September 2020

SUPPORTING STATEMENT
BRUCELLOSIS AND BOVINE TUBERCULOSIS:
IMPORTATION OF CATTLE AND BISON
OMB CFN 0579-0442
Docket APHIS 2011-0044

NOTE: In response to public comments received for the proposed rule Federal Register notice, the rule has undergone major revision before being published as a final rule. The information collection request was also revised and the title renamed.

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease.

The AHPA is contained in Title X, Subtitle E, Sections 10401-18 of P.L. 107-171, May 13, 2002, the Farm Security and Rural Investment Act of 2002.

Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing the United States' ability to compete in the world market of animal and animal product trade.

The agency charged with carrying out this disease prevention mission is the Animal and Plant Health Inspection Service (APHIS). APHIS regulations for preventing the dissemination of animal diseases within the United States are contained in Title 9 of the *Code of Federal Regulations* (9 CFR), Subchapter B: Cooperative Control and Eradication of Livestock or Poultry Diseases, and Subchapter D: Exportation and Importation of Animals (Including Poultry) and Animal Products. Veterinary Services (VS), a division within APHIS, is responsible for administering these regulations. APHIS amended its import regulations to establish a system to classify foreign regions at particular status levels for bovine tuberculosis (TB) and brucellosis; to establish provisions for modifying the TB or brucellosis classification of a foreign region; and establishing conditions for the importation of cattle and bison from regions with the various classifications.

TB is a contagious disease of both animals and humans. Bovine TB, caused by *M. bovis*, can be transmitted from livestock to humans and other animals. Brucellosis is an infectious disease of animals and humans caused by the bacteria of the genus *Brucella*. The disease is characterized

by abortions and impaired fertility in its principal animal hosts. Brucellosis is mainly a disease of cattle, bison, and swine; *Brucella abortus* is associated with the disease in cattle and bison. There is no economically feasible treatment for brucellosis in livestock.

APHIS is asking OMB to approve for three years use of the information collection activities set forth below in connection with its efforts to prevent TB and brucellosis spread in the United States from imported animals.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

APHIS will use the following information activities to prevent importation of cattle and bison infected with or exposed to TB and brucellosis.

Request for Regional Classification; (9 CFR 93.438(a), 93.441(a)); (Foreign Government)
When the veterinary authorities of a foreign region wish to apply for regional classification for either TB or brucellosis status under Part 93, they must communicate this desire to APHIS via a letter, a copy of which may be emailed. This request letter follows no particular format and may contain as much information as the sender feels necessary.

Application for Recognition of Regional Classification; (9 CFR 93.438(a), 93.441(a)); (Foreign Government)
In addition to the request letter, the region's veterinary authorities must submit certain information about the region as outlined in 9 CFR 93.438(a) and 9 CFR 93.441(a), preferably in the form of a questionnaire available on the APHIS web site. If APHIS receives a request letter without this information, APHIS will provide the questionnaire to the requesting entity and indicate that it needs the information to initiate an evaluation. The region's veterinary authorities must complete and return the questionnaire to APHIS.

The questionnaire (actually comprised of separate sets of questions, one for each disease) is designed to give APHIS specific information necessary to accurately evaluate the animal health status of a region and the associated risk of opening U.S. markets to animal commodities from that region. The questionnaire solicits information regarding the occurrence of and surveillance for TB and brucellosis as well as veterinary controls and oversight. The questionnaire also asks whether TB and brucellosis are notifiable diseases within the region. It further asks whether the region has programs in place for TB and brucellosis that include 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 tests for TB and brucellosis, and documentation of these investigations; documented management of affected herds in a manner designed to quickly eradicate TB and brucellosis from those herds; regulatory controls on the movement of livestock into, within, and from the region that correspond to the risk of dissemination of TB and brucellosis; access to, oversight of, and quality controls for diagnostic testing for TB and brucellosis within the region; and, for brucellosis, vaccination in an APHIS-approved manner if the region vaccinates for brucellosis.

In many instances, the information requested already exists and must simply be entered into the questionnaire format. However, an additional burden is incurred when the respondents must translate information, such as official acts or regulations, into English.

Request for Additional Information about a Region; (9 CFR 93.438(a), 93.441(a)); (Foreign Government)
In some instances, APHIS may determine that the initial information package is incomplete or that it needs more information than was originally requested. If this is the case, APHIS will ask the region to provide additional information. No official form is involved in this collection process; in many cases, the information already exists and will simply need to be sent to APHIS.

Maintaining Classification and Reclassification; (9 CFR 93.438(d), 93.441(d)); (Foreign Government)
If APHIS classifies a region under 9 CFR 93.438 or 9 CFR 93.441, that region may be required to submit additional information or allow APHIS to conduct additional information collection activities so the region can maintain its classification. Moreover, if APHIS determines that a region's classification 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.

Official Identification and Certification; (9 CFR 93.439(b), 9 CFR 93.442(b)); (Foreign Government, Business)
Unless otherwise specified by the APHIS Administrator, bovines imported into the United States for any purpose must be officially identified and accompanied by a certificate, issued in accordance with 9 CFR 93.405(a), that lists the official identification of the animals presented for import.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Requests for regional classification and maintaining classification and reclassification may be sent to APHIS by letter, fax, or email. These documents are not candidates for electronic submission. APHIS has not developed a submission database because the number of yearly submissions is low.

The Application for Recognition of Regional Classification questionnaire will be available at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/ct_reg_request. The data associated with the APHIS regionalization program, including the questionnaire, can be sent to APHIS by letter, fax, or email. The document is not a candidate for electronic submission. APHIS has not developed an electronic submission database because the number of yearly submissions is low.

Identification certificates are available through foreign governments and must physically accompany the export shipment.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

The information that APHIS collects is not available from any other source. APHIS is the only Federal agency responsible for preventing, detecting, controlling, and eradicating TB and brucellosis from the United States.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

APHIS estimates about 25 percent of the respondents are small business entities. The information APHIS collects in connection with this program is the absolute minimum needed to prevent, detect, control, and eradicate TB and brucellosis from the United States.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

Failure to collect this information would make it much more difficult for APHIS to prevent, detect, control, and eradicate TB and brucellosis from the United States. Outbreaks of the diseases would have severe economic consequences on the U.S. cattle industry.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

This information collection is conducted in a manner consistent with the guidelines established in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the Agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program. APHIS contacted them by email and phone to discuss the information APHIS collects to administer its import evaluation and certification practices. We discussed with them how we and they obtain the necessary data and how frequently; how much data is available; the convenience and clarity of reporting formats and other collection instruments; and the clarity of, and necessity for, any recordkeeping

requirements. The respondents stated via email or phone that they had no concerns with any of these items and had no further recommendations.

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The proposed rule was published in the Federal Register on December 16, 2015, and included a 60-day public comment period which was extended (80 FR 78461 and 81 FR 12832). VS received 211 comments and subsequently withdrew those portions of the proposed rule that would have affected the provisions governing domestic brucellosis and tuberculosis programs. A notice announcing the partial withdrawal was published in the Federal Register on March 27, 2019. Comments and actions concerning changes to Part 93, which comprise the final rule, are addressed in the final rule Federal Register notice published on September 17, 2020 (85 FR 57944).

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

No additional assurance of confidentiality is provided with this information collection. However, the confidentiality of information is protected under 5 U.S.C. 552a.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity will ask no questions of a personal or sensitive nature.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.**

  See APHIS Form 71.

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.**

  APHIS estimates the total annualized cost to these respondents to be $38,352. APHIS arrived at this figure by multiplying the hours of estimated response time (907 hours) by the estimated average hourly wage ($29.59) of the respondents and then multiplying the result by 1.429 to capture benefit costs.

  Estimated hourly wages for foreign animal health authorities ($25) was obtained from program international contacts, and for importers/exporters (SOCC 41-4012, $34.19), from the U.S. DOL Bureau of Labor Statistics Occupational Employment Statistics May 2019 Occupation Profiles Report (http://www.bls.gov/current/oes_stru.htm).

  According to DOL BLS news release USDL-20-0451 released March 19, 2020, employee benefits account for 30 percent of employee costs, and wages account for the remaining 70 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.429.

13. Provide estimates of the total annual cost burden to respondents or record keepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

No annual cost burden is associated with capital and startup costs, operation and maintenance expenditures, and purchase of services.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

See APHIS 79. The annualized cost to the Federal Government is estimated at $144,555.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

This final rule information collection request contains 62 responses and 907 hours of burden. There are 21 respondents consisting of businesses and foreign governments. Changes to the rule resulted in a net decrease of 177 responses and 38,156 hours of burden from the proposed rule information collection request.

This information collection request reflects a partial withdrawal of sections reported in the proposed rule published in the *Federal Register* on December 16, 2015, that, if finalized, would have consolidated the regulations governing bovine tuberculosis and those governing brucellosis. Specifically, VS withdrew those portions of the proposed rule that would have affected the provisions governing domestic brucellosis and tuberculosis programs; that is, Parts 50, 51, (indemnity, to be amended to align with the new structure under proposed Part 76 and the elimination/amendments of Parts 77 and 78), 71 (marketing, similar realignment), 76 (the new proposed part that would have contained the administration, classification, management, reporting, and movement requirements for the combined programs, and incorporating a program standards document that was also essentially withdrawn), 77, 78, (the current actual program regulations, which would have been withdrawn entirely for Part 77 and for Parts B and C for Part 78), 86 (traceability, to be amended only slightly to account for the changes to Parts 77 and 78), and 161 (veterinary accreditation, alignment changes only) of 9 CFR. VS took this action after considering the comments it received following the publication of the proposed rule. VS received 211 comments, many objecting to:

- Requirements to submit detailed Animal Health Plans and the plan to base State status on implementation and maintenance of such plans, citing lack of adequate personnel, resources, and funding within States, a differentiation with international standards, and the need for foreign trade partners to re-evaluate their requirements for importing U.S. cattle;

- A proposal to completely drop accreditation for areas with known sources of bovine tuberculosis and brucellosis that present a risk, as well as proposals to require whole herd tests and individual animal tests for captive cervids as a condition of interstate movement unless they came from brucellosis-accredited herds. Cervid producers feared losing existing accreditation, and many pointed out that a national solution for what they viewed as a regional problem was inappropriate.

- A proposal to test exhibit, rodeo, and event cattle and bison 60 days before initial interstate movement and at 180-day intervals after, with limited exceptions. Commenters pointed out that exhibited animals are at much lower risk for disease transmission than rodeo and event cattle.

- Proposals to conduct surveillance testing of known wildlife sources of bovine tuberculosis and brucellosis that pose a risk of transmission to program animals. State animal health and wildlife authorities objected on the basis of overall cost and staffing required, lack of authority to carry out such surveillance, and the stringency of the requirement.

- And, generally, the proposal to combine the two diseases into one program overall, citing differences in disease epidemiology, management, and surveillance not only for the separate diseases but also for the affected species (cattle, bison, and cervids).

The current final rule covers only changes to 9 CFR Part 93 governing the importation of bovine species with respect to bovine tuberculosis and brucellosis. The final rule contains almost all of the proposed changes to Part 93 apart from a requirement that importers from Level V bovine tuberculosis regions enter into a Cooperative and Trust Fund Agreement, with the importer depositing funds with APHIS in an amount determined to cover all of APHIS' costs in providing services in accordance with the Cooperative and Trust Fund Agreement. (Two items that appeared in the collection submitted for the proposed rule relating to a trust fund agreement and deposit of funds did not relate to the proposed rule Cooperative and Trust Fund Agreement provision and were included in the earlier package in error.) APHIS also removed the requirement for two whole herd tests for bovine tuberculosis on the premises of origin conducted no less than 9 months and no more than 15 months apart, with at least the second test administered by an APHIS veterinarian and conducted no less than 60 days before import, with negative results. A notice announcing the partial withdrawal was published in the Federal Register on March 27, 2019.

Consequently, none of the previously reported activities were carried forward, as comments received resulted in the rule revision and the new information collection activities reported in this request. Explanations are provided in the final rule *Federal Register* notice (85 FR 57944).

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

APHIS has no plans to publish information it collects in connection with this program.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

No forms are associated with this information collection.

18. Explain each exception to the certification statement, "Certification for Paperwork Reduction Act."

APHIS can certify compliance with all provisions of the Act.

B. Collections of Information Employing Statistical Methods

Statistical methods are not employed in this information collection activity.