affected herd after evaluating the circumstances surrounding each herd. APHIS will continue to offer indemnity (depending on the availability of funding) to compensate producers considering depopulation when the evaluation indicates that other options will not mitigate disease spread, there is an imminent public or animal health risk, and/or it is cost-beneficial to do so. Where depopulation and indemnity are not considered appropriate, APHIS will continue to rely on State animal health agencies to maintain affected herds under quarantine and implement a program to periodically test the animals for brucellosis and remove and destroy those that do not test negative. ``Test and remove'' strategies can be an effective alternative to depopulation provided that the State or area maintains all affected herds under quarantine and applies adequate measures within the State to detect and prevent the spread of brucellosis, including from infected wildlife. When a Class Free State or area implements all of these measures, APHIS does not believe it is necessary to reclassify the State or area to a lower status or to restrict the interstate movement of all cattle and bison from the State or area in order to prevent the interstate spread of brucellosis.

Changes to Requirements for Maintaining Class Free Status

For the reasons given above, we are removing the requirement that a Class Free State or area must lose its Class Free status if two or more herds are found to have brucellosis within 24 months or if a brucellosis-affected herd is not depopulated within 60 days. We will allow a Class Free State or area to maintain its Class Free status if:

The affected herds are maintained under quarantine;

A herd plan has been implemented for each affected herd to prevent the spread of brucellosis;

The animals under quarantine are periodically tested for brucellosis as required by the Administrator and all animals that do not test negative are removed and destroyed until there is no evidence of brucellosis within the herd; and

The State conducts surveillance adequate to detect brucellosis if it is present in other herds or species.

We are retaining the provision that an epidemiological investigation must be performed and that herds adjacent to the affected herd, herds from which animals may have been brought into the affected herd, and herds which may have had contact with or accepted animals

from affected herds, must be epidemiologically investigated to confirm that brucellosis has not spread.

The Administrator may reclassify a State or area to a lower status if these conditions are not met or under any other circumstances if the Administrator determines it is necessary to do so to prevent the spread of brucellosis.

Cattle and bison from Class Free States or areas that maintain affected herds under quarantine without loss of Class Free status would be subject to the same interstate movement requirements as cattle and bison from Class Free States or areas with 0.0 percent of field strain brucellosis, except as otherwise required by a brucellosis management plan, as discussed below.

Consistent with this change in the regulations, APHIS is allowing Idaho to use a test and remove strategy on a brucellosis-affected herd identified in November 2009 without loss of Class Free status.

Another change to the requirements for maintaining Class Free status concerns brucellosis management plans. We are requiring any Class Free State or area in which the Administrator has determined wildlife are infected with B. abortus to develop and implement a brucellosis management plan approved by the Administrator. The existence of B. abortus in wildlife will be determined by the Administrator, based on, but not limited to, histopathology, testing data, or epidemiology. The Administrator may also require a Class Free State or area to develop and implement a brucellosis management plan under any other circumstances if the Administrator determines it is necessary to prevent the spread of brucellosis. The State must sign a memorandum of understanding (MOU) with the Administrator that describes its brucellosis management plan. The brucellosis management plan must define and explain the basis for the geographic area in which a disease risk exists from B. abortus and to which the brucellosis management plan applies. The brucellosis management plan must also describe the surveillance activities that the State will conduct to identify occurrence of B. abortus in domestic livestock and wildlife and potential risks for spread of the disease. The brucellosis management plan must also describe mitigation activities to prevent the spread of B. abortus from domestic livestock and/or wildlife, as applicable. The Administrator may reclassify to a lower status any State or area that has

not implemented an approved brucellosis management plan within 6 months of being required to develop one.

For States or areas that have been Class Free for 5 or more years and do not have B. abortus in wildlife, we are also revising requirements for maintaining Class-Free status by removing the requirement for twice-yearly brucellosis ring testing of dairy cattle herds producing milk for sale and the requirement for each State to collect blood samples from at least 95 percent of all cows and bulls 2 years of age or over at each recognized slaughtering facility and subject the samples to an official brucellosis test. Instead, we will require that all recognized slaughtering establishments in such States or areas must, upon request by APHIS, agree to participate in slaughter surveillance testing as part of a new national bovine brucellosis surveillance plan being developed by APHIS. The new plan, along with the changes made in this interim rule, will allow us to reduce the level of surveillance testing in States or areas that have been Class

Free for 5 or more years and do not have B. abortus in wildlife. This will eliminate redundancies in slaughter surveillance testing and increase the efficiency of the bovine brucellosis slaughter surveillance program, allowing us to focus activities on States and areas of greater risk for spreading brucellosis (i.e., States and areas that have B. abortus in wildlife). The slaughter surveillance sampling strategy APHIS is developing as part of the new national bovine brucellosis surveillance plan provides 95 percent confidence of detecting brucellosis at a prevalence level of less than 1 infected animal per 1 million animals (0.0001 percent) in the National dairy and beef cattle populations. Information about the statistical analysis and the new national brucellosis surveillance plan is available to the public on APHIS' brucellosis Web site (http://www.aphis.usda.gov/animal_health/animal_diseases/brucellosis/).

Changes to Requirements for Herd Blood Tests

The regulations include, in some cases, requirements for blood testing of herds from which cattle and bison intended for interstate movement originate or blood testing of herds identified as adjacent, source, or contact herds in an epidemiologic investigation. In the definition for herd blood test, the regulations list cattle and bison to be included in herd blood tests. Prior to this interim rule, we required the following sexually intact cattle and bison to be included in herd blood tests:

Cattle and bison 6 months of age and older if not vaccinated;

Cattle and bison 20 months of age and older if vaccinated and a dairy breed;

Cattle and bison 24 months of age and older if vaccinated and a beef breed; and

Cattle and bison of any age if vaccinated and parturient or post-parturient.

These age requirements were established because the previously used B. abortus Strain 19 vaccine had the propensity to cause false positive test results in younger vaccinated animals. The B. abortus RB 51 vaccine that is now in use, and that has been in use for the past 13 years, does not have the propensity to cause false positive test results. Therefore, we are making a change in our definition of herd blood test to require that all sexually intact cattle and bison 6 months of age and older be included in all herd blood tests (vaccinated cattle and bison of any age that are parturient or post-parturient will continue to be included in herd blood tests). When herd blood tests are required, the inclusion of official vaccinates 6 months of age and older will ensure that brucellosis is detected in younger animals that may be infected.

Changes to Requirements for Certified Brucellosis-Free Herds

Under the current regulations, interstate movement restrictions for cattle or bison from certified brucellosis-free herds may be less restrictive than those applied to other cattle or bison moving from the State or area. The requirements for achieving certified brucellosis-free herd status are contained in the definition of certified brucellosis-free herd. For dairy herds, the regulations have provided that certification may be achieved through negative results to two herd blood tests or through negative results to a series of brucellosis ring

tests, followed by a negative herd blood test.

The brucellosis ring test is conducted on milk from dairy animals. Additional types of brucellosis tests for milk are under development and may be approved for use in the brucellosis program. To allow for use of new milk tests, if approved, we are amending the provisions for certifying dairy herds to provide for use of either the brucellosis ring test or another official brucellosis milk test approved by the Administrator.

To maintain certification, the regulations have required that dairy herds must test negative to a herd blood test conducted within a certain period of time following the initial certification. As an alternative, this rule will allow dairy herds to maintain certification through negative results to a series of four brucellosis ring tests, or through another testing protocol if the Administrator finds that the protocol is adequate to determine there is no evidence of brucellosis in the herd.

These changes will give producers more options for achieving and maintaining certified brucellosis-free status for dairy herds.

Miscellaneous Changes

As explained earlier, the regulations require Class Free States or areas to conduct certain surveillance testing in order to maintain Class Free status. Under this interim rule, States that have not been Class Free for 5 or more years or that have B. abortus in wildlife must continue to conduct the same level of surveillance testing as in the past. However, as an alternative to conducting brucellosis ring tests, this interim rule will allow use of another official brucellosis milk test if one is approved by the Administrator for use in the brucellosis program. This change is in the definition of Class Free State or area, paragraph (a)(1)(ii)(A).

We are also making several other minor changes to the regulations. We are correcting an oversight in paragraph (d) under the definition for approved intermediate handling facility by extending the period of time from 1 year to 2 years for retaining documents related to cattle and bison that are or have been in the facility. We are making this change to be consistent with current record-keeping practices required under Sec. 71.20 of the regulations, which contains provisions for stockyards, livestock facilities, buying stations, concentration points, or ``any other premises under State or Federal veterinary supervision where livestock are assembled'' to acquire and retain status as approved facilities. One of the requirements for qualifying as an approved facility, including an approved intermediate handling facility, is the retention, for a period of 2 years, of all documents such as weight tickets, sales slips, and records of origin, identification, and destination that relate to livestock that are in, or that have been in, the facility. When the 2-year record requirement was established in Sec. 71.20 on October 31, 1996 (61 FR 56155-56165, Docket No. 96-041-1), we neglected to make the corresponding change in the definition of approved intermediate handling facilities. We are correcting that oversight now.

[[Page 81093]]

In addition, in paragraph (c)(1) under the definition for certificate, we are correcting a typographical error by replacing the word ``stabled'' with the word ``stapled.''

Finally, we are reorganizing the requirements under the definitions for Certified brucellosis-free herd and Class Free State or area to make them clearer to read.

Immediate Action

Immediate action is warranted to remove requirements that present an obstacle to effectively managing the brucellosis program. Changes to the requirements for maintaining Class Free status, in particular, are necessary so that APHIS and States can use available resources on program activities that will have the greatest impact on disease management and disease risk mitigation. The changes in age requirements for sexually intact vaccinates to be included in herd blood testing are necessary to ensure that brucellosis is detected in younger animals that may be infected. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this action effective less than 30 days after publication in the Federal Register.

We will consider comments we receive during the comment period for this interim rule (see DATES above). After the comment period closes, we will publish another document in the Federal Register. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

This interim rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis identifies beef cattle and dairy operations as the small entities most likely to be affected by this action and considers the effects of the rule on the beef and dairy industry. Based on the information presented in the analysis, the Administrator has certified that this action will not have a significant economic impact on a substantial number of small entities. The full economic analysis may be viewed on the Regulations.gov Web site (see ADDRESSES for instructions for accessing Regulations.gov). Copies of the economic analysis are also available from the person listed under FOR FURTHER INFORMATION CONTACT.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Has no retroactive effect; and (2) does not require administrative proceedings before parties may file suit in court challenging this rule.

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 interim 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-2009-0083. Please send a copy of your comments to: (1) Docket No. APHIS-2009-0083, 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, Rroom 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 60 days of publication of this interim rule.

The APHIS bovine brucellosis program regulations in 9 CFR part 78 provide a system for classifying States or portions of States according to the rate of Brucella abortus infection present and the general effectiveness of a brucellosis control and eradication program. The program also provides for the creation of brucellosis management areas within a State and for testing and movement mitigation activities before regulated animals are permitted to move interstate. This system enhances the ability of States to move healthy, brucellosis-free cattle and bison interstate and internationally. This management area and testing system also enhances the effectiveness of the Bovine Brucellosis Eradication Program by decreasing the likelihood that infected animals will be moved interstate or internationally.

The creation of brucellosis management areas allow States that have found B. abortus in wildlife (which are nonregulated animals) to mitigate the risk of transmission and spread of disease while maintaining the State's disease-free status in regulated domestic livestock. The State must sign a memorandum of understanding (MOU) with the Administrator that describes its brucellosis management plan. The brucellosis management plan developed by the State must define the geographic brucellosis management area and describe the surveillance and mitigation activities that the State will conduct to identify occurrence of B. abortus in domestic livestock and wildlife and potential risks for spread of the disease.

The information provided by these documents is critical to APHIS' mission to prevent the introduction or spread of bovine brucellosis. APHIS is asking the Office of Management and Budget (OMB) to approve the use of these information-gathering activities for 3 years in connection with APHIS' bovine brucellosis program.

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

(1) Evaluate whether the 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 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 300 hours per response.

Respondents: State animal health and wildlife officials.

Estimated annual number of respondents: 3.

Estimated annual number of responses per respondent: 2.

Estimated annual number of responses: 6

[[Page 81094]]

Estimated total annual burden on respondents: 1,800 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 Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government 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 interim rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

List of Subjects in 9 CFR Part 78

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

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Accordingly, we are amending 9 CFR part 78 as follows:

PART 78--BRUCELLOSIS

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1. 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.

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2. Section 78.1 is amended as follows:
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a. In the definition of Approved intermediate handling facility, by revising paragraph (d) to read as set forth below.
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b. In the definition of Certificate, by revising paragraph (c)(1) to read as set forth below.
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c. By revising the definitions of Certified brucellosis-free herd, Class Free State or area, and Herd blood test to read as set forth below.

Sec. 78.1 Definitions.

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Approved intermediate handling facility.

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(d) Any document relating to cattle or bison which are or have been in the facility shall be maintained by the facility for a period of 2 years;

* * * * *

Certificate.

* * * * *

(c) * * *

(1) A legible copy of the official brand inspection certificate must be stapled to the original and each copy of the certificate;

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Certified brucellosis-free herd. A herd of cattle or bison which has qualified for and whose owner has been issued a certified brucellosis-free herd certificate signed by the appropriate State animal health official and the Veterinarian in Charge.

(a) Certification. The following methods may be used to qualify a herd:

(1) By conducting at least two consecutive negative herd blood tests not less than 10 months nor more than 14 months apart; or

(2) As an alternative for dairy cattle, by conducting a minimum of four consecutive negative brucellosis ring tests, or other official brucellosis milk test approved by the Administrator, at not less than 90-day intervals, followed by a negative herd blood test within 90 days after the last negative brucellosis ring test or other official brucellosis milk test approved by the Administrator.

(b) Maintaining certification. Certified brucellosis-free herd status will remain in effect for 1 year beginning with the date of issuance of the certified brucellosis-free herd certificate. The following methods may be used to maintain herd certification:

(1) A negative herd blood test must be conducted within 10 to 12 months of the last certification date for continuous status. Lapsed certification may be reinstated if a herd blood test is conducted within 14 months of the last certification date. A new recertification test date may be established if requested by the owner and if the herd is negative to a herd blood test on that date, provided that date is within 1 year of the previous certification date.

(2) As an alternative for dairy cattle, a minimum of four consecutive negative brucellosis ring tests, or other official brucellosis milk test approved by the Administrator, must be conducted at approximately 90-day intervals, with the fourth test conducted within 60 days before the 1-year anniversary of the previous certification date.

(3) The Administrator may allow another testing protocol to be used if the Administrator determines that such a protocol is adequate to determine there is no evidence of brucellosis in the herd.

(c) Loss of certification. A herd which loses certified brucellosis-free herd status because a brucellosis reactor is found in the herd may be recertified only by repeating the certification process, except that certified brucellosis-free herd status may be reinstated without repeating the certification process if epidemiological studies and bacteriological cultures conducted by an

APHIS representative or State representative show that the herd was not affected with Brucella abortus.

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Class Free State or area. A State or area which meets standards for classification as a Class Free State or area and is certified as such on initial classification or on reclassification by the State animal health official, the Veterinarian in Charge, and the Administrator. For initial classification or reclassification, all cattle herds in the State or area must have remained free of Brucella abortus for 12 consecutive months, based on surveillance and epidemiologic investigations as required for Class A States or areas, and the State or area must have a cattle herd infection rate, based on the number of herds found to have brucellosis reactors within the State or area during any 12 consecutive months due to Brucella abortus, of 0.0 percent or 0 herds per 1,000. Any reclassification will be made in accordance with Sec. 78.40 of this part. All cattle herds in the State or area in which brucellosis has been known to exist must be released from any State or Federal brucellosis quarantine prior to classification. In addition, if any herds of other species of domestic livestock have been found to be affected with brucellosis, they must be subjected to an official test and found negative, slaughtered, or quarantined so that no foci of brucellosis in any species of domestic livestock are left uncontrolled. The following are the standards to maintain Class Free status.

(a) Surveillance. (1) Testing requirements. (i) States or areas that have been Class Free for 5 consecutive years or longer and that do not have B. abortus in wildlife. All recognized slaughtering establishments in the State or area, upon request by APHIS, must agree to participate in market cattle identification (MCI) testing as part of the national brucellosis surveillance plan.

(ii) States or areas that have not been Class Free for 5 consecutive years or longer or that have B. abortus in wildlife. The State or area must carry out testing as provided in paragraphs (a)(1)(ii)(A) and (a)(1)(ii)(B) of this definition:

(A) Brucellosis ring test. The State or area shall conduct as many brucellosis ring tests per year as are necessary to ensure that all herds producing milk for sale are tested at least twice per year at approximately 6-month intervals. Another official brucellosis milk test

may be used as approved by the Administrator.

(B) Market Cattle Identification (MCI) program. All recognized slaughtering establishments in the State or area must participate in the MCI program. Blood samples shall be collected from at least 95 percent of all cows and bulls 2 years of age or over at each recognized slaughtering establishment and subjected to an official test.

(2) Brucellosis reactors. All Class Free States or areas must comply with the following requirements upon detection of a brucellosis reactor:

(i) Tracebacks. The State or area must trace at least 90 percent of all brucellosis reactors found in the course of MCI testing to the farm of origin.

(ii) Successfully closed cases. The State or area must successfully close at least 95 percent of the MCI reactor cases traced to the farm of origin during the 12-consecutive-month period immediately prior to the most recent anniversary of the date the State or area was

classified Class Free. To successfully close an MCI reactor case, State representatives or APHIS representatives must conduct an epidemiologic investigation at the farm of origin within 15 days after notification by the cooperative State-Federal laboratory that brucellosis reactors were found on the MCI test. Herd blood tests must be conducted or the herd must be confined to the premises under quarantine within 30 days after notification that brucellosis reactors were found on the MCI test, unless a designated epidemiologist determines that:

(A) The brucellosis reactor is located in a herd in a different State than the State where the MCI blood sample was collected. In such cases a State representative or APHIS representative must give written notice of the MCI test results to the State animal health official in the State where the brucellosis reactor is located; or

(B) Evidence indicates that the brucellosis reactor is from a herd that no longer presents a risk of spreading brucellosis, or is from a herd that is unlikely to be infected with brucellosis. Such evidence could include, but is not limited to, situations where:

(1) The brucellosis reactor is traced back to a herd that has been sold for slaughter in entirety;

(2) The brucellosis reactor is traced back to a herd that is certified brucellosis free and is 100-percent vaccinated; or

(3) The brucellosis reactor showed a low titer in the MCI test and is traced back to a dairy herd that is 100 percent vaccinated and has tested negative to the most recent brucellosis ring test required by this section for herds producing milk for sale.

(iii) Epidemiologic surveillance. (A) Adjacent herds. All adjacent herds or other herds having contact with cattle in a herd known to be affected shall be placed under quarantine and have an approved individual herd plan in effect within 15 days after notification of brucellosis in the herd known to be affected;

(B) Epidemiologically traced herds. All herds from which cattle are moved into a herd known to be affected and all herds which have received cattle from a herd known to be affected shall be placed under quarantine and have an approved individual herd plan in effect within 15 days of locating the source herd or recipient herd. Each State shall ensure that such approved individual herd plans are effectively complied with, as determined by the Administrator.

(b) Herd infection rate. (1) Affected herds. Except as provided in paragraph (b)(4) of this definition, all cattle herds in the State or area must remain free of Brucella abortus.

(2) Epidemiologic investigation. Within 15 days after notification by the cooperative State-Federal laboratory that brucellosis reactors have been found in any herd, State representatives or APHIS representatives shall investigate that herd to identify possible sources of brucellosis. All possible sources of brucellosis identified shall be contacted within an additional 15 days to determine appropriate action.

(3) Approved herd plans. All herds known to be affected shall have approved individual herd plans in effect within 15 days after notification by a State representative or APHIS representative of a brucellosis reactor in the herd. Each State shall ensure that such approved individual herd plans are effectively complied with, as determined by the Administrator.

(4) Affected herd. If any herd in a Class Free State or area is found to be affected with brucellosis, the State or area may retain its Class Free status if it meets the conditions of this paragraph; provided that the Administrator may reclassify a State or area to a

lower status upon finding that continued detection of brucellosis presents a risk that the disease will spread.

(i) The affected herd. (A) The affected herd must be quarantined immediately, and, within 60 days, tested for brucellosis and depopulated; or

(B) The affected herd must be quarantined immediately and tested for brucellosis as required by the Administrator until there is no evidence of brucellosis in the herd; and

(ii) Other herds. An epidemiological investigation must be performed within 60 days of the detection of an infected animal in a herd. All herds on premises adjacent to the affected herd (adjacent herds), all herds from which animals may have been brought into the affected herd (source herds), and all herds that may have had contact with or accepted animals from the affected herd (contact herds) must be epidemiologically investigated, and each of those herds must be placed under an approved individual herd plan. If the investigating epidemiologist determines that a herd blood test for a particular adjacent herd, source herd, or contact herd is not warranted, the epidemiologist must include that determination, and the reasons supporting it, in the individual herd plan.

(iii) APHIS review. After the close of the 60-day period following the date an animal in the herd is determined to be infected, APHIS will conduct a review to confirm that the requirements of paragraphs (b)(4)(i) and (b)(4)(ii) of this definition have been satisfied and that the State or area is in compliance with all other applicable provisions.

(c) Brucellosis management plans. (1) Any State in which the Administrator has determined wildlife are infected with B. abortus must develop and implement a brucellosis management plan approved by the Administrator. The existence of B. abortus in wildlife will be determined by the Administrator, based on, but not limited to, histopathology, testing data, or epidemiology. The Administrator may also require a Class Free State or area to develop and implement a brucellosis management plan under any other circumstances if the Administrator determines it is necessary to prevent the spread of brucellosis. The State must sign a memorandum of understanding (MOU) with the Administrator that describes its brucellosis management plan. The MOU must be updated annually. The Administrator may reclassify to a lower status any State or area that has not implemented an approved brucellosis management plan within 6 months of being required to develop one.

(2) The brucellosis management plan reflected in the MOU must:

(i) Define and explain the basis for the geographic area in which a disease risk exists from B. abortus and to which the brucellosis management plan activities apply;

(ii) Describe epidemiologic assessment and surveillance activities to identify occurrence of B. abortus in

domestic livestock and wildlife and potential risks for spread of disease; and

(iii) Describe mitigation activities to prevent the spread of B. abortus from domestic livestock and/or wildlife, as applicable, within or from the brucellosis management area.

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Herd blood test. A blood test for brucellosis conducted in a herd

on all cattle or bison 6 months of age or over, except steers and spayed heifers.

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Done in Washington, DC, this 17th day of December 2010.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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