Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 78

[Docket No. 02–070–1]

Official Brucellosis Tests

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the brucellosis regulations to add the fluorescence polarization assay to the list of official tests for determining the brucellosis disease status of test-eligible cattle, bison, and swine. We believe this proposed action is warranted because the fluorescence polarization assay has been shown to provide an efficient, accurate, automated, and cost-effective means of determining the brucellosis status of test eligible cattle, bison, and swine. Adding the fluorescence polarization assay to the list of official tests for brucellosis in cattle, bison, and swine would help to prevent the spread of brucellosis by making available an additional tool for its diagnosis in those animals.

DATES: We will consider all comments that we receive on or before June 21, 2004.

ADDRESSES: You may submit comments by any of the following methods:

- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. 02–070–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 02–070–1.
- *E-mail:* Address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 02–070–1'' on the subject line.
- *Agency Web Site:* Go to *http://www.aphis.usda.gov/ppd/rad/cominst.html* for a form you can use to submit an e-mail comment through the APHIS Web site.
- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

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: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: Dr. Arnold Gertonson, National Center for Animal Health Programs, VS, APHIS, 2150 Centre Avenue, Bldg. B, MSC 3E20, Fort Collins, CO 80526–8117; (970) 494–7363.

SUPPLEMENTARY INFORMATION:

Background

Brucellosis is a contagious disease affecting animals and humans, caused by bacteria of the genus *Brucella*. In its principal animal hosts—cattle, bison, and swine—brucellosis is characterized by abortion and impaired fertility. The regulations in 9 CFR part 78 (referred to below as the regulations) govern the interstate movement of cattle, bison, and swine in order to help prevent the spread of brucellosis.

Brucellosis has been seen as a serious threat to U.S. agriculture for decades. Prior to 1934, when the Cooperative State/Federal Brucellosis Eradication Program (the program) began work to eliminate the disease from the country, brucellosis control was limited mainly to individual herds. The program relies heavily on the cooperation of livestock producers and States; in order for States to achieve brucellosis Class Free status, none of their cattle or bison can be found infected for a minimum of 12 consecutive months under an active surveillance program. Currently, 48 States, plus Puerto Rico and the U.S. Virgin Islands, hold Class Free status. Two States have a herd infection rate of less than 0.25 percent and hold Class A status. There are no States in Class B status (herd infection rates between 0.25 percent and 1.5 percent) or in Class C (herd infection rates greater than 1.5 percent). We expect the program to achieve the goal of nationwide eradication of brucellosis from livestock in the near future.

In order to achieve this goal, surveillance must include the use of accurate and efficient official brucellosis tests. Official brucellosis tests are used to determine the brucellosis disease status of cattle, bison, and swine. The regulations provide that certain cattle, bison, and swine must, among other requirements, test negative to an official brucellosis test prior to interstate movement. Official brucellosis tests are also used to determine eligibility for indemnity payment for animals destroyed because of brucellosis. In § 78.1 of the regulations, the definition of *official test* lists those tests that have been designated as official tests for determining the brucellosis disease status of cattle, bison, and swine.

The Animal and Plant Health Inspection Service (APHIS) has determined that a rapid diagnostic detection test that uses fluorescence polarization technology will be highly useful in detecting the presence of *Brucella* antibodies, and we are proposing to add this test as an official test. The test, known as the fluorescence polarization assay (referred to below as the FP assay), provides a cost-effective, accurate, quick, and simple-to-perform (both in the laboratory and in the field) means of determining the brucellosis status of test eligible cattle, bison, and swine. In trials summarized in four scientific publications, the FP assay has proven to be faster and at least as accurate as other official tests used for diagnosis of brucellosis in cattle, bison, and swine.

Like other brucellosis tests, the purpose of the FP assay is to determine if the animal in question is infected with the *Brucella* bacterium. Brucellosis infection is confirmed by the presence of antibodies to that bacterium in serum collected from the animal. Specifically, the FP assay determines any potential

brucellosis antigen-antibody reaction by measuring changes in the polarization of fluorescent-labeled molecules. Very few molecules are fluorophores (naturally fluorescent). In order to make a non-fluorescent molecule fluorescent, a fluorophore must be attached to it; the resulting fluorescent molecule is called a ''tracer.''

To conduct the FP assay, a technician adds a sample of animal serum to a test tube. The technician then mixes the test antigen—in this case, *Brucella* bacteria—with fluorophores to create fluorescent *Brucella* antigen tracers that he or she adds to the tube containing the animal serum at a predetermined ratio so that virtually all of the tracer molecules are bound to *Brucella* antibodies, if they are present. The fluorophore tracer is easy to track in solution; its fluorescence lifetime (the time between absorbing a photon and emitting one) is on the same scale as the rotation (all molecules rotate in solution) of the molecule to which it is attached. Therefore, tracers' sizes can be continuously measured once they are added to the tube containing the serum. Since the presence of *Brucella* antibodies in the animal serum will cause *Brucella* antigen within the tracer to split from the fluorophore and attach to the antibody, tracers will decrease in size. This size decrease, therefore, indicates that the animal from which the serum sample was drawn is infected with *Brucella* bacteria, and the test results would be interpreted as positive. If the fluorophores do not decrease in size, *Brucella* antigen-antibody binding has not occurred, the test results would be interpreted as negative, and the animal from which the serum sample was drawn would be classified as such.

The FP assay has been shown to be a highly accurate assay for detection of antibodies to *Brucella abortus* in cattle and bison sera and *Brucella suis* in swine sera. A homogenous immunoassay such as the FP assay can be accomplished rapidly and does not require repetitive steps to wash away unbound reagents as other immunoassays require. The output of the test is objective because it does not require interpretation on the part of the technician running the sample. In addition, the ease and rapidity of this testing technology suggest it is highly adaptable to field application.

Research suggests that the FP performs as well as, or better than, other serologic tools commonly used to diagnose brucellosis in cattle, bison, and swine. This research demonstrates that the FP rarely mistakenly classifies uninfected animals as positive. Therefore, this test has a high degree of specificity. The research also shows that the FP rarely mistakenly classifies infected animals as negative. Therefore, this test has a high degree of sensitivity.

The FP assay has been standardized to use a consistent concentration of reagents and measurement techniques such that the test agrees between replicates of known status. The process has been commercially developed by Viral Antigens, Incorporated, and licensed by the U.S. Department of Agriculture. Furthermore, the FP technology has already been developed for numerous other applications such as detecting illicit drugs and monitoring for drugs and other macromolecules.

We are confident that the FP assay will be an accurate, cost-effective, and efficient addition to the list of official tests for determining the brucellosis status of test-eligible cattle, bison, and swine. A complete report of field testing trial and testing results for validation of the FP assay in cattle, bison, and swine is available at *http://www.aphis.usda.gov/vs/nahps/brucellosis/* or by contacting the person listed above under **FOR FURTHER INFORMATION CONTACT**.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

We are proposing to amend the brucellosis regulations to add the FP assay to the list of official tests for determining the brucellosis disease status of test-eligible cattle, bison, and swine. We believe this proposed action is warranted because the FP assay has been shown to provide an efficient, accurate, automated, and cost-effective means of determining the brucellosis status of test-eligible cattle, bison, and swine. Adding the FP assay to the list of official tests for brucellosis in cattle, bison, and swine would help to prevent the spread of brucellosis by making available an additional tool for its diagnosis in those animals.

This new test would help to prevent the spread of brucellosis by identifying infected cattle, bison, and swine. Preventing the spread of brucellosis is critical because of its potentially costly consequences for U.S. herd owners and consumers. In 1952, when brucellosis was widespread throughout the United States, annual losses from lowered milk production, aborted calves and pigs, and reduced breeding efficiency were estimated to total more than $400 million. Since then, eradication efforts have reduced annual losses due to brucellosis to less than $1 million. However, studies have shown that if eradication efforts were stopped, the cost of producing beef and milk would increase by an estimated $80 million annually in less than 10 years.

While the test would provide long-term benefits by identifying animals infected with brucellosis, herd owners with animals that are found to be positive as a result of the FP assay, or any other official test, may experience some negative consequences. Once an infected herd is identified, the infection is contained by quarantining all infected animals and limiting their movement to slaughter only, until the disease can be eliminated from the herd. Quarantines affect the current income of herd owners, and depopulation affects their future income. Depopulation costs are mitigated by the sale of affected animals and indemnity payments, but, in many cases, indemnification provides only partial compensation.

However, there is no basis to conclude that the addition of the FP assay as an official test for brucellosis will result in more positive finds in privately owned herds than another official test might indicate. Although research indicates that the FP assay can be a more accurate test, improved accuracy does not necessarily mean more positive finds; instead, the FP assay may yield fewer false positives than other tests, simply because it is more accurate.

We do not expect that adding the FP assay to the list of official tests for brucellosis would affect the market price of animals tested. Although more rapid testing may allow faster marketing, the effect on herd owners is not expected to be significant.

The Regulatory Flexibility Act requires that agencies consider the economic impact of rule changes on small businesses, organizations, and governmental jurisdictions. We expect that the entities that would be affected by the addition of the FP assay to the list of official brucellosis tests would be herd owners, test reagent and equipment producers, livestock markets, shows, and exhibitions, and livestock buyers and sellers. It is anticipated that affected entities would be positively affected because the use of this test should provide greater assurance of the brucellosis status of the animals tested.

Affected herd owners are likely to be small in size (when judged by the U.S. Small Business Administration's (SBA) standards). This determination is based on composite data for providers of the same and similar services. The latest Census data show that, in 1997, there were 742,203 farms in the United States

primarily engaged in beef cattle ranching and farming and dairy cattle and milk production. In 1997, 98 percent of those farms had sales of less than $500,000, which is well below the SBA's small entity threshold of $750,000 for farms in that category. Similarly, in 1997, there were 46,353 U.S. farms primarily engaged in raising hogs and pigs. Of those farms, 87 percent had sales that year of less than $500,000, which is well below the SBA's small entity threshold of $750,000 for farms in that category. Additionally, in 1997, there were 10,045 farms listed under North American Industry Classification System code 11299, the classification category that includes farms primarily engaged in bison farming. The per-farm average sale for those 10,045 farms in 1997 was $105,624, which is well below the SBA's small entity threshold of $750,000 for farms in that category. Accordingly, most herd owners potentially affected by this proposed rule would be small entities.

The test would be performed at Federal/State cooperative brucellosis laboratories. Depending upon the Federal/State brucellosis cooperative agreement, APHIS may supply the reagents and equipment for performing this test. If APHIS supplies the reagents and equipment, it is anticipated that the test cost to the livestock producer would be the same as for the other brucellosis test options.

Currently, the reagents are sold in two kit sizes, 1,000 tests kit ($1.00/test) and 10,000 tests kit ($0.50/test). The costs to the laboratory to perform the test would vary depending upon the number of tests performed.

An area that may affect the livestock producer may be whether or not the test is performed by a federally accredited veterinarian at a livestock market. If the market inspecting veterinarian uses the test, the cost may vary depending upon the agreement the veterinarian has with the State to perform brucellosis testing at the market.

It is anticipated that the test reagent and equipment producers would benefit from increased sales due to increased usage of the test. With increased usage of the test, the cost of the reagents and equipment should decline over time.

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

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

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 78

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

Accordingly, we propose to amend 9 CFR part 78 as follows:

PART 78—BRUCELLOSIS

1. The authority citation for part 78 would continue to read as follows:

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

2. In § 78.1, in the definition for *official test,* paragraph (a)(13) would be redesignated as paragraph (a)(14) and new paragraphs (a)(13) and (b)(5) would be added to read as follows.

§ 78.1 Definitions.

* * * * *

Official test. (a) * * *

(13) *Fluorescence polarization assay (FP assay).* An automated serologic test to determine the brucellosis status of test-eligible cattle and bison when conducted according to instructions approved by APHIS. FP assays are interpreted as either positive, negative, or suspect. If a sample reads <10 millipolarization units (mP) above the mean negative control, the sample is considered negative. If a sample reads >20 mP above the mean negative control, the sample is considered positive. Samples that read between 10 and 20 mP above the negative control mean should be retested using 20 microliters of sample. If the 20-microliter sample is >20 mP above the mean negative control, the sample is considered positive. If the 20-microliter sample is still in the 10 to 20 mP range above the mean negative control, the sample is considered suspect. If the 20-microliter sample is <10 mP above the mean negative control, the sample is considered negative. Cattle and bison negative to the FP assay are classified as brucellosis negative. Cattle and bison with positive FP assay results are classified as brucellosis reactors, while cattle and bison with suspect FPA results are classified as brucellosis suspects.

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(b) * * *

(5) *Fluorescence polarization assay (FP assay).* An automated serologic test to determine the brucellosis status of test-eligible swine when conducted according to instructions approved by APHIS. FP assays are interpreted as either positive, negative, or suspect. If a sample reads <10 millipolarization units (mP) above the mean negative control, the sample is considered negative. If a sample reads >20 mP above the mean negative control, the sample is considered positive. Samples that read between 10 and 20 mP above the negative control mean must be retested using 20 microliters of sample. If the 20-microliter sample is >20 mP above the mean negative control, the sample is considered positive. If the 20-microliter sample is still in the 10 to 20 mP range above the mean negative control, the sample is considered suspect. If the 20-microliter sample is <10 mP above the mean negative control, the sample is considered negative. Swine with negative FPA results are classified as brucellosis negative. Swine with positive FP assay results are classified as brucellosis reactors, while swine with suspect FPA results are classified as brucellosis suspects.

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Done in Washington, DC, this 29th day of April 2004.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04–10311 Filed 5–5–04; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 1000

[Docket No. FR–4676–N–13]

Native American Housing Assistance and Self-Determination Negotiated Rulemaking Committee

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.