



This document is scheduled to be published in the Federal Register on 11/10/2014 and available online at <http://federalregister.gov/a/2014-26580>, and on FDsys.gov

BILLING CODE: 3410-34-P

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: Final rule.

SUMMARY: We are adopting as a final rule, with changes, an interim rule that amended the brucellosis regulations to, among other things, 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. This document amends the interim rule to change the age at which cattle and domestic bison are included in herd blood tests from 6 months to 18 months of age for all sexually intact cattle and domestic bison, except when conducting herd blood tests as part of affected herd investigations or other epidemiological investigations. In addition, the rule allows certain States the option of either conducting brucellosis ring tests and participating in the slaughter surveillance program or developing an alternative surveillance plan that would have to meet or exceed the level of disease detection provided by combined brucellosis ring testing and slaughter surveillance testing. The rule also makes several minor changes in order to clarify the regulations. These changes are necessary to create flexibility in the brucellosis program, to

refocus resources to control and prevent the spread of brucellosis, and to protect and maintain the economic viability of the domestic livestock industry.

EFFECTIVE DATE: [Insert date 30 days after date of publication in the Federal Register].

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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.

Previously, the brucellosis Class Free classification had been 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 that were in place required Class Free States or areas to conduct surveillance by carrying out as many brucellosis ring tests per year as were necessary to ensure that all cattle herds producing milk for sale were tested at least twice per year at approximately 6-month intervals. In addition, the regulations had 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 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 was found to be affected with brucellosis, the herd was required to be depopulated within 60 days of an infected animal being detected. If two or more herds were found to be affected with brucellosis within a 2-year period or if an affected herd was not depopulated within 60 days, the State or area lost its Class Free status. The regulations provided no exceptions to these requirements for reclassification.

In an interim rule¹ effective and published in the Federal Register (75 FR 81090-81096, Docket No. APHIS-2009-0083) on December 27, 2010, we amended the 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 B. abortus in wildlife. The interim rule also removed 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, the interim rule reduced the age at which most

¹ To view the interim rule and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0083>.

cattle are included in herd blood tests and also added a requirement that any Class Free State or area with B. abortus in wildlife develop and implement a brucellosis management plan (BMP) approved by the Administrator in order to maintain Class Free status. Finally, the interim rule provided an alternative testing protocol for maintaining the certified brucellosis-free status of dairy herds, to give dairy producers more flexibility for the herd certification process. These changes were 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.

We solicited comments concerning the interim rule for 60 days ending February 25, 2011. We extended the deadline for comments until March 11, 2011, in a document published in the Federal Register on February 4, 2011 (76 FR 6322-6323). We received 30 comments by that date. They were from private citizens, State agencies, industry groups, animal welfare organizations, environmental groups, and members of Congress. The commenters raised a number of issues, which are discussed below by topic.

Depopulation and Indemnity

As stated in the interim rule, the Animal and Plant Health Inspection Service (APHIS) no longer uniformly recommends whole herd depopulation for disease management for various reasons, including the fact that the number of brucellosis-infected animals found in a herd is often small. When depopulation and indemnity are not considered appropriate, affected herds may be maintained under quarantine and periodically tested. Those animals that do not test negative for brucellosis will be removed and destroyed.

Many of the commenters stated that, in some cases, depopulation may be the most cost-effective option for reducing the spread of brucellosis, for example when herd quarantine conditions prevent access to public grazing sites. Therefore, they stated that depopulation should

remain an option and that APHIS should pay indemnity at fair market value for depopulating herds in such situations.

Depopulation with indemnity remains an option for mitigating the risk of spread of brucellosis. However, there is little fiscal or scientific justification to depopulate, for example, a herd in an area where brucellosis is endemic in wildlife and wildlife is considered the most likely source of infection. Whole-herd depopulation under such circumstances does little to eliminate the source of infection. The decision to depopulate will be made on a case-by-case basis as a joint decision between State animal health officials and APHIS and will be based on the specific herd situation, epidemiologic factors, herd owner considerations, the ability to devise and execute an acceptable affected herd plan, and the availability of indemnity funds.

We are continuing to work toward a new direction for both the bovine brucellosis and bovine tuberculosis programs and are developing a rule to revise the regulations regarding both programs.

Two commenters asked that, in the event that herds are quarantined, APHIS consider ways to help livestock producers remain economically viable if their herds are unable to access public grazing land for long periods of time. The commenters suggested providing alternate food sources or providing other land that could be used for grazing.

While APHIS does not have jurisdiction over land use, we continue to work with other State and Federal agencies to explore ways to assist livestock producers in complying with the regulations and will consider the specific herd situation when determining the best course of action upon discovering brucellosis in a herd.

In the interim rule, we stated as part of our reasoning for reevaluating our universal recommendation for whole herd depopulation that, in addition to changing social values, the

“recognition of the environmental consequences of animal disposal and the value of proteins derived from livestock” impel us to consider new approaches to disease control. One commenter asked APHIS to clarify these statements, stating that they are misleading given that brucellosis reactors and depopulated animals enter the food chain.

We recognize that, upon depopulation, test-negative, brucellosis-exposed animals may go through normal slaughter channels and enter the food chain. For animals exposed to brucellosis, as opposed to other diseases such as bovine tuberculosis, this has been and remains an acceptable disposal option. However, we continue to believe that it is difficult to justify the depopulation of an entire herd of valuable breeding or dairy cattle when only a few animals in the herd may be brucellosis reactors. A viable alternative to whole herd depopulation is a risk-based affected-herd management plan that includes test-and-removal protocols and mitigation strategies to prevent intraherd transmission of disease.

Reclassification

As stated in the interim rule, when a Class Free 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, 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. Therefore, we removed 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.

Two commenters expressed concerns regarding the removal of the requirement that a Class Free State or area may have no more than one affected herd in a 2-year period in order to

maintain its status. Several commenters asked for specifics of when a State would be reclassified from Class Free to a lower status. One commenter said it was not appropriate to designate a State or area as Class Free if a number of herds within the State or area are being held under quarantine and suggested a new designation for such States or areas. One commenter stated that APHIS should adopt a process similar to that already in place for the bovine tuberculosis program for determining when to release herds from quarantine.

Reclassification from Class Free to a lower status will occur on a case-by-case basis when we determine that additional restrictions on the movement of all cattle from a State are necessary to prevent the interstate spread of B. abortus. However, in general, we intend to use a science-based, designated surveillance area approach that addresses disease risk more effectively than the geopolitical, State-based approach we had previously used. This change also reflects the World Organization for Animal Health (OIE) concept of regionalization by designating disease management areas to facilitate disease risk mitigation, allow flexibility in modifying boundaries, and provide confidence in the United States' disease-free designation. In addition, it enables APHIS to focus resources on geographic areas where B. abortus actually exists, while minimizing the economic impact on producers. New designations for State status based on risk and risk mitigation is one of the components under discussion in the development of the comprehensive bovine brucellosis and tuberculosis rulemaking.

A process similar to the process in place for releasing herds from quarantine for tuberculosis is already in place for releasing herds from quarantine for brucellosis in paragraph (b)(4)(i) under the definition for Class Free State or area.

Slaughter Surveillance

In the interim rule, we removed 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 amended the regulations to require all recognized slaughtering establishments in States or areas that have been Class Free for 5 or more years and have no B. abortus in wildlife, upon request by APHIS, to agree to participate in slaughter surveillance testing as part of a new national bovine brucellosis surveillance plan being developed by APHIS.

Several commenters asked how adequate slaughter surveillance would be achieved given that the majority of cattle from States that have B. abortus in wildlife or that have been Class Free for less than 5 years move interstate for slaughter to facilities in States that have been Class Free for 5 years or more and that do not have B. abortus in wildlife. The commenters expressed concern that there would be a disincentive to accept cattle from States that have brucellosis in wildlife or that have been Class Free for less than 5 years.

We recognize that the majority of cattle from States that have B. abortus in wildlife go to slaughter in States that have been Class Free for 5 years or more and that do not have B. abortus in wildlife. However, the revised slaughter surveillance sampling strategy will not impact the adequacy of surveillance since all recognized slaughter establishments, regardless of duration of Class Free status or presence of B. abortus in wildlife, must agree to participate in surveillance testing upon request by APHIS as part of the national brucellosis surveillance plan. Slaughter establishments that will be receiving cattle from States or areas that have B. abortus in wildlife or that have been Class Free for less than 5 years were chosen to participate in the testing because they already accept such cattle, and it is important to continue surveillance in these higher-risk

populations. As there is no difference in the collection of samples at slaughter from cattle from States that have been Class Free for 5 years or more and that do not have B. abortus in wildlife and samples taken from cattle from other States, or the proportion of cattle from which samples are taken, there will not be a disincentive for slaughter plants to accept certain cattle.

One commenter stated that a standardized testing protocol should allow for the use of additional brucellosis tests when deemed necessary.

The standardized testing protocol being implemented as part of the new national bovine brucellosis surveillance strategy is specifically for the initial testing of all bovine brucellosis slaughter surveillance samples. Any samples that test other than negative for bovine brucellosis will be appropriately classified and subjected to additional testing and epidemiological investigation at the discretion of a designated brucellosis epidemiologist. This would include the use of other official brucellosis serology tests.

One commenter expressed concern regarding the removal through the interim rule of the requirement for twice-yearly brucellosis ring testing of dairy cattle herds producing milk for sale in States that have been Class Free for 5 or more years and do not have brucellosis in wildlife.

In 2006, the National Surveillance Unit (NSU) of Veterinary Services' (VS) Centers for Epidemiology and Animal Health (CEAH) evaluated the brucellosis program surveillance activities and identified redundancies and imbalances in surveillance testing. In 2007, NSU provided recommendations based on this evaluation to a Federal-State Working Group on National Brucellosis Surveillance Planning. The NSU evaluation determined that first point testing and brucellosis ring testing were redundant when combined with slaughter surveillance because, often, market and dairy cattle are tested repeatedly, providing no greater value over the original negative test. This finding led to our decision to remove the requirement for twice-

yearly brucellosis ring testing of dairy cattle herds producing milk for sale in States that have been Class Free for 5 or more years and do not have brucellosis in wildlife. A document titled “National Brucellosis Surveillance Strategy,” available at http://www.aphis.usda.gov/animal_health/animal_diseases/brucellosis/downloads/natl_bruc_surv_strategy.pdf, describes the new national brucellosis surveillance strategy, its goals and objectives, and the basis and rationale for the surveillance activities used.

One commenter expressed the hope that APHIS will publish the draft of the new national bovine brucellosis surveillance plan and solicit public comment, stating that APHIS is likely legally obligated to do so under the Administrative Procedure Act.

In the “Concept Paper for a New Direction for the Bovine Brucellosis Program,” which we made available for public comment in a notice published in the Federal Register on October 5, 2009 (74 FR 51115-51116, Docket No. APHIS-2009-0006), we announced our intention to develop a national surveillance strategy for brucellosis, which would involve revisions to the brucellosis regulations. Any further revisions to the brucellosis regulations will also be made available for public comment.

Approved backtags provide unique identification for individual animals. One commenter asked how the reduced slaughter surveillance sampling will affect the brucellosis back-tagging program.

Use of U.S. Department of Agriculture (USDA) approved backtags will continue to be a viable option for identifying cattle moving to slaughter. The use of USDA approved backtags is independent of the brucellosis program; therefore, the decrease in bovine brucellosis slaughter surveillance detailed in the interim rule will not affect the option of using backtags to identify cattle moving to slaughter.

Brucellosis Management Plans and Memorandum of Understanding

One commenter asked for specifics of the memorandum of understanding (MOU) required in the interim rule and stated that Federal wildlife agencies must also work toward controlling brucellosis, since most infected wildlife occurs on Federal lands, and State wildlife agencies do not have the resources to control brucellosis on their own.

The MOU is an agreement signed by the State and APHIS indicating that the State will develop a BMP. As stated in the interim rule, it is the BMP that must define and explain the basis for the geographic area in which the disease risk exists and to which the BMP activities apply; 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 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. We would expect that States' animal health and wildlife agencies would work cooperatively with their Federal agency counterparts in the development of BMPs.

One commenter asked if the Department of the Interior's National Park Service would be included in the MOU, given that a number of brucellosis-infected elk and bison reside within the Yellowstone and Grand Teton National Parks.

The MOU and accompanying BMP are an agreement between APHIS and the State. APHIS does not have jurisdiction or authority over national park lands. Therefore, we cannot require that the National Park Service sign the MOU. As noted, we would expect that States' animal health and wildlife agencies would work cooperatively with their Federal agency counterparts, such as the National Park Service, in the development of BMPs.

Several commenters expressed concern about who holds legal authority over wildlife. One commenter stated that APHIS does not have legal authority over wildlife and that, therefore, requiring BMPs to be approved by the Administrator is illegal and usurps the authority of individual States. One commenter stated that, in most cases, State agriculture or animal health officials do not have authority over wildlife; therefore, the commenter asked whether it would be acceptable if the Commissioner of Agriculture of the State submits the MOU.

APHIS has the authority to require livestock moving in interstate commerce to be safeguarded from exposure to B. abortus in wildlife if such requirements are necessary to prevent the spread of B. abortus. In addition, APHIS is authorized under the Animal Health Protection Act (AHPA, 7 U.S.C. 8301 et seq.) to cooperate and enter into contracts, cooperative agreements, MOUs, or other agreements with other Federal agencies, States or political subdivisions of States, national or local governments of foreign countries, domestic or international organizations or associations, Indian tribes and other persons in order to promulgate regulations and issue orders as deemed necessary to protect animal health, the health and welfare of the people of the United States, the economic interests of livestock and related industries of the United States, the environmental health of the United States, and interstate commerce and foreign commerce of the United States in animals and other related articles. As stated in the interim rule, the State must sign an MOU with the APHIS Administrator that describes its BMP. The term “State” refers to all State agencies with the appropriate authority over management plan activities. In certain States this may mean that multiple signatures may be needed on the MOU. States will determine, based on their individual State government structures, the appropriate authority to submit the MOU.

One commenter asked what would be acceptable as a BMP and how the Administrator would determine whether a BMP was implemented appropriately. One commenter asked what the appeals process would be if APHIS does not approve a State's BMP.

As stated previously, the BMP must define and explain the basis for the geographic area in which the disease risk exists and to which the BMP activities apply; 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 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. We anticipate that APHIS, State wildlife agencies, and Federal wildlife agencies would work cooperatively to develop and implement the State's BMP. Once submitted, APHIS would review the BMP along with the State and would discuss and resolve any concerns together prior to approval. The MOU for the BMP would then be signed by the Administrator. States would have to submit annual reports that would reflect implementation of the activities described in the BMP. States are provided the opportunity to respond to and provide additional information if necessary to address any deficiencies or concerns noted in APHIS' review of the annual report.

Several commenters stated that the wildlife agencies of Wyoming, Idaho, and Montana already have established brucellosis management protocols. One commenter stated that these should only be revised if appropriate. A second commenter stated that if APHIS wants revisions to Wyoming's plan, then APHIS needs to offset the costs associated with the revisions. One commenter detailed Wyoming's surveillance program for wildlife and asked whether APHIS believes it meets the definition of "adequate surveillance" as mentioned in the interim rule.

We recognize that these three States in the Greater Yellowstone Area (GYA) have already developed brucellosis management protocols. In fact, the protocols served as the basis for the development of the BMPs required under paragraph (c) under the definition for Class Free State or area for all three GYA States, which have been approved and are now in place. APHIS understands and shares the concerns regarding the development and funding of cooperative agreements to support brucellosis activities, including BMP activities, in the GYA States. We are committed to continuing to explore all possible funding options for GYA brucellosis efforts and to frequently communicating with the State animal health officials regarding available resources.

Resources and Funding

Many commenters asked for specifics regarding the availability and allocation of resources, including personnel and Federal funding, for implementing surveillance and BMP activities mentioned in the interim rule.

We are committed to providing all available Federal funding, continuing to explore all possible funding options, and frequently communicating with State animal health officials regarding available resources. We continue to work with States to effectively and efficiently apply these limited resources.

Testing Age

Prior to the 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. However, because 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, the interim rule amended 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). This change was intended to ensure that brucellosis is detected in younger animals that may be infected.

Many commenters expressed concern regarding the reduction in testing age to 6 months because they felt that the testing would not be practical or necessary, or would present a financial burden to producers. Two commenters asked for clarification of whether this reduction in testing age to 6 months pertains only to cattle tested during an epidemiological investigation or whether it also applies to cattle tested prior to interstate movement. One commenter suggested that if the reduction in testing age to 6 months was onerous to producers, the testing age should be reduced to 12 months.

Based on the commenters' concerns, we have reevaluated the change. In this final rule, we are changing the age of cattle and bison to be included when conducting herd blood tests in order to harmonize it with the age of testing for test-eligible cattle and bison for interstate movement that are not official vaccinates or that are official calfhod vaccinates which are parturient or postparturient. Currently, test-eligible cattle and bison are defined in § 78.1 as:

- Cattle and bison which are not official vaccinates and which have lost their first pair of temporary incisors (18 months of age or over), except steers and spayed heifers;
- Official calfhood vaccinates 18 months of age or over which are parturient or postparturient;
- Official calfhood vaccinates of beef breeds or bison with the first pair of permanent incisors fully erupted (2 years of age or over); and
- Official calfhood vaccinates of dairy breeds with partial eruption of the first pair of permanent incisors (20 months of age or over).

Harmonizing these ages so that whole herd blood testing includes cattle 18 months of age or over is desirable because it provides a standard testing age, thereby preventing confusion. In addition, raising the age at which cattle and bison are required to be included in whole herd blood tests would address some of the concerns raised by commenters. Testing all cattle and bison 18 months old and older targets sexually mature animals, which present the greatest risk for transmission of brucellosis. Steers and spayed heifers are exempt from testing when conducting herd blood tests. Therefore, we are changing the age of cattle and bison to be included in the herd blood tests to 18 months of age and older for all sexually intact cattle and domestic bison, except when conducting herd blood tests as part of affected herd investigations or other epidemiological investigations or when the Administrator determines testing at a younger age is necessary to prevent the spread of brucellosis.

We are also changing the age of testing for test-eligible cattle and bison for interstate movement that are official calfhood vaccinates and that are beef or dairy breeds. As previously stated, the B. abortus Strain 19 vaccine had the propensity to cause false positive test results in younger vaccinated animals. This was particularly a problem for beef and dairy breeds, which

led to the current required testing ages. As the propensity for false positive test results has been eliminated, we are now able to lower the age at which beef and dairy breeds are eligible for testing. Besides ensuring that more animals are included in brucellosis testing, this change will add further consistency to the age at which cattle and bison are tested for brucellosis, further preventing confusion.

Surveillance Activities

One commenter stated that blood testing for cattle leaving surveillance areas should be maintained, but that tattooing and random blood testing within a surveillance area is counterproductive and unnecessary given that it has yet to detect an infection that is not related to traceback from an already known infection. One commenter stated that requiring a herd test prior to interstate movement would be an undue burden on producers and that the State of Wyoming's requirement for a test within 30 days of movement is sufficient to prevent disease spread. One commenter stated that testing regimens should follow standard acceptable testing intervals such as those outlined in the Brucellosis Uniform Methods and Rules or as part of an approved herd plan for that particular herd.

We disagree with the commenter that tattooing and random blood testing within a surveillance area (the geographic area described in a State's BMP) are unnecessary and counterproductive. The recent case of brucellosis in a domestic bison herd within Montana was found due to blood testing as part of Montana's designated surveillance area herd management plan. This rulemaking does not include any changes to the current interstate movement requirements as reflected in 9 CFR part 78. This rulemaking does require a State, under certain conditions, to develop a brucellosis management plan that includes mitigation activities to prevent the spread of B. abortus from domestic livestock and/or wildlife, as applicable, within or

from the brucellosis management area. As part of the plan, the individual State may include requirements for testing prior to movement of animals. Testing animals prior to movement is intended to reduce the potential for disease transmission and to mitigate risk. We agree that standard acceptable testing intervals and testing as part of an approved herd plan are important brucellosis risk mitigations.

Wildlife

One commenter did not support test and remove strategies as a general brucellosis management tool for wildlife species. Another commenter stated that, rather than focusing on removal of infected wildlife, it makes more sense to focus financial resources and efforts on brucellosis testing of live animals moving out of, or even into, designated surveillance areas, but that testing should not only be focused on the GYA.

The test-and-remove strategy mentioned in the interim rule is intended for use in herds of domestic livestock and not on wildlife. We expect that States will develop appropriate strategies to mitigate the possible risk involved in the intrastate movement of livestock and wildlife into or out of designated surveillance areas. States that present a higher risk of the spread of brucellosis (i.e., those that have not been Class Free for 5 or more years and/or that have brucellosis in wildlife) are expected to address the risk of the spread of brucellosis between domestic livestock and wildlife in their BMP required by the regulations.

Several commenters expressed concern about the transmission of brucellosis from elk to cattle in the GYA. Three commenters stated that studies should be undertaken in collaboration with wildlife agencies to determine the cause behind the increase in frequency of brucellosis transmission from elk to cattle. Two of these commenters stated that APHIS should shut down elk feeding grounds, as they contribute to high brucellosis prevalence in elk.

We agree that more research is needed regarding the transmission of brucellosis from elk to cattle. APHIS participates in the Consortium for the Advancement of Brucellosis Science, whose mission includes identifying research priorities, securing funding, and generating requests for short- and long-term projects. This consortium is composed of wildlife agency officials, university researchers, and others, including many officials from the GYA. We believe that this consortium is an ideal forum to work collaboratively to study the transmission of brucellosis from elk to cattle within the GYA.

While we recognize the commenters' concern regarding the possibility of transmission of brucellosis from elk to domestic cattle and bison via elk feeding grounds, elk feeding grounds are under State rather than Federal jurisdiction. Therefore, APHIS does not have the authority to shut down these elk feeding grounds.

Miscellaneous

Several commenters asked that APHIS work with other agencies and organizations to develop a more effective brucellosis vaccine.

We agree with the commenters regarding the development of more effective brucellosis vaccines. As mentioned previously, APHIS participates in the Consortium for the Advancement of Brucellosis Science. We believe that this consortium is an ideal forum for brucellosis vaccine research.

One commenter stated that the reference to calfhood vaccination in the definition for Class Free State or area should be removed because those references encourage cattle owners in Class Free States to vaccinate their calves in order to limit the amount of blood testing on the herd. The commenter further stated that calfhood vaccination should only be encouraged in areas with brucellosis in wildlife.

We disagree with the commenter that the regulations encourage cattle owners in Class Free States to vaccinate calves in order to limit herd blood testing. While APHIS recommends calfhood vaccination in high risk areas, such as States or areas that have been Class Free for less than 5 years and/or that have brucellosis in wildlife, the Federal brucellosis program does not require vaccination. In addition, we are harmonizing the age of testing for herd blood tests and test-eligible cattle and bison for interstate movement to require that all sexually intact cattle and domestic bison 18 months of age and older, regardless of vaccination status, be included in herd blood testing, except in specific circumstances previously described. This change will eliminate any possible incentive for cattle owners to vaccinate their calves in order to limit herd blood testing.

One commenter stated that APHIS must provide an explanation of how we complied with the National Environmental Policy Act of 1964 (NEPA) in preparing the interim rule, whether that is making the environmental assessment available or, if categorically excluded, providing an explanation of why the rule was excluded from analysis.

As required under NEPA, agencies must consider the potential environmental effects of Federal actions, including potential effects on human health. Under APHIS' NEPA implementing procedures in 7 CFR 372.5(c)(1), certain measures are categorically excluded from the need for an environmental assessment or environmental impact statement due to their routine nature. These routine measures include monitoring, inspections, quarantines, testing and identification of animal herds for disease, and permanent identification of animals. Because the interim rule involved routine activities related to the regulation of the interstate movement of domestic cattle and bison to prevent the spread of brucellosis and presented negligible environmental impact, the interim rule was categorically excluded from NEPA review.

One commenter stated that, under the definition for Class Free State or area in paragraph (a)(2)(iii) involving epidemiological surveillance, the word “bison” should be included whenever cattle are referenced. One commenter stated that we should clarify that the testing and movement requirements in the regulations apply to domestic bison and that the terms “herd” and “bison” need to be clearly defined to refer to either domestic or wild bison, as appropriate. Another commenter stated that, except for the first reference to bison within the interim rule, all other references to bison should be changed to domestic bison.

The provisions of the AHPA apply only to livestock, and thus only to cattle and domestic bison, for purposes of interstate movement. Therefore, we do not believe it is necessary to amend the regulations to specifically refer to domestic bison. However, we agree that the word “bison,” referring to domestic bison, should be included whenever cattle are referenced. Therefore, we are amending 9 CFR part 78 to include the word “bison” where appropriate.

The definition of Class Free State or area in § 78.1, as revised by the interim rule, states that “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” in order to maintain Class Free State status. These actions are intended to ensure that no foci of brucellosis in any species of domestic livestock are left uncontrolled. Two commenters asked that we define “other herds or species.”

These other species of domestic livestock would include those species of domestic livestock, such as swine or captive cervids, that are susceptible to and pose a risk of further spread of B. abortus. We do not believe it is necessary to define other herds or species in the regulations.

Paragraph (b)(4) of the definition for Class Free State or area involves herd infection rates. One commenter stated that the words “continued detection” in that paragraph should be clarified as, according to the commenter, continued detection of brucellosis in the GYA is proof that the surveillance system is working as intended.

The words “continued detection” refer to an increasing herd infection rate within a State or area during any 12 consecutive months, which could potentially indicate the need for reclassification to a lower status. Traditionally, a State’s brucellosis class status has been predicated on a set herd infection rate. The interim rule removed the requirement for the reclassification of a State’s Class Free status to a lower status based strictly on a herd infection rate and provides flexibility in reclassifying States or areas based on risk. To clarify this intent, we are moving the provision in paragraph (b)(4) under the definition for Class Free State or area 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 to the introductory paragraph of the definition for Class Free State or area before the words “Any reclassification will be made in accordance with § 78.40 of this part.” Section 78.40 describes the process by which States may be reclassified to a lower status.

In paragraph (a)(1)(ii) of the definition of Class Free State or area, the interim rule required States or areas that have not been Class Free for 5 consecutive years or more or that have brucellosis in wildlife to carry out brucellosis ring testing or other official brucellosis milk testing approved by the Administrator, and participate in slaughter surveillance. However, some of those States or areas may be able to achieve the same level of surveillance through means other than brucellosis ring testing and slaughter surveillance, which could be more efficient for these States or areas. To account for this situation, we are adding a paragraph (a)(1)(ii)(C) under

the definition for Class Free State or area to allow States or areas that have not been Class Free for 5 consecutive years or longer or that have B. abortus in wildlife to develop an alternative surveillance plan in conjunction with the State animal health official and the area veterinarian in charge. Therefore, these States would have the option of either conducting brucellosis ring tests and participating in the slaughter surveillance program or they must develop an alternative surveillance plan that would have to meet or exceed the level of disease detection provided by combined brucellosis ring testing and collection of blood samples from at least 95 percent of test eligible slaughter cattle slaughtered within the States. The alternative surveillance plan would have to be approved by the Administrator. Making this change will create flexibility in the brucellosis program.

Therefore, for the reasons given in the interim rule and in this document, we are adopting the interim rule as a final rule, with the changes discussed in this document.

This final rule also affirms the information contained in the interim rule concerning Executive Orders 12866, 12372, and 12988.

Further, this action 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.

Regulatory Flexibility Act

This final rule follows an interim rule that amended the 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. The interim rule also removed the provision for automatic reclassification from Class Free to Class A 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. One of the changes that the interim rule made to the brucellosis regulations contained in 9 CFR part 78 was to require that all sexually intact cattle and bison 6 months of age and older be included in all herd blood tests. This final rule changes the age at which all sexually intact cattle and domestic bison are included in herd blood tests from 6 months to 18 months.

With this rule, producers will forgo payment of testing fees for sexually intact animals between 6 and 18 months of age when performing whole herd tests. For both elective and program-required herd blood tests, increasing the minimum testing age will benefit producers by (i) reducing the number of animals required to be tested and therefore the time and labor expended in gathering and handling animals for testing, and (ii) eliminating any stress-induced weight loss related to herd blood testing of sexually intact animals between 6 and 18 months of age. In recent years, about 500,000 head of cattle have been included in herd blood tests annually. Approximately 70 to 80 percent of this testing has been elective.

Based on Small Business Administration standards and data from the 2012 Census of Agriculture, the majority of beef and dairy operations are small. This rule will result in cost savings for many of these operations, and will not have a significant economic impact on a substantial number of small entities.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

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 final rule

have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, we will publish a document in the Federal Register.

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 rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

List of Subjects in 9 CFR Part 78

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

Accordingly, the interim rule amending 9 CFR part 78 that was published at 75 FR 81090-81096 on December 27, 2010, is adopted as a final rule with the following changes:

PART 78--BRUCELLOSIS

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.

2. Section 78.1 is amended as follows:

- a. In the definitions for official brand inspection certificate, official brand recording agency, and originate, by adding the words “or bison” after the word “cattle” each time it appears.

b. In the definitions for Class A State or area, Class B State or area, and Class C State or area, in paragraphs (a)(3) and (b)(1), by adding the words “or bison” after the word “cattle” each time it appears.

c. The definition for Class Free State or area is amended as follows:

i. In the introductory text, by adding a sentence before the third sentence.

ii. By revising paragraph (a)(1)(ii) introductory text.

iii. By adding a new paragraph (a)(1)(ii)(C).

iv. In paragraphs (a)(2)(iii)(A) and (a)(2)(iii)(B), by adding the words “or bison” after the word “cattle” each time it appears.

v. In paragraph (b)(1), by adding the words “and bison” after the word “cattle”.

vi. In paragraph (b)(4) introductory text, by removing the words “; 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”.

d. By revising the definition of herd blood test.

The additions and revisions read as follows:

§ 78.1 Definitions.

* * * * *

Class Free State or area. * * * 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. * * *

(a) * * *

(1) * * *

(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) or (a)(1)(ii)(C) of this definition:

* * * * *

(C) Alternative surveillance plan. As an alternative to the testing described in paragraphs (a)(1)(ii)(A) and (a)(1)(ii)(B) of this definition, the State or area may develop an alternative surveillance plan that would have to meet or exceed the level of disease detection provided by combined brucellosis ring testing and collection of blood samples from at least 95 percent of test eligible slaughter cattle slaughtered within the State. The alternative surveillance plan must be developed in conjunction with the State animal health official and the area veterinarian in charge.

* * * * *

Herd blood test. A blood test for brucellosis conducted in a herd on all cattle and bison 18 months of age, except for steers and spayed heifers, and except when conducting herd blood

tests as part of affected herd investigations or other epidemiological investigations or when the Administrator determines testing at a younger age is necessary to prevent the spread of brucellosis.

* * * * *

Done in Washington, DC, this 3rd day of November 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014-26580 Filed 11/07/2014 at 8:45 am; Publication Date: 11/10/2014]