

SUPPORTING STATEMENT
Brucellosis and Bovine Tuberculosis: Importation of Cattle and Bison
OMB Control No. 0579-0442

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 [7 U.S.C. 8301 et. seq.]

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.

In 2020, APHIS amended its import regulations to establish a system to classify foreign regions at designated 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 3 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 uses 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 established 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 (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 is available under the Classification for Bovine Tuberculosis (TB) and Brucellosis tab on the Regionalization Evaluation Services home page on the APHIS Web site, https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/res/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 consulted with the following individuals concerning the information collection activities associated with this program. APHIS emailed and called these people to discuss the information APHIS collects to administer its import evaluation and certification practices; they said they had no concerns about the information needed to evaluate regions for brucellosis or bovine TB status or how APHIS collected that information.

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On Friday, March 31, 2023, APHIS published in the Federal Register (88 FR 19239), a 60-day notice seeking public comments on its plan to request a 3-year renewal of this collection of information. APHIS received three comments from the public which do not have an impact on this information collection.

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 \$42,687. APHIS arrived at this figure by multiplying the hours of estimated response time (907 hours) by the estimated average hourly wage (\$32.48) of the respondents and then multiplying the result by 1.449 to capture benefit costs.

The average hourly rates used to calculate the estimates include the following:

SOCC Code	Average Salary	Occupation Description
no code	\$28.00	Foreign Animal Health Authorities
41-4012	\$36.96	Importers/Exporters
	\$32.48	Average Hourly Salary

The rates were found at the U.S. Bureau of Labor Statistics website https://www.bls.gov/oes/current/oes_stru.htm.

According to DOL BLS news release USDL-23-0488 dated March 17, 2023 (see <https://www.bls.gov/news.release/pdf/ecec.pdf>), benefits account for 31 percent of employee costs, and wages account for the remaining 69 percent. Mathematically, total costs can be calculated as a function of wages, resulting in a multiplier of 1.449.

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 \$179,064.

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

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	62	0	0	0	0	62
Annual Time Burden (Hr)	907	0	0	0	0	907

In this renewal, there are no changes in the estimated burden. Increases in the reported dollar amounts are due solely to wage increases for the members of the public involved and the APHIS employees reviewing the information collected.

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.