November 2023

SUPPORTING STATEMENT
IMPORTATION OF FRESH BEEF FROM PARAGUAY
DOCKET APHIS-2018-0007
OMB CFN 0579-0487

NOTE: Upon publication of the associated final rule and OMB approval of this information collection package, APHIS plans to merge this information collection into information collection 0579-0372.

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 (7 U.S.C. 8301, et seq.) 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.

Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing our ability to compete globally in animal and animal product trade.

As part of this mission, the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases not currently present or prevalent in this country. The regulations in Title 9, *Code of Federal Regulations* (CFR), Parts 93 and 94 prohibit or restrict the importation of specified animals and animal products to prevent the introduction into the United States of various animal diseases, including foot-and-mouth disease (FMD). FMD is a dangerous and destructive communicable disease of ruminants and swine which is not currently present in the United States.

APHIS' animal import regulations in 9 CFR 94.1, 9 CFR 94.11, and 9 CFR 94.29 place certain restrictions on the importation of fresh (chilled or frozen) beef and beef products from Uruguay, Brazil, and Argentina into the United States. Under these regulations, APHIS must collect information (via a Foreign Meat Inspection Certificate) prepared by an authorized veterinary official of the government of the exporting region certifying that specific conditions for importation have been met. To ensure compliance of these conditions are met, APHIS completes on-site evaluation and inspection of foreign slaughtering facilities. APHIS amended the regulations to include imported fresh beef from the country of Paraguay in the restrictions imposed by 9 CFR 94.29.

APHIS is asking OMB to approve for three years the use of these information collection activities to ensure that fresh beef exported from Paraguay pose negligible risk of introducing FMD (among other diseases) into the United States.

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.

Foreign Meat Inspection Certificate (9 CFR 94.11, 9 CFR 94.29) Foreign Government
Imported beef from Paraguay is required to be accompanied by a foreign meat inspection certificate that is completed and signed by an authorized veterinary official of the Government of Paraguay.

The certificate must verify:

- The beef is from animals that have been born, raised, and slaughtered in Paraguay.
- FMD has not been diagnosed in the exporting region of Paraguay within the previous 12 months.
- The beef comes from bovines that originated from premises where FMD has not been present during the lifetime of any bovines slaughtered for the export of beef to the United States.
- The meat comes from bovines that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.
- The meat comes from bovines that received ante-mortem and post-mortem veterinary inspections, paying particular attention to the head and feet, at the slaughtering establishment, with no evidence found of vesicular disease.
- The meat consists only of bovine parts that are, by standard practice, part of the animal's carcass that is placed in a chiller for maturation after slaughter and before removal of any bone, blood clots, or lymphoid tissue. The bovine parts that may not be imported include all parts of the head, feet, hump, hooves, and internal organs.
- All bone and visually identifiable blood clots and lymphoid tissue have been removed from the meat.
- The meat has not been in contact with meat from regions other than those listed in 9 CFR 94.1(a)(2).
- The meat comes from carcasses that were allowed to maturate at 40 to 50˚F (4 to 10˚C) for a minimum of 24 hours after slaughter and that reached a pH below 6.0 in the loin muscle at the end of the maturation period. Measurements of pH must be taken at the middle of both longissimus dorsi muscles. Any carcass in which pH does not reach less than 6.0 may be allowed to maturate an additional 24 hours and be retested, and if the carcass still has not reached a pH of less than 6.0 after 48 hours, the meat from the carcass may not be exported to the United States.

APHIS uses the Foreign Meat Inspection Certificate and the Onsite Evaluation and Inspection of Facilities to ensure that exported fresh beef from Paraguay poses negligible risk of introducing disease into the United States.

Onsite Evaluation and Inspection and Recordkeeping (9 CFR 94.29(k)) (Business)
To verify that facilities processing fresh beef from Paraguay are following the procedures necessary to lead to the results listed in the Foreign Meat Inspection Certificate, APHIS requires the establishment in which cattle are slaughtered to allow periodic on-site evaluation and subsequent inspection of their facilities, records, and operations by an APHIS representative. Facility personnel must participate in the evaluation and inspection which include, but are not limited to, supplying necessary records. APHIS requires facilities to retain, for at least 2 years, all necessary records used for the onsite evaluation and inspection process.

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.

For trade partners who have fully automated systems, APHIS will accept computer extracts of electronic health certification data. These certificates are included in the government wide use of the International Trade Data System (ITDS) via the Automated Commercial Environment (ACE) to improve business operations and further Agency missions.

Evaluations and inspections physically take place at facilities and are therefore not candidates for electronic submission.

Facilities may use electronic recordkeeping systems.

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 APHIS collects in connection with this program is not available from any other source. APHIS is the only Agency responsible for preventing the introduction of exotic animal diseases into the United States.

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

The information APHIS collects is the absolute minimum needed to effectively evaluate the FMD and other disease risk associated with fresh beef imports from Paraguay. The veterinarians who complete the required forms are considered foreign entities and thus are not “small entities” for purposes of Executive Order 12866 or the Regulatory Flexibility Act.

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.

If the information was collected less frequently or not collected, APHIS would be unable to establish an effective defense against the entry and spread of FMD and other animal diseases from imports of fresh beef from Paraguay. The result would cause serious health consequences for U.S. livestock and economic consequences for the U.S. livestock 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.

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than 3 years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

No special circumstances exist that would require this information collection to be conducted in a manner inconsistent with the general information collection guidelines 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 contacted these respondents by email and phone to discuss the information APHIS collects to administer its meat import requirements, specifically how it is obtained, how frequently, the convenience and clarity of reporting formats and other collection instruments; and the clarity of, and necessity for, any recordkeeping requirements. The respondents had no concerns with any of these items and had no further recommendations.

Steve Sanger
Orleans International, Incorporation
30600 Northwestern Hwy, Suite 300
Farmington Hills, MI 48334
Tel. (248) 855-5556

Tiffany Lee
Director, Regulatory and Scientific Affairs
North American Meat Institute
1150 Connecticut Ave NW, 12th floor
Washington, DC 20036
Tel. (202) 587-4248

Rick Smaligo
Sampco, Inc.
651 W. Washington Blvd, Suite 300
Chicago, IL 60661
(312) 346-1506

Notice of this proposed rule was published in the Federal Register on March 27, 2023, and included a 60-day public comment period (see 88 FR 18077). During this time, interested members of the public had opportunity to provide APHIS with their input concerning the usefulness, legitimacy, and merit of the information collection activities APHIS is proposing. No comments were received affecting the activities and estimates in this request.

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

This information collection does not involve any 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 will be 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 does not ask any 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.**

  Respondents are authorized veterinary officials employed by the Government of Paraguay as well as managers of foreign facilities that process fresh beef. APHIS estimates the total cost to respondents to be $160.43 by multiplying the total burden hours (4) by the estimated average hourly wage of the veterinary officials and managers ($27.68) and then multiplying the result ($110.72) by 1.449 to capture benefit costs.

  The average hourly rates used to calculate the estimate are for foreign veterinarians, $32.04; foreign exporters, $18.00; and foreign processors of restricted animal materials, $33.00. APHIS determined the estimated hourly wages using information from the USDA's International Services personnel in foreign regions, the U.S. Department of Labor website https://www.bls.gov/oes/current/oes_stru.htm, foreign veterinarian information found at www.healthassistancepartnership.org/veterinarian-salary/, and Salary.com.

  According to DOL BLS news release USDL-23-0488, (dated 03/17/2023, www.bls.gov/news.release/ ecec.Nr0.htm), 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 recordkeepers 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 $4,976.

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	3	0	3	0	0	0
Annual Time Burden (Hr)	4	0	4	0	0	0
Annual Cost Burden ($)	0	0	0	0	0	0

This is a new information collection for a final rule.

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

APHIS has no plans to publish the 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.

There are no forms associated with this information collection.

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

APHIS can certify compliance with all provisions in the Act.

B. Collections of Information Employing Statistical Methods

Statistical methods are not employed in this information collection activity.