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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 93

[Docket No. APHIS-2011-0044]

RIN 0579-AD65

Brucellosis and Bovine Tuberculosis: Importation of Cattle and Bison

AGENCY: Animal and Plant Health Inspection Service, Agriculture Department (USDA).

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of cattle and bison with respect to bovine tuberculosis and brucellosis to establish a system to classify foreign regions as a particular status level for bovine tuberculosis and a particular status level for brucellosis. We are also establishing provisions for modifying the bovine tuberculosis or brucellosis classification of a foreign region. Finally, we are establishing conditions for the importation of cattle and bison from regions with the various classifications. The changes will make the requirements clearer and assure that they more effectively mitigate the risk of introduction of these diseases into the United States.

DATES: Effective [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Kelly Rhodes, Senior Staff Veterinarian, Regionalization Evaluation Services, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1236; (301) 851-3300.

## SUPPLEMENTARY INFORMATION:

### Background

The regulations in 9 CFR part 93, subpart D (§§ 93.400-93.436, referred to below as part 93 or the subpart), contain requirements for the importation of ruminants into the United States to address the risk of introducing or disseminating diseases of livestock within the United States. Part 93 currently contains provisions that address the risk that imported bovines (cattle or bison) may introduce or disseminate brucellosis or bovine tuberculosis (referred to below as tuberculosis) within the United States. The current regulations, which may be divided into requirements that are generally applicable to most exporting countries and specific requirements that are applicable to Canada, Mexico, and the Republic of Ireland, do not account for changes in disease programs or disease prevalence that could increase or decrease the risk of spread of brucellosis or bovine tuberculosis posed by the importation of cattle or bison from foreign regions.

On December 16, 2015, we published in the *Federal Register* (80 FR 78461-78520, Docket No. APHIS-2011-0044) a proposal<sup>1</sup> to amend the regulations by consolidating the domestic regulations governing tuberculosis and those governing brucellosis, as well as to revise the tuberculosis- and brucellosis-related import requirements for cattle and bison to make these requirements clearer and ensure that they more effectively mitigate the risk of introduction of these diseases into the United States.

We solicited comments concerning our proposal for 90 days ending March 15, 2016. We extended the deadline for comments until May 16, 2016, in a document published in the *Federal*

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<sup>1</sup> To view the proposed rule, supporting documents, and the comments we received, go to <https://www.regulations.gov/docket?D=APHIS-2011-0044>.

*Register* on March 11, 2016 (81 FR 12832-12833). We received 164 comments by the close of the extended comment period. Of those comments, 122 addressed the domestic provisions of the proposed rule and 42 addressed the import-related provisions. The comments were from captive cervid producers and captive cervid breeders' associations, cattle industry groups, State agriculture departments, State game and fish departments, veterinarians, representatives of foreign governments, and private citizens.

#### Domestic Regulations

After considering all the comments we received, we concluded that it is necessary to reexamine the proposed changes to the domestic tuberculosis and brucellosis programs. Therefore, in a document published in the *Federal Register* on March 27, 2019 (84 FR 11448-11449, Docket No. APHIS-2011-0044), we withdrew the proposed amendments to parts 50, 51, 71, 76, 77, 78, 86, and 161 in our December 16, 2015, proposed rule.

#### Import Regulations

We proposed to establish a system that would classify regions for tuberculosis or brucellosis based on whether the region has a program for tuberculosis or brucellosis control that meets certain standards and on the prevalence of the disease. We proposed the following classifications: Levels I through V for tuberculosis and Levels I through III for brucellosis. The classification system is based on prevalence as an indicator of risk. Level I regions have the lowest prevalence and bovine animals from these regions may be imported without testing. Prevalence increases with each successive level, as do the associated import requirements. The specific requirements for each level are set out in § 93.437 for tuberculosis, and in § 93.440 for brucellosis.

We further proposed to allow regions to request evaluation for a particular classification, to establish a process by which the United States Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) would evaluate such requests, and to allow APHIS to lower a region's classification based on emerging evidence. Finally, we proposed to establish conditions for the importation of cattle and bison that correspond to the tuberculosis or brucellosis classification of the region from which the cattle or bison would be exported. APHIS recognizes that there are three countries that enjoy particular status under the current part 93 regulations. These regions will continue to be able to trade with the United States under the terms of the status they currently hold until this final rule is effective and we act to adjust their status using the new approach spelled out in this final rule.

Commenters raised a number of concerns about the proposed rule. They are discussed below by topic.

#### International Standards

Some commenters asked whether the proposed import standards would be consistent with international guidelines for tuberculosis and brucellosis developed by the World Organization for Animal Health (OIE).

APHIS considered several alternative regulatory approaches to revising regulations governing the importation of cattle and bison with respect to bovine tuberculosis and brucellosis, including following OIE guidance on tuberculosis and brucellosis. The Terrestrial Animal Health Code of the OIE lays out three options for safe trade in bovine animals with regard to tuberculosis and brucellosis. These options can be categorized as (1) free country; (2) free herd; and (3) not free, respectively. APHIS conducted an analysis that compared adopting the OIE

standards with the adaptation of U.S. domestic regulations for importation, as in this final rule.<sup>2</sup> APHIS concluded in that analysis that the adapted U.S. regulations are more restrictive in some cases than the OIE Terrestrial Code and less restrictive in others, depending on the classification level. APHIS further concluded that both the OIE Terrestrial Code and U.S. regulations adapted to importation would substantially mitigate import risk. However, the U.S. regulations reduce the risk to negligible levels; import risk under the OIE Terrestrial Code may exceed the U.S. appropriate level of protection. Unlike the adapted U.S. regulations, the OIE Terrestrial Code does not take into account the difference in tuberculosis risk between feeder animals and breeding animals, or factors that influence the ability of the exporting region to accurately comply with diagnostic testing and certification requirements. APHIS concluded in its analysis that the OIE Terrestrial Code is not sufficiently flexible to address the variable bovine tuberculosis prevalence levels reported by U.S. trading partners without either jeopardizing the status of U.S. eradication programs or constituting an unnecessary burden for the exporting country. Applying the adapted U.S. regulations would provide considerable flexibility in addressing the wide range of prevalence levels and programmatic approaches in exporting regions. Applying the adapted regulations is also consistent with the regionalization approach that APHIS takes for other diseases. Therefore, we determined from our analysis of relevant scientific data that risks to U.S. production were better addressed through the approach developed in this rule than through adoption of OIE Terrestrial Code.

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<sup>2</sup> The risk assessment can be viewed at <https://www.regulations.gov/document?D=APHIS-2011-0044-0046>.

## Requesting Regional Classification for Tuberculosis

One commenter stated that the classification for a region should take into account the prevalence of both tuberculosis and brucellosis in the region. The commenter did not explain why they believed classification for one disease should be based on prevalence of both diseases.

APHIS disagrees with the commenter. Tuberculosis and brucellosis are different diseases with different risk factors, different transmission mechanisms, and differences in our ability to detect them. The existence of one has little influence on presence or absence of the other. However, foreign regions will need to be evaluated for both in order to export cattle to the United States other than for direct slaughter. Keeping disease evaluations and classifications separate is also consistent with our domestic policy.

One commenter stated that § 93.438 needs to clarify that it is period prevalence, and herd prevalence, rather than in-herd prevalence.

We agree. Prevalence is calculated over the time period described for each level, based on the number of affected herds. In some instances, the Administrator may allow calculation of period prevalence based on affected herd-years to avoid penalizing regions with small herd numbers. We have added a definition of *prevalence* to § 93.400 to clarify this.

Two commenters asked if a large regional request could mask pockets of high prevalence of tuberculosis.

APHIS agrees that there is potential to artificially dilute the apparent prevalence in large regions. Each region must therefore satisfy the regulatory requirements outlined in § 93.438, not just meet a certain prevalence level. Regions that satisfy the requirements have a strong tuberculosis program and demonstrated ability to effectively detect and contain tuberculosis infection, thereby limiting the risk to the United States. Regions that do not satisfy the

requirements would be classified as Level V. All tuberculosis cases originating from a given region will be used in the prevalence calculations.

One commenter asked if Level I countries will need to supply information equivalent to an animal health plan required of a State or Tribe as described under the proposed rule.

APHIS notes that we proposed the requirement for an animal health plan as a change to the domestic tuberculosis regulations and we are making no changes to those regulations at this time. However, foreign regions seeking classification at any level would have to supply a detailed description of tuberculosis program activities. The region would generally also undergo a site visit, during which APHIS would evaluate and document compliance with the evaluation criteria outlined in § 93.438.

One commenter stated that the proposed criteria for requesting regional classification for tuberculosis do not work for biologically free countries. This commenter also stated that Australia has successfully eradicated tuberculosis and should be recognized as free of the disease.

We designed this rule to efficiently address the wide range of risk posed by U.S. trading partners with regard to tuberculosis and brucellosis. Australia is the only country that we are aware of that has made claims to biological freedom from tuberculosis. We are not making any changes based on this comment because we do not see a direct benefit to exporting regions, since cattle from Level I regions are already exempt from tuberculosis testing, and also because creating a classification for biologically free regions (i.e., zero prevalence) would lead to trade disruptions should an outbreak occur. Our review of Australia's status is ongoing.

One commenter stated that surveillance should be required for all countries submitting a request for classification. However, another commenter expressed concern that the proposed

requirements for surveillance do not recognize regions whose status for tuberculosis exceeds that of the United States, for example, those with a claim to biological freedom from the disease.

APHIS agrees that surveillance should be required for all regions submitting a request for a classification other than Level V, although the degree and intensity of surveillance may vary depending on regional conditions including past surveillance and findings. We anticipate that most such regions will have surveillance in place similar to the United States, involving a combination of slaughter surveillance and live animal testing. In rare instances, a region may have reached the point that they are confident that reducing active live animal and slaughter surveillance will not ultimately lead to a resurgence of the disease. In evaluating such regions, APHIS would still assess whether the historical and current surveillance measures provide equivalent assurance of tuberculosis detection to that in the United States.

One commenter noted that the proposed rule stated that guidance on how to complete a request for classification in a manner that will allow APHIS to review it expeditiously would be available on the APHIS website. The commenter asked what timeframe would be considered expeditious, and stated that it should be defined as meaning weeks or months, not years.

The time to complete the process from receipt of the initial request to publication of the final notice may vary considerably based on several factors, some of which are not under APHIS control. For example, the initial request might not be accompanied by sufficient information, so we would need to gather additional information. The length of time this takes would depend on the completeness of the initial submission, the complexity of the situation, and the responsiveness of the foreign region to requests for additional information.

After the initial request and information gathering, we would then conduct a site visit, which we consider to be a necessary component of an evaluation. Planning and scheduling the

site visit takes at least 2 to 3 months. After the site visit, it takes at least 1 month to complete the report, longer if we need to request follow-up information or clarification.

In some instances, we will be able to classify a region after the first site visit, in which case we could use either the site visit report or a summary as the supporting document for the notice. However, in some cases we may not be able to classify the region at the status level it desires. In those cases we might proceed in one of several ways. For example, we might classify the region at a lower status level (higher risk level) based on our findings. Other possibilities could include not proceeding further with the evaluation, or working with the region to improve their tuberculosis program and status before proceeding. In these cases, there may be progress reports, additional information, and possibly another site visit, all of which would need to be compiled into a summary document to support a notice if we moved forward to that step.

A commenter noted that the proposed rule stated if we consider a request for classification complete, we would publish a notice in the *Federal Register* proposing to classify the region, and making available to the public the information upon which this proposed classification is based. The notice would request public comment. The commenter asked how APHIS intends to more quickly and efficiently publish these classification changes. The commenter also asked what the expected timeframe for the notices would be, and stated that the final rule needs to identify these timeframes.

Classification and reclassification would occur through publication of a notice in the *Federal Register* as described in § 93.438(c) and (d). The notice-based process offers substantial time savings over traditional rulemaking. It is the fastest method for making such changes available to APHIS that still provides the public opportunity to comment on each proposed action. However, there are factors outside our control that can affect the timing of publication

and that make specifying the timeframes in the regulations infeasible. If we believe that the time required for reclassification via the notice-based process would result in a real and substantial increase in risk to animal health in the United States, we would act administratively to mitigate the risk while pursuing the notice-based process.

#### Import Requirements/Tuberculosis

Two commenters expressed support for the proposed requirements for the importation of bovines from foreign regions with respect to tuberculosis.

Several commenters asked if the Governments of Canada and Mexico supported the proposed requirements.

APHIS discussed the proposed tiered classification system and anticipated impact on cattle trade with representatives of the Governments of Canada and Mexico while developing the proposed rule. Neither expressed opposition to the proposed changes to the import requirements during these meetings nor in comments received on the proposed rule<sup>3</sup>.

Several commenters asked whether APHIS has the resources to carry out the proposed port-of-entry testing and expressed concern that the testing could cause logistical problems. The commenters stated that the requirements should be reconsidered.

APHIS disagrees. The proposed port-of-entry testing is very similar to that currently required for cattle from Canada and Mexico, which contribute nearly 100 percent of cattle imported into the United States. We do not anticipate that the proposed port-of-entry testing would cause logistical problems in excess of those currently experienced.

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<sup>3</sup> The comment submitted by the Government of Canada on the proposed rule can be viewed online at <https://www.regulations.gov/document?D=APHIS-2011-0044-0096>. The comment submitted by the Government of Mexico can be viewed online at <https://www.regulations.gov/document?D=APHIS-2011-0044-0205>.

Two commenters asked if APHIS would provide additional resources to support port-of-entry testing for tuberculosis and support management of cattle held there pending test results when inspections are done on the U.S. side of the border.

As we explained above, the testing requirements we proposed are very close to those currently in place for cattle from Canada and Mexico. Since the requirements are not changing significantly, we do not anticipate that the resource needs will change significantly.

Two commenters asked if an APHIS veterinarian or a veterinarian from Mexico would be responsible for testing imported cattle at the port of entry.

When testing cattle at the port of entry is required by APHIS regulations, APHIS veterinarians would conduct the testing.

Several commenters questioned the scientific basis for setting the minimum testing age at 6 months for imported steers and spayed heifers.

Setting the minimum test age at 6 months is based on historic precedent in our domestic program. However, we agree with the commenters that since animals presented for import may only receive a single test to determine tuberculosis status, all ages should be test eligible. We are amending § 93.439 to remove the specified minimum test ages in response to this comment.

One commenter asked if the prohibition on Holsteins and Holstein crosses also extends to bovines exposed to Holsteins and Holstein crosses.

No. There is no practical way to accurately certify to this requirement.

One commenter stated that Level I status appears to require herd testing for animals and germplasm.

That is not the case. This rule set forth the requirements for importation of live cattle into the United States. Herd testing is not required for live cattle from regions that qualify as Level I

for tuberculosis or brucellosis. Requirements for germplasm are contained in 9 CFR part 98, which we are not amending in this rulemaking.

One commenter stated that the definition of *immediate slaughter* should specify that these cattle are transported in sealed conveyances directly to the slaughterhouse and killed within 3 days of arrival.

We agree that bovines imported for immediate slaughter should be transported from the port of entry to the slaughtering establishment in a conveyance sealed with seals of the U.S. Government. Only bovines from Canada and Mexico are eligible for immediate slaughter, since bovines from other regions must undergo quarantine. The provisions for immediate slaughter bovines from Canada and Mexico appear in §§ 93.420 and 93.429, respectively. These sections specify travel in a sealed conveyance as well as other mitigation measures. While we had proposed to exempt bovines from the provisions of § 93.429, we neglected to specify appropriate mitigation measures for immediate slaughter cattle elsewhere in part 93. As a result, we do not intend to make the proposed change to § 93.429, which will preserve not only the requirement for travel in sealed conveyances but other mitigation measures specified for immediate slaughter bovines from Mexico. As a corollary, we are not adopting the provisions for bovines for immediate slaughter proposed in § 93.442(c) concerning brucellosis.

APHIS notes that the definition of *immediate slaughter* in § 93.400 specifies that the consignment is slaughtered within 2 weeks of entry. Only bovines from Canada and Mexico may be imported for slaughter without first undergoing quarantine. The 2 weeks allow time for slaughter and, in the case of Mexico, address residue concerns due to dipping. We are making no changes based on this portion of the comment.

Two commenters asked if official identification numbers of the animals will need to be written on the certificate for Level II accredited herds.

Yes. APHIS notes that § 93.439 as proposed says in 11 separate places that bovines must be (1) officially identified and (2) accompanied by a certificate that says that they are officially identified. To address this unnecessary repetition, we are amending § 93.439 to include a blanket statement in § 93.439(b) that all bovines imported under this section must be officially identified and accompanied by a certificate, issued in accordance with § 93.405(a), that indicates that they are officially identified. We will also amend § 93.439 to require that the certificate must record the means by which the bovines are officially identified. This action would also apply the requirements for official identification and certifications to bovines from Level I, which the proposal inadvertently omitted.

We are making matching changes for brucellosis by including a blanket statement in § 93.442(b) regarding official identification and certification, to apply also to bovines from Level I regions, and by amending paragraphs (d) and (e) in § 93.442 to remove the repetitive references to these requirements.

One commenter asked if animals from a Level II region under 6 months of age are allowed to be imported into the United States.

Yes. Animals from a Level II region under 6 months of age may be imported in accordance with § 93.439(d). These animals would be eligible for any required testing for tuberculosis under the provisions of that section, since we are removing the minimum age as described above.

Some commenters stated that animals from a Level II region under 6 months of age need to be tested in the United States when they reach maturity.

APHIS disagrees. As we explained above, we have amended several sections in § 93.439 to clarify that bovines of all ages are test eligible if testing for tuberculosis is required for importation. Retesting of bovines from Level II regions is not supported by our risk analysis or in line with current practice.

Some commenters stated that the proposed testing and movement requirements from States with Inconsistent status were more restrictive than the requirements for animals imported from Level III regions.

As we explained above, we have amended § 93.439 to clarify the testing requirements for imported cattle, including those from Level III regions. APHIS notes that the testing requirements we are adopting for importation from Level III regions are consistent with those currently required for domestic cattle moving from modified accredited States, as set out in 9 CFR 77.12(b). We also note that Inconsistent status was a term of art we proposed for our domestic tuberculosis regulations, and we are making no changes to the domestic tuberculosis regulations at this time. We will take this comment into consideration if we proceed with changes to the domestic regulations in the future.

Some commenters expressed concern that Level III requirements are not sufficiently stringent to address disease risk.

APHIS disagrees. As we explained above, the testing requirements for cattle imported from Level III regions are consistent with the testing requirements for domestic cattle moving from modified accredited States domestically. These testing requirements have been demonstrated to be sufficient to prevent the spread of disease within the United States and we are confident they will prevent disease introduction from Level III regions.

Some commenters stated that Level III regions should not have accredited herds.

We note that Level III regions are subject to APHIS evaluation of the tuberculosis program and must meet the evaluation criteria specified in § 93.438. They cannot attain Level III status without demonstrating sufficient program strength to, among other things, maintain accreditation and supervision of accredited herds. We are making no changes in response to this comment.

Some commenters stated that cattle from accredited herds in Level III regions should have a negative test for tuberculosis within 60 days prior to importation.

APHIS disagrees with regard to steers and spayed heifers from accredited herds in Level III regions. As we explained above, Level III regions must meet evaluation criteria and demonstrate program strength. However, we agree that sexually intact bovines present a greater risk for introduction and dissemination of *Mycobacterium bovis*. Our risk assessment supports an individual negative test at the port of entry or during post-arrival quarantine, with negative results, for all sexually intact animals from Levels II-IV. We included this requirement in the proposed § 93.439(f)(1) for sexually intact bovines from accredited herds in Level IV regions but not for Levels II and III. We are therefore amending paragraphs (d)(1) and (e)(1) in § 93.439 to require testing at the port of entry or during post-arrival quarantine for sexually intact bovines from accredited herds in Level II and III, respectively.

Some commenters stated that Level III animals not from accredited herds and not destined for immediate slaughter need to be test eligible and at least individually tested.

APHIS agrees with the commenters. We have amended § 93.439(e)(2) to provide for testing of sexually intact animals from non-accredited herds in Level III regions at the border. As we explained above, we are also removing minimum age for individual testing, meaning all steers, spayed heifers, and sexually intact cattle from these herds will be eligible for testing.

Four commenters asked if it is necessary for cattle from Level III regions to be tested at the farm of origin.

No. We mistakenly proposed to require premises of origin testing for steers and spayed heifers from Level III regions, as well as steers and spayed heifers from Level IV regions. We have amended paragraphs (e)(3)(ii) and (f)(3)(ii) in § 93.439 to remove the requirement for testing to occur on the premises of origin.

One commenter asked if Level IV regions need to have an acceptable tuberculosis program in place.

Yes, as specified in § 93.437(d), Level IV regions would need to have an acceptable tuberculosis program in place.

One commenter stated that Level IV steers and spayed heifers not from accredited herds and not destined for immediate slaughter need to be test eligible and at least individually tested.

We agree with this commenter. Section 93.439(f)(3)(ii) requires a negative individual test of steers and spayed heifers from non-accredited herds in Level IV regions within 60 days prior to export, unless the bovines are exported within 60 days of the whole herd test and were included in that test. As noted above, we have amended this section to remove the proposed minimum test age of 2 months so that all bovines are test eligible.

Five commenters stated that the testing interval for whole herd tests for Level IV sexually intact non-accredited bovines needs to be specified. The commenters were specifically concerned about the lack of a declared maximum limit for the time between the second test and time of movement.

We agree with the commenters. The proposed rule specified an interval of 9 to 15 months between the whole herd tests but not the amount of time that can pass between the

second whole herd test and export. We have amended § 93.439(f)(2)(i) to specify that the second whole herd test must be administered no less than 60 days and no more than 12 months before export.

One commenter asked how individual animal testing will be administered for cattle from accredited herds in Level IV regions.

The proposed rule did not distinguish between sexually intact and steers and spayed heifers from accredited herds in Level IV regions with regard to testing, which was an oversight. An individual test at the port of entry is only required for sexually intact cattle from accredited herds; steers and spayed heifers need a test within 60 days prior to export. We have amended § 93.439(f)(1) to correct this oversight. Actual testing would follow the procedures currently in place for animals from Mexico; for virtually all other countries, testing would take place during quarantine.

Nine commenters stated that Level V bovines should be prohibited importation into the United States.

We foresee three types of regions that APHIS would classify as Level V for tuberculosis. The first would be regions that APHIS determines to have an adequate tuberculosis program, but a prevalence rate over 0.5 percent. Because of the high prevalence, we would only allow limited quantities of animals with documented genetic histories (pedigrees, breed registries, genetic documentation, etc.). In general, we foresee a preclearance program with mitigations equivalent to those in the proposed rule being adequate for such imports, but could see instances in which additional mitigations (such as more extensive APHIS oversight in-country) may be necessary. Section 93.401(a) provides that the Administrator may in specific cases prescribe conditions for

ruminants or products to be brought into or through the United States and we would establish such conditions for regions that need additional mitigations.

The second would be regions that can demonstrate a low prevalence based on surveillance, but do not request a full evaluation of their tuberculosis programs. These countries would eschew evaluation simply as being too much work based on expected levels of exports. We consider a preclearance program with mitigation equivalent to those in the proposed rule to be adequate for such imports, but could foresee instances in which alternate strategies (such as having the region provide documentation of accreditation standards or adherence to transnational animal health regulations) obviate the need for some of the requirements. As a result, we would allow limited imports from such regions with additional mitigations in accordance with the provisions of § 93.401(a), and post import protocols relevant to the countries on the APHIS website.

The third scenario would be when a region requests an evaluation from us, and APHIS determines that the region does not have an adequate tuberculosis program. In such instances, we foresee a preclearance program with mitigations equivalent to those in the proposed rule, but in which APHIS administers all in-country tests, as the only way of adequately mitigating disease risk.

We are amending § 93.439(g) to clarify this point and allow for the various scenarios above by stating that importation of bovines for purposes other than immediate slaughter may occur at the Administrator's discretion, subject to a preclearance program administered by APHIS and detailed in an import protocol that we would post on the APHIS website. Such bovines would still be subject to an individual test for tuberculosis at the port of entry or during

post-arrival quarantine, with negative results, as well as all applicable identification and certification requirements of part 93.

Finally, through a drafting error, the rule failed to consider bovines for immediate slaughter from Level V regions. As discussed above, this would only apply to parts of Mexico and is provided for in existing § 93.429.

Four commenters stated that Level V countries need to at least have a veterinary infrastructure and tuberculosis control program.

APHIS disagrees that these are necessarily requirements. As we discussed above, we consider preclearance programs with mitigation equivalent to those in the proposed rule to be adequate for such imports in most cases, and we have the ability to establish additional mitigations as needed.

Two commenters stated that embryos should be authorized for importation from Level V countries.

As we explained above, the requirements for germplasm are contained in part 98, which we are not amending in this rulemaking. As long as embryos meet the relevant requirements in part 98, they could be imported into the United States.

#### Requesting Regional Classification for Brucellosis

One commenter stated that Level I regions should be required to have been free for 2 years and in a country with a low prevalence.

APHIS notes that § 93.440(a) specifies that a region recognized as Level I for brucellosis must have a prevalence less than 0.001 percent for at least 2 years (24 consecutive months). Regions eligible for Level I or II must have demonstrated regulatory controls on the movement of livestock into, within, and from the region that correspond to the risk of dissemination of

brucellosis associated with such movement. We are confident that these requirements will effectively mitigate the risk of introducing brucellosis into the United States.

One commenter stated that the process and timeframe for reclassification of a region for brucellosis should be specified in the regulations. The commenter also asked how APHIS intends to carry out the classification and reclassification in a timely manner.

The process for classification and reclassification of a region for brucellosis is the same as the process for classification and reclassification of a region for tuberculosis we described above, and is provided for in § 93.441(b) and (c). As we explained, the time to complete the process from receipt of the initial request to publication of the notice may vary considerably based on several factors, some of which are not under APHIS control. It is therefore not feasible to specify timeframes in the regulations. As with the process for tuberculosis, if we believed that the time required for reclassification via the notice-based process would result in a real and substantial increase in risk to animal health in the United States, we would act administratively to mitigate the risk while pursuing the notice-based process.

#### Import Requirements/Brucellosis

Two commenters stated that sexually intact cattle under 6 months of age should be prohibited importation.

APHIS disagrees. However, as discussed above for tuberculosis, we believe that all ages should be test eligible since some animals may only receive a single test to determine brucellosis status. We are therefore amending paragraphs (d) and (e) in § 93.442 to remove the specified minimum test ages for brucellosis as for tuberculosis.

We are also amending paragraph (a) in § 93.442 to remove the prohibition on importation of ruminants who have had a non-negative test response to any test for *Brucella* spp. at any time.

This provision was not in line with procedures to export cattle from the United States. We allow animals that were non-negative on a *Brucella* spp. test to be exported provided that they had negative responses on subsequent testing. This change will provide consistency between our import and export requirements.

#### Miscellaneous

One commenter expressed concern that the definition of *herd of origin*, as proposed, could allow a constant flow of additional animals of disparate status into a herd, and these animals could still move as if they originated from that herd.

We agree with the commenter and are amending the definition of *herd of origin* by defining a herd of origin as a herd of one or more sires and dams and their offspring from which animals in a consignment presented for export to the United States originate, and by specifying that a herd of origin may be the birth herd or the herd where the animal has resided for a minimum 4-month period immediately prior to movement, unless otherwise specified in an import protocol. We are also amending the definition to allow additional animals to be moved into a herd of origin during or after the 4-month qualifying period only if they originate from an accredited herd or originate from a herd of origin that tested negative to a whole herd test conducted within the last 12 months and the individual animals being moved into the herd also tested negative to any additional individual tests for tuberculosis and brucellosis required by the Administrator. These changes are consistent with the definition that appears in the Bovine Tuberculosis Eradication Uniform Methods and Rules, effective January 1, 2005,<sup>4</sup> and with current requirements for live animals and germplasm.

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<sup>4</sup> This document may be accessed on the APHIS website at <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/cattle-disease-information/national-tuberculosis-eradication-program>.

We are amending the definition of *individual test* in § 93.401 to remove the words “for purposes of this part, testing of individual animals as part of a whole herd test does not constitute an individual test” because this requirement is not necessary in the context of this final rule and could cause confusion.

We are amending the definition of *whole herd test for brucellosis* in § 93.401 to specify that only sexually intact bovines need to be tested for brucellosis. There is no evidence that sexually neutered animals can transmit brucellosis and therefore no reason to test them.

Since the publication of the proposed rule, § 93.427 has been amended to change the branding requirements for steers and spayed heifers imported from Mexico (83 FR 64223-64225, Docket No. APHIS-2016-0050). We have therefore amended paragraph (a) of that section to be consistent with the new requirements.

We have made editorial changes to § 93.439 to consolidate the requirements for testing of sexually intact bovines from both accredited and non-accredited herds from a Level II region for tuberculosis because all sexually intact cattle from such regions are required to be tested at the port regardless of herd status. The provisions now appear in paragraph (d)(1) of that section.

Similarly, we have made editorial changes to § 93.442 to consolidate the requirements for the importation of steers and spayed heifers from all regions with respect to brucellosis. The provisions now appear in paragraph (c) of that section.

We have made minor, nonsubstantive changes to §§ 93.401(d), 93.438(a), and 93.441(a) to improve the clarity of those paragraphs.

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

## Executive Orders 12866, 13563, 13771, and Regulatory Flexibility Act

This final rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget. This rule is not subject to the requirements of Executive Order 13771 because this rule results in no more than *de minimis* costs. Details on the estimated costs of this final rule can be found in the rule's economic analysis.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available on the Regulations.gov website (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

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

This rule amends the regulations governing the importation of cattle and bison with respect to bovine tuberculosis and brucellosis. The changes will make these requirements clearer and assure that they more effectively mitigate the risk of introduction of these diseases into the United States.

The potential economic effects associated with this rule are not significant. The requirements for the importation of cattle and bison from foreign regions will not change significantly as a result of this rule, and where they do change they will affect very few producers or importers.

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

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

currently Accreditation Preparatory for tuberculosis will likely be classified as Level IV and an additional whole herd tuberculosis test will be required for imports of sexually intact cattle from those regions. This rule also removes the requirement for a whole herd test and an individual test for sexually intact cattle from regions classified as Level I.

Some U.S. entities may be indirectly affected by changes in testing requirements. It is possible that small additional testing costs for some Mexican breeding cattle may result in an increase in U.S. import prices. Conversely, small cost savings due to the removal of a whole herd test requirement for some Mexican heifers may result in a decrease in U.S. import prices. However, these price impacts if they were to occur would be extremely minor.

A very small number of sexually intact cattle are imported from Mexico. In 2018, they numbered 290 head.<sup>5</sup> Costs of additional whole herd testing are dependent on the size of the herd from which bovines destined for export originate. Any imports of sexually intact cattle from non-accredited herds in Level III regions will be subject to an additional whole herd brucellosis test in order to export to the United States and will incur the cost of that testing. Cattle from accredited herds in Level III regions will not need any herd testing beyond that required for accreditation, just an individual test at the port. The majority of those cattle are likely to be of higher genetic quality and come from accredited herds. Sexually intact cattle imported from Level IV regions will also be subject to the additional whole herd tuberculosis test for export to the United States and incur the cost of that testing. The impact of the changes to testing requirements will be very limited. Any additional costs will represent a small portion of the value of the imported bovines. Very few cattle would be affected, and the per head cost

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<sup>5</sup> Source: SENASICA, competent veterinary authority of Mexico. Personal correspondence with APHIS. May 2019.

associated with brucellosis and tuberculosis testing is equivalent to between 0.3 and 0.5 percent of the average per head value (\$1,249) of imported Mexican breeding cattle in 2018.<sup>6</sup> Even if all imported sexually intact Mexican cattle imported in 2018 had been subject to additional testing, the additional cost would have been between \$1,100 and \$1,800 for those 290 head. Whether this additional testing cost would affect prices paid by U.S. importers would depend on the competitiveness of the market for Mexican breeding cattle and responsiveness of U.S. importers of Mexican breeding cattle to small price changes. We expect any impact would be negligible.

This rule also removes the requirement for a whole herd test and an individual test for sexually intact cattle from regions classified as Level I. APHIS intends to recognize the Mexican State of Sonora as Level I. While about 19 percent of the cattle imported from Sonora are currently spayed heifers, following the implementation of this rule they will likely be sexually intact. The only reason to spay heifers under the current rule is to avoid the cost of testing for brucellosis. Those Mexican producers may save the cost of spaying. The cost associated with spaying is equivalent to between 1.1 percent and 1.4 percent of the average per head value (\$720) of imported Mexican heifers, excluding purebred breeding cattle, in 2018.<sup>7</sup> In total, those Mexican producers could potentially save a total of about \$500,000 to \$625,000 in costs by not spaying those imported heifers. These savings would represent less than 0.4 percent of the value of all imported Mexican heifers (about \$181 million in 2018), and less than 0.2 percent of the value of all heifers imported into the United States in 2018 (about \$505 million in 2018).

As with the breeding cattle, whether this cost savings would affect prices paid by U.S. importers would depend on the competitiveness of the market for Mexican heifers and

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<sup>6</sup> Source: U.S. Census Bureau, Economic Indicators Division. <http://usatrade.census.gov>.

<sup>7</sup> Source: U.S. Census Bureau, Economic Indicators Division. <http://usatrade.census.gov>.

responsiveness of U.S. importers of Mexican heifers to small price changes. We expect any impact would be very small.

The effects of this rule on foreign producers of cattle and bison represent a very small portion of the value of imported Mexican cattle. The potential additional cost associated with brucellosis and tuberculosis testing would be equivalent to between 0.3 and 0.5 percent of the average per head value of imported Mexican breeding cattle. The potential cost savings from not spaying heifers would be less than 0.4 percent of the value of all imported Mexican heifers. It is possible that the small additional testing costs may be reflected in an increase in the price of some imported Mexican breeding cattle, or the small cost savings from not spaying heifers may be reflected in a decrease in the price of some imported Mexican heifers. However, given the very small costs or cost savings relative to the value of the market, these price impacts if they were to occur will be, at most, extremely minor. Under these circumstances, the APHIS Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities.

#### Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Government. Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government

basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Based on the foregoing, the USDA's Office of Tribal Relations (OTR) has assessed the impact of this rule on Indian Tribes and determined that consultation is not recommended at this time. If consultation is requested, OTR will work with the APHIS to ensure quality consultation is provided.

#### 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 requirements included in this final rule, which were filed under 0579-0442, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the *Federal Register* providing notice of what action we plan to take.

#### 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 Mr. Joseph Moxey, APHIS' Information Collection Coordinator, at (301) 851-2483.

#### List of Subjects in 9 CFR Part 93

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

Accordingly, we are amending 9 CFR part 93 as follows:

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, FISH, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

1. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

2. Section 93.400 is amended as follows:

- a. By adding, in alphabetical order, definitions for *Accredited herd for brucellosis*, *Accredited herd for tuberculosis*, and *Brucellosis*;
- b. By removing the definition for *Brucellosis certified-free province or territory of Canada*;
- c. By revising the definition for *Herd of origin*;
- d. By adding, in alphabetical order, definitions for *Import protocol*, *Individual test*, *Non-negative test results*, and *Notifiable disease*;
- e. By removing the definition for *Official tuberculin test*;
- f. By adding, in alphabetical order, definitions for *Prevalence*, *Spayed heifer*, *Steer*, and *Tuberculosis*;
- g. By removing the definitions for *Tuberculosis-free herd* and *Whole herd test*; and
- h. By adding, in alphabetical order, definitions for *Whole herd test for brucellosis* and *Whole herd test for tuberculosis*.

The additions and revision read as follows:

§ 93.400 Definitions.

\* \* \* \* \*

*Accredited herd for brucellosis.* A herd that meets APHIS' standards for accreditation for brucellosis status. Standards for accreditation are specified in import protocols.

*Accredited herd for tuberculosis.* A herd that meets APHIS' standards for accreditation for bovine tuberculosis status. Standards for accreditation are specified in import protocols.

\* \* \* \* \*

*Brucellosis.* Infection with or disease caused by *Brucella abortus*.

\* \* \* \* \*

*Herd of origin.* A herd of one or more sires and dams and their offspring from which animals in a consignment presented for export to the United States originate. The herd of origin may be the birth herd or the herd where the animal has resided for a minimum 4-month period immediately prior to movement, unless otherwise specified in an import criteria. Additional animals can be moved into a herd of origin during or after the 4-month qualifying period only if they:

(1) Originate from an accredited herd; or

(2) Originate from a herd of origin that tested negative to a whole herd test conducted within the last 12 months and the individual animals being moved into the herd also tested negative to any additional individual tests for tuberculosis and brucellosis required by the Administrator.

\* \* \* \* \*

*Import protocol.* A document issued by APHIS and provided to officials of the competent veterinary authority of an exporting region that specifies in detail the mitigation measures that will comply with the regulations in this part regarding the import of certain animals or commodities.

*Individual test.* A test for brucellosis or tuberculosis that is approved by the Administrator and that is administered individually in accordance with this part to ruminants that are susceptible to brucellosis or tuberculosis.

\* \* \* \* \*

*Non-negative test results.* Any test results for tuberculosis or brucellosis within the suspect, reactor, or positive range parameters of a pathogen assay that has been approved by the Administrator.

\* \* \* \* \*

*Notifiable disease.* A disease for which confirmed or suspected occurrences within a region must be reported to the competent veterinary authority or other competent authority of that region.

\* \* \* \* \*

*Prevalence.* The number of affected herds occurring during the period specified in §§ 93.437 and 93.440. In some instances, the Administrator may allow calculation of prevalence based on affected herd-years to avoid penalizing regions with small herd numbers.

\* \* \* \* \*

*Spayed heifer.* A female bovine that has been neutered in a manner otherwise approved by the Administrator and specified in an import protocol.

\* \* \* \* \*

*Steer.* A sexually neutered male bovine.

\* \* \* \* \*

*Tuberculosis.* Infection with or disease caused by *Mycobacterium bovis*.

\* \* \* \* \*

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

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

\* \* \* \* \*

3. Section 93.401 is amended by adding paragraph (d) to read as follows:

§ 93.401 General prohibitions; exceptions.

\* \* \* \* \*

(d) *Cleaning and disinfection prior to shipment.* A means of conveyance used to transport an animal to the United States in accordance with this subpart must be cleaned and disinfected in a manner specified within an import protocol prior to transport, unless an exemption has been granted by the Administrator.

§ 93.406 [Amended]

4. Section 93.406 is amended by removing and reserving paragraphs (a), (c), and (d).

§ 93.408 [Amended]

5. In § 93.408, the first sentence is amended by removing the citation “§§ 93.421 and 93.426” and adding in its place the citation “§ 93.421”.

6. In each undesignated center heading in subpart D listed in the first column, redesignate the footnote number in the second column as the footnote number in the third column:

Undesignated center heading in subpart D	Old footnote	New footnote
Canada	8	9
Central America and West Indies	9	10
Mexico	10	11

7. Section 93.418 is amended as follows:

a. By removing and reserving paragraphs (b) and (c);

b. By adding a heading for paragraph (d); and

c. In paragraph (d) introductory text, by removing the words “the requirements of paragraphs (a) through (c)” and adding the words “the other requirements” in their place.

The addition reads as follows:

§ 93.418 Cattle and other bovines from Canada.

\* \* \* \* \*

(d) *Conditions for importation.* \* \* \*

§ 93.423 [Amended]

8. In § 93.423, the first sentence in paragraph (a) is amended by removing the words “Ruminants intended for” and adding the words “In addition to all other applicable requirements of the regulations in this part, ruminants intended for” in their place.

9. In § 93.424, paragraph (b) is revised to read as follows:

§ 93.424 Import permits and applications for inspection of ruminants.

\* \* \* \* \*

(b) For ruminants intended for importation into the United States from Mexico the importer or his or her agent shall deliver to the veterinary inspector at the port of entry an application, in writing, for inspection, so that the veterinary inspector and customs representatives may make mutual satisfactory arrangements for the orderly inspection of the animals. The veterinary inspector at the port of entry will provide the importer or his or her agent with a written statement assigning a date when the animals may be presented for import inspection.

10. Section 93.427 is amended as follows:

- a. By revising paragraphs (a) and (c);
- b. By removing and reserving paragraph (d); and
- c. In paragraph (e) introductory text, by removing the words “paragraphs (a) through (d) of”.

The revisions read as follows:

§ 93.427 Cattle and other bovines from Mexico.

(a) *Cattle and other ruminants from Mexico.* Cattle and other ruminants from Mexico, except animals being transported in bond for immediate return to Mexico or animals imported

for immediate slaughter, may be detained at the port of entry, and there subjected to such disinfection, blood tests, other tests, and dipping as required in this part to determine their freedom from any communicable disease or infection of such disease. The importer shall be responsible for the care, feed, and handling of the animals during the period of detention. In addition, each steer or spayed heifer imported into the United States from Mexico shall be identified with a distinct, permanent, and legible "M" mark applied with a freeze brand, hot iron, or other method prior to arrival at a port of entry, unless the steer or spayed heifer is being transported in bond for immediate return to Mexico or imported for slaughter in accordance with § 93.429. The "M" mark shall be between 3 inches (7.5 cm) and 5 inches (12.5 cm) high and wide, and shall be applied to each animal's right hip, within 4 inches (10 cm) of the midline of the tailhead (that is, the top of the brand should be within 4 inches (10 cm) of the midline of the tailhead, and placed above the hook and pin bones). The brand should also be within 18 inches (45.7 cm) of the anus.

\* \* \* \* \*

(c) *Importation of Holsteins from Mexico.* The importation of Holstein steers, Holstein spayed heifers, Holstein cross steers, and Holstein cross spayed heifers from Mexico is prohibited.

\* \* \* \* \*

§ 93.432 [Removed and Reserved]

11. Section 93.432 is removed and reserved.

12. Section 93.437 is added to read as follows:

§ 93.437 Tuberculosis status of foreign regions.

(a) *Level I regions.* APHIS considers certain regions of the world to have a program that meets APHIS requirements for tuberculosis classification in accordance with § 93.438, and a prevalence of tuberculosis in their domestic bovine herds of less than 0.001 percent over at least the previous 2 years (24 consecutive months).

(b) *Level II regions.* APHIS considers certain regions of the world to have a program that meets APHIS requirements for tuberculosis classification in accordance with § 93.438, and a prevalence of tuberculosis in their domestic bovine herds equal to or greater than 0.001 percent, but less than 0.01 percent, over the previous 2 years (24 consecutive months).

(c) *Level III regions.* APHIS considers certain regions of the world to have a program that meets APHIS requirements for tuberculosis classification in accordance with § 93.438, and a prevalence of tuberculosis in their domestic bovine herds equal to or greater than 0.01 percent, but less than 0.1 percent, over the previous year (12 consecutive months).

(d) *Level IV regions.* APHIS considers certain regions of the world to have a program that meets APHIS requirements for tuberculosis classification in accordance with § 93.438, and a prevalence of tuberculosis in their domestic bovine herds equal to or greater than 0.1 percent, but less than 0.5 percent, over the previous year (12 consecutive months).

(e) *Level V regions.* APHIS considers certain regions of the world not to have a program that meets APHIS requirements for tuberculosis classification in accordance with § 93.438, to have a prevalence of tuberculosis in their domestic bovine herds equal to or greater than 0.5 percent, or to be unassessed by APHIS with regard to tuberculosis.

(f) *Listing of regions.* Lists of all Level I regions, Level II regions, Level III regions, Level IV regions, and Level V regions for tuberculosis are found online, at

[http://www.aphis.usda.gov/import\\_export/animals/live\\_animals.shtml](http://www.aphis.usda.gov/import_export/animals/live_animals.shtml). Changes to the lists will be made in accordance with § 93.438.

13. Section 93.438 is added to read as follows:

§ 93.438 Process for requesting regional classification for tuberculosis.

(a) *Request for regional classification; requirements.* A representative of the national government(s) of any country or countries who has the authority to make such a request may request that APHIS classify a region for tuberculosis. Requests for classification or reclassification must be submitted to APHIS electronically or through the mail as provided at [http://www.aphis.usda.gov/import\\_export/animals/live\\_animals.shtml](http://www.aphis.usda.gov/import_export/animals/live_animals.shtml). Guidance regarding how to complete a request in a manner that will allow APHIS to review it expeditiously is available at [http://www.aphis.usda.gov/import\\_export/animals/reg\\_request.shtml](http://www.aphis.usda.gov/import_export/animals/reg_request.shtml), and may also be obtained by contacting the National Director, Regionalization Evaluation Services, Strategy and Policy Unit, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737. At a minimum, in order for APHIS to consider the request complete, it must define the boundaries of the region, specify the prevalence level for tuberculosis within the region, and demonstrate the following:

- (1) That there is effective veterinary control and oversight within the region;
- (2) That tuberculosis is a notifiable disease within the region; and
- (3) That the region has a program in place for tuberculosis that includes, at a minimum:
  - (i) Epidemiological investigations following the discovery of any infected animals or affected herds, or any animals or herds that have had non-negative test results following a test for tuberculosis, and documentation of these investigations;
  - (ii) Management of affected herds in a manner designed to eradicate tuberculosis from those herds in a timely manner, and documentation regarding this management;

(iii) Regulatory controls on the movement of livestock into, within, and from the region that correspond to the risk of dissemination of tuberculosis associated with such movement; and

(iv) Access to, oversight of, and quality controls for diagnostic testing for tuberculosis within the region.

(4) That the region has surveillance in place that is equivalent to or exceeds Federal standards for surveillance within the United States.

(b) *APHIS evaluation.* If, after reviewing and evaluating the request for classification, APHIS believes the region can be accurately classified for tuberculosis, APHIS will publish a notice in the *Federal Register* proposing to classify the region according to § 93.437, and making the information upon which this proposed classification is based available to the public for review and comment. The notice will request public comment.

(c) *APHIS determination.* (1) If no comments are received on the notice, or if comments are received but do not affect APHIS' proposed classification, APHIS will publish a subsequent notice in the *Federal Register* announcing that classification to be final and adding the region to the appropriate list on the APHIS website.

(2) If comments received on the notice suggest that the region be classified according to a different tuberculosis classification, and APHIS agrees with the comments, APHIS will publish a subsequent notice in the *Federal Register* making the information supplied by commenters available to the public, and proposing to classify the region according to this different classification. The notice will request public comment.

(3) If comments received on the notice suggest that insufficient information was supplied on which to base a tuberculosis classification, and APHIS agrees with the comments, APHIS will

publish a subsequent notice in the *Federal Register* specifying the additional information needed before APHIS can classify the region.

(d) *Maintaining classification and reclassification initiated by APHIS.* If a region is classified under the provisions of this section, that region may be required to submit additional information or allow APHIS to conduct additional information collection activities in order for that region to maintain its classification. Moreover, if APHIS determines that a region's classification for tuberculosis is no longer accurate, APHIS will publish a notice in the *Federal Register* announcing the revised classification and setting forth the reasons for this reclassification.

(Approved by the Office of Management and Budget under control number 0579-0442)

14. Section 93.439 is added to read as follows:

§ 93.439 Importation of ruminants from certain regions of the world; tuberculosis.

(a) *Importation of certain ruminants prohibited.* Notwithstanding any other provisions of this section, ruminants that are known to be infected with or exposed to tuberculosis and ruminants that have had a non-negative response to any test for tuberculosis at any time are prohibited importation into the United States.

(b) *Identification of bovines imported for any purpose.* Unless otherwise specified by the Administrator, bovines imported into the United States for any purpose must be officially identified and accompanied by a certificate, issued in accordance with § 93.405(a), that lists the official identification of the animals presented for import.

(c) *Importation of bovines from a Level I region.* Unless specified otherwise by the Administrator, bovines may be imported into the United States from a Level I region for tuberculosis in accordance with paragraph (b) of this section.<sup>12</sup>

(d) *Importation of bovines from a Level II region.* (1) Sexually intact bovines may be imported into the United States from a Level II region for tuberculosis for purposes other than immediate slaughter provided that the bovines are subjected to an individual test for tuberculosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411, with negative results.

(2) Steers or spayed heifers may be imported into the United States from a Level II region for tuberculosis for purposes other than immediate slaughter in accordance with paragraph (b) of this section.

(e) *Importation of bovines from a Level III region.* (1) Bovines directly from currently accredited herds for tuberculosis. Bovines may be imported into the United States for purposes other than immediate slaughter directly from a currently accredited herd for tuberculosis in a Level III region for tuberculosis, provided that:

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

(ii) If sexually intact, the bovines are subjected to an individual test for tuberculosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411, with negative results.

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<sup>12</sup> The importation of such bovines, as well as that of all other bovines covered by this section, is still subject to all other relevant restrictions of this part.

(2) Sexually intact bovines that do not originate directly from a currently accredited herd for tuberculosis may be imported into the United States from a Level III region for tuberculosis for purposes other than immediate slaughter, provided that:

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

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

(iii) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the animals meet the conditions for importation in paragraph (e)(2)(i) of this section.

(3) Steers or spayed heifers that do not originate directly from a currently accredited herd for tuberculosis may be imported into the United States from a Level III region for tuberculosis for purposes other than immediate slaughter provided that:

(i) The steers or spayed heifers are subjected to an individual test for tuberculosis no more than 60 days prior to export of the bovines to the United States, with negative results; and

(ii) The steers or spayed heifers are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the animals meet the conditions for importation in paragraph (e)(3)(i) of this section.

(f) *Importation of bovines from a Level IV region.* (1) Bovines may be imported into the United States for purposes other than immediate slaughter directly from a currently accredited herd for tuberculosis in a Level IV region for tuberculosis, provided that:

(i) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines originate directly from a currently accredited herd for tuberculosis and, if steers or spayed heifers, meet the conditions for importation in paragraph (f)(1)(iii) of this section; and

(ii) If sexually intact, the bovines are subjected to an individual test for tuberculosis at the port of entry into the United States or during post-arrival quarantine in accordance with § 93.411, with negative results; and

(iii) If steers and spayed heifers, the bovines are subjected to an individual test for tuberculosis no more than 60 days prior to export of the bovines to the United States, with negative results.

(2) Sexually intact bovines that do not originate directly from a currently accredited herd for tuberculosis may be imported into the United States from a Level IV region for tuberculosis for purposes other than immediate slaughter, provided that:

(i) The bovines originate from a herd that was subjected to two whole herd tests for tuberculosis on its premises of origin and conducted no less than 9 months and no more than 15 months apart, with the second whole herd test conducted no less than 60 days and no more than 12 months prior the export of the bovines to the United States, with negative results each time; and

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

(iii) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines meet the requirements in paragraph (f)(2)(i) of this section.

(3) Steers or spayed heifers that do not originate directly from a currently accredited herd for tuberculosis may be imported into the United States from a Level IV region for tuberculosis for purposes other than immediate slaughter provided that:

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

(ii) The bovines are subjected to an additional individual test for tuberculosis no more than 60 days prior to export of the bovines to the United States, with negative results, except that the individual test is not required if the bovines are exported within 60 days of the whole herd test and were included in that test; and

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

(g) *Importation of bovines from a Level V region.* At the discretion of the Administrator, bovines may be imported into the United States from a Level V region for tuberculosis for purposes other than immediate slaughter, provided that:

(1) The bovines are subject to a pre-clearance program administered by APHIS and detailed in an import protocol published on the APHIS website; and

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

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

(Approved by the Office of Management and Budget under control number 0579-0442)

15. Section 93.440 is added to read as follows:

§ 93.440 Brucellosis status of foreign regions.

(a) *Level I regions.* APHIS considers certain regions of the world to have a program that meets APHIS requirements for brucellosis classification in accordance with § 93.441, and a prevalence of brucellosis in their domestic bovine herds of less than 0.001 percent over at least the previous 2 years (24 consecutive months).

(b) *Level II regions.* APHIS considers certain regions of the world to have a program that meets APHIS requirements for brucellosis classification in accordance with § 93.441, and a prevalence of brucellosis in their domestic bovine herds equal to or greater than 0.001 percent, but less than 0.01 percent over at least the previous 2 years (24 consecutive months).

(c) *Level III regions.* APHIS considers certain regions of the world not to have a program that meets APHIS requirements for brucellosis classification in accordance with § 93.441, to have a herd prevalence equal to or greater than 0.01 percent, or to be unassessed by APHIS with regard to brucellosis prevalence.

(d) *Listing of regions.* Lists of all Level I, Level II, and Level III regions for brucellosis are found online, at [http://www.aphis.usda.gov/import\\_export/animals/live\\_animals.shtml](http://www.aphis.usda.gov/import_export/animals/live_animals.shtml).

Changes to the lists will be made in accordance with § 93.441.

16. Section 93.441 is added to read as follows:

§ 93.441 Process for requesting regional classification for brucellosis.

(a) *Request for regional classification; requirements.* A representative of the national government(s) of any country or countries who has the authority to make such a request may request that APHIS classify a region for brucellosis. Requests for classification or reclassification must be submitted to APHIS electronically or through the mail as provided at [http://www.aphis.usda.gov/import\\_export/animals/live\\_animals.shtml](http://www.aphis.usda.gov/import_export/animals/live_animals.shtml). Guidance regarding how to complete a request in a manner that will allow APHIS to review it expeditiously is available at [http://www.aphis.usda.gov/import\\_export/animals/reg\\_request.shtml](http://www.aphis.usda.gov/import_export/animals/reg_request.shtml), and may also be obtained by contacting the National Director, Regionalization Evaluation Services, Strategy and Policy Unit, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD, 20737. At a minimum, in order for APHIS to consider the request complete, it must define the boundaries of the region, specify the prevalence level for brucellosis within the region, and demonstrate the following:

- (1) That there is effective veterinary control and oversight within the region;
- (2) That brucellosis is a notifiable disease within the region;
- (3) That the region has a program for brucellosis in place that includes, at a minimum:
  - (i) Epidemiological investigations following the discovery of any infected animals or affected herds, or any animals or herds that have had non-negative test results following a test for brucellosis, and documentation of these investigations;
  - (ii) Management of affected herds in a manner designed to eradicate brucellosis from those herds, and documentation regarding this management;
  - (iii) Regulatory controls on the movement of livestock into, within, and from the region that correspond to the risk of dissemination of brucellosis associated with such movement; and
  - (iv) Access to, oversight of, and quality controls on diagnostic testing for brucellosis within the region;

(4) That the region has surveillance in place that is equivalent to or exceeds Federal standards for brucellosis surveillance within the United States; and

(5) That, if the region vaccinates for brucellosis, it is in a manner that has been approved by APHIS.

(b) *APHIS evaluation.* If, after reviewing and evaluating the request for classification, APHIS believes the region can be accurately classified for brucellosis, APHIS will publish a notice in the *Federal Register* proposing to classify the region according to § 93.440, and making available to the public the information upon which this proposed classification is based. The notice will request public comment.

(c) *APHIS determination.* (1) If no comments are received on the notice, or if comments are received but do not affect APHIS' proposed classification, APHIS will publish a subsequent notice in the *Federal Register* announcing that classification to be final and adding the region to the appropriate list on the Internet.

(2) If comments received on the notice suggest that the region be classified according to a different brucellosis classification, and APHIS agrees with the comments, APHIS will publish a subsequent notice in the *Federal Register* making the information supplied by commenters available to the public, and proposing to classify the region according to this different classification. The notice will request public comment.

(3) If comments received on the notice suggest that insufficient information was supplied on which to base a brucellosis classification, and APHIS agrees with the comments, APHIS will publish a subsequent notice in the *Federal Register* specifying the additional information needed before APHIS can classify the region.

(d) *Maintaining classification and reclassification initiated by APHIS.* If a region is classified under the provisions of this section, that region may be required to submit additional information or allow APHIS to conduct additional information collection activities in order for that region to maintain its classification. Moreover, if APHIS determines that a region's classification for brucellosis is no longer accurate, APHIS will publish a notice in the *Federal Register* announcing the revised classification and setting forth the reasons for this reclassification.

(Approved by the Office of Management and Budget under control number 0579-0442)

17. Section 93.442 is added to read as follows:

§ 93.442 Importation of ruminants from certain regions of the world; brucellosis.

(a) *Importation of certain ruminants prohibited.* Notwithstanding any other provisions of this section, ruminants that are known to be infected with or exposed to brucellosis are prohibited importation into the United States.

(b) *Identification of bovines imported for any purpose.* Unless otherwise specified by the Administrator, bovines imported into the United States for any purpose must be officially identified and accompanied by a certificate, issued in accordance with § 93.405(a), that lists the official identification of the animals presented for import.

(c) *Importation of steers and spayed heifers.* Unless otherwise specified by the Administrator, steers and spayed heifers may be imported into the United States from a region in accordance with paragraph (b) of this section, without further restrictions under this part.

(d) *Importation of sexually intact bovines from Level I regions.* Unless specified otherwise by the Administrator, sexually intact bovines may be imported into the United States from a Level I region for brucellosis in accordance with paragraph (b) of this section.<sup>13</sup>

(e) *Importation of sexually intact bovines from a Level II region.* (1) Sexually intact bovines directly from currently accredited herds for brucellosis. Sexually intact bovines may be imported into the United States for purposes other than immediate slaughter from a currently accredited herd for brucellosis in a Level II region for brucellosis, provided that the bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines originate directly from a currently accredited herd for brucellosis.

(2) Sexually intact bovines that do not originate directly from a currently accredited herd for brucellosis. Sexually intact bovines that do not originate directly from a currently accredited herd for brucellosis may be imported into the United States from a Level II region for brucellosis for purposes other than immediate slaughter, provided that:

(i) The bovines originate from a herd that was subjected to a whole herd test for brucellosis on its premises of origin no more than 90 days and no less than 30 days prior to the export of the bovines to the United States, with negative results; and

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

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<sup>13</sup> The importation of such bovines, as well as that of all other bovines covered by this section, is still subject to all other relevant restrictions of this chapter.

(iii) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines meet the requirements in paragraph (d)(2)(i) of this section.

(f) *Importation of sexually intact bovines from a Level III region.* (1) Sexually intact bovines directly from currently accredited herds for brucellosis. Sexually intact bovines may be imported into the United States for purposes other than immediate slaughter from a currently accredited herd for brucellosis in a Level III region for brucellosis, provided that:

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

(ii) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines originate directly from a currently accredited herd for brucellosis.

(2) Sexually intact bovines that do not originate directly from a currently accredited herd for brucellosis. Sexually intact bovines that do not originate directly from a currently accredited herd for brucellosis may be imported into the United States from a Level III region for brucellosis for purposes other than immediate slaughter, provided that:

(i) The bovines originate from a herd that was subjected to two whole herd tests for brucellosis on its premises of origin conducted no less than 9 months and no more than 15 months apart, with the second test taking place no more than 90 days and no less than 30 days prior to the export of the bovines to the United States, with negative results each time; and

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

(iii) The bovines are accompanied by a certificate, issued in accordance with § 93.405(a), with an additional statement that the bovines meet the requirements in paragraph (e)(2)(i) of this section.

(Approved by the Office of Management and Budget under control number 0579-0442)

Done in Washington, DC, this 14th day of September 2020.

Lorren Walker,

Acting Undersecretary, Marketing and Regulatory Programs.

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