

**SUPPORTING STATEMENT - OMB NO. 0579-0372
IMPORTATION OF BEEF AND OVINE MEAT FROM URUGUAY AND BEEF FROM
ARGENTINA AND BRAZIL**

Note: The 0579-0449 *Importation of Bone-in Ovine Meat from Uruguay* collection has been combined into this (0579-0372) collection for this renewal. Once OMB approves the renewal of 0579-0372, 0579-0449 will be retired.

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 rinderpest and 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 beef and ovine meat from Uruguay into the United States. Under these regulations, APHIS must collect information, prepared by an authorized certified official of the Government of Uruguay, certifying that specific conditions for importation have been met. APHIS amended 9 CFR 94.29 to expand the kind of ovine meat allowed into the United States to include bone-in lamb.

APHIS further restricts imports of fresh (chilled or frozen) beef and beef products from a region in northern Argentina composed of the Provinces of Buenos Aires, Catamarca, Chaco, Córdoba, Corrientes, Entre Ríos, Formosa, Jujuy, Mendoza, Misiones, La Pampa, La Rioja, Salta, San Juan, San Luis, Santa Fe, Santiago del Estero, and Tucumán, as well as from a region in Brazil composed of the States of Bahia, Distrito Federal, Espirito Santo, Goias, Mato Grosso, Mato Grosso do Sul, Minas Gerais, Parana, Rio Grande do Sul, Rio de Janeiro, Rondonia, Sao Paulo, Sergipe, and Tocantis, into the United States under 9 CFR 94.29. APHIS must collect information (via a Foreign Meat Inspection Certificate), prepared by an authorized veterinary official of the Governments of Argentina and Brazil, certifying that specific conditions for importation have been met. For some of those conditions to be met, APHIS must complete an on-site evaluation and inspection of foreign slaughtering facilities.

APHIS is asking OMB to approve its use of these information collection activities to ensure that ovine products and beef from Uruguay, and beef and beef products from Argentina and Brazil, 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.

9 CFR 94.11; 9 CFR 94.29. Uruguay - Foreign Meat Inspection Certificate (Foreign Government)

Imported beef and ovine meat from Uruguay must be accompanied by a foreign meat inspection certificate that is completed and signed by an authorized veterinary official of the Government of Uruguay.

The certificate must verify:

- The meat is beef or ovine meat from animals that have been born, raised, and slaughtered in Uruguay.
- The meat comes from sheep that received FMD testing and 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.
- If FMD is detected anywhere in Uruguay, the export of beef or ovine meat from all of Uruguay to the United States is prohibited until at least 6 months have elapsed since the depopulation, cleaning, and disinfection of the last infected premises. If a restricted zone for FMD is established anywhere in Uruguay, the export of beef or ovine meat from that restricted zone to the United States is prohibited until at least 12 months have elapsed since the depopulation, cleaning, and disinfection of the last infected premises in the restricted zone.
- The meat comes from sheep or cattle that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.

- The meat comes from sheep or cattle 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 beef or ovine parts that are, by standard practice, part of the animal's carcass that is placed in a chiller for maturation after slaughter. The bovine or ovine 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 mature at 40 to 50°F (4 to 10°C) for a minimum of 36 hours after slaughter and that reached a pH of 5.8 or less 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 5.8 or less may be allowed to mature an additional 24 hours and be retested, and if the carcass still has not reached a pH of 5.8 or less after 60 hours, the meat from the carcass may not be exported to the United States.

Bone-in ovine meat from Uruguay requires additional certification under 9 CFR 94.11. This additional certification must give the name and official establishment number of the establishment where the animals were slaughtered, and shall state that:

- The slaughtering establishment is not permitted to receive animals that originated in, or have ever been in, or that have been aboard a means of conveyance at the time such means of conveyance called at or landed at a port in, a region where FMD exists.
- The slaughtering establishment is not permitted to receive meat or other animal products derived from ruminants or swine which originated in an FMD-affected region, or meat or other animal products from an FMD-free region transported through an FMD-affected region except in containers sealed with serially numbered seals of the national government of the noninfected region of origin.

APHIS will use the Foreign Meat Inspection Certificate and the Onsite Evaluation and Inspection of Facilities (included later in this information collection package) to ensure that beef and ovine products from Uruguay pose negligible risk of introducing disease into the United States.

9 CFR 94.29(g)(2)(iii) - Animal Identification (Business)

Bone-in meat from Uruguay may be exported to the United States if it is derived from select lambs never vaccinated for FMD maintained in an APHIS-approved program in a segregated facility. Official, unique identification tags (visual tag in the left ear and RFID tag in the right ear) are applied to all select lambs before entry into the select lamb facility. The identification number of each lamb is verified at multiple steps within the select lamb program. The tags, with information captured in Uruguay's National Livestock Information System, allow U.S. and

Uruguayan officials to trace lambs and ensure their health status from their place of birth to slaughter.

Applying individual identification tags to the select lambs and requiring identification of select lambs with uniquely numbered ear tags helps assure only FMD test-negative lambs are ultimately exempted from the deboning requirement. The unique identification number of the select lambs is linked to their individual FMD test status, allowing officials to verify each animal's health status.

9 CFR 94.29 - Testing of Select Lambs (Business)

Individual testing of select lambs for antibodies to FMD virus is done before movement off the source farm. Producers work with veterinarians with the local animal health division of Uruguay's national Directorate of Livestock Services to facilitate blood sample collection from select lambs at the source farm and record data into the Uruguay National Livestock Information System. Samples are sent to the central laboratory of the Veterinary Laboratories Division of the Directorate for FMD testing. If all tests of select lambs in the source flock are negative, the lambs move to the select lamb facility. If any animal were to test positive to the screening test, the group of lambs is held for follow-up testing. If these test results are negative, the remaining lambs are released to the select lamb facility; however, lambs that tested positive are not allowed to move to the facility. If the follow-up test is positive, then movement restrictions will be placed on the source farm while an investigation is conducted to determine if evidence of FMD virus circulation exists. Test results are reported within approximately 1 day of submission. Movement must occur within 7 days after testing and verification by an authorized veterinary official of the government of Uruguay on the Foreign Meat Inspection Certificate (listed above).

9 CFR 94.29. Argentina - Foreign Meat Inspection Certificate (Foreign Government)

Imported beef from northern Argentina must be accompanied by a foreign meat inspection certificate that is completed and signed by an authorized veterinary official of the Government of Argentina.

The certificate must verify:

- The meat is from animals that have been born, raised, and slaughtered in the exporting region of Argentina.
- If FMD is detected in the exporting region of Argentina, the export of beef from all of Argentina to the United States is prohibited until at least 12 months have elapsed since the depopulation, cleaning, and disinfection of the last infected premises.
- The meat comes from cattle that originated from premises where foot-and-mouth disease has not been present during the lifetime of any cattle slaughtered for the export of beef to the United States.
- The meat comes from cattle that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.
- The meat comes from cattle 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 parts that are, by standard practice, part of the animal's carcass that is placed in a chiller for maturation after slaughter. The 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).
- The meat comes from carcasses that were allowed to mature at 40 to 50°F (4 to 10°C) for a minimum of 24 hours after slaughter and that reached a pH of 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 mature 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.

9 CFR 94.29. Brazil - Foreign Meat Inspection Certificate (Foreign Government)

Imported beef from the specific regions in Brazil must be accompanied by a foreign meat inspection certificate that is completed and signed by an authorized veterinary official of the Brazilian Government to ensure that the beef and beef products are safe for importation.

The certificate must verify:

- The meat is beef from cattle that have been born, raised, and slaughtered in the specific region of Brazil set forth in the regulations.
- FMD has not been diagnosed in the specific region of Brazil within the previous 12 months.
- The beef came from cattle that originated from premises where FMD has not been present during the lifetime of any cattle slaughtered for the export of beef to the United States.
- The beef came from cattle that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.
- The beef came from cattle that received antemortem and postmortem veterinary inspections, paying particular attention to the head and feet, at the slaughtering establishment, with no evidence found of vesicular disease.
- The beef 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. Bovine parts that may not be imported include all parts of bovine heads, feet, hump, hooves, and internal organs.
- All bone and visually identifiable blood clots and lymphoid tissue have been removed from the beef.
- The beef has not been in contact with meat from regions other than those listed in 9 CFR 94.1(a)(2).
- The beef came from bovine carcasses that were allowed to mature at 40 to 50°F (4 to 10°C) for a minimum of 36 hours after slaughter and that reached a pH of 5.8 or less in the loin muscle at the end of the maturation period. Measurements for pH must be taken at the middle of both longissimus dorsi muscles. Any carcass in which the pH does not reach 5.8 or less may be allowed to mature an additional 24 hours and be retested,

and if the carcass still has not reached a pH of 5.8 or less after 60 hours, the meat from the carcass may not be exported to the United States.

9 CFR 94.29(k). Onsite Evaluation and Inspection (and recordkeeping) (Business)

To verify that facilities processing ovine meat from Uruguay, and beef and beef products from Uruguay, Argentina, and Brazil, are following the procedures necessary to lead to the results listed in the Foreign Meat Inspection Certificate, APHIS requires the establishment in which cattle and sheep 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 accepts 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.

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

Identification tags also accompany/are attached to the animals in the shipment, and are thus not candidates for electronic transmission.

Testing information must accompany the animal and specimens, as well, not making it a candidate 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 ovine and beef product imports from Uruguay as well as beef and beef products from Argentina and Brazil. The veterinarians who complete the required forms and the producers who affix the required identification 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 Uruguay beef and ovine product imports as well as imports of beef and beef products from Argentina and Brazil. 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;**
Select lamb test results are reported within approximately 1 day of submission and movement must occur within 7 days after testing.
- **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 other 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:

Steve Sanger
Orleans International, Incorporation
30600 Northwestern Highway
Suite 300
Farmington Hills, Michigan 48334
(248) 855-5556

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

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

APHIS contacted these respondents by email and phone to discuss the information APHIS collects to administer its meat import requirements. 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.

On Monday, April 6, 2020, APHIS published a 60-day notice on pages 19132-19133 of the Federal Register (85 FR 19132) seeking public comment on its plans to request renewal of this collection of information. There were zero (0) comments received.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration 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 asks 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. Burden estimates were developed from discussions with Uruguayan, Argentinian, and Brazilian Federal animal health authorities who complete the certificates necessary to export ovine meat, beef, and beef products to the United States, as well as managers of facilities preparing the meat and products for export.

• 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 Governments of Uruguay, Argentina, and Brazil, as well as managers of foreign facilities that process meat and meat products. APHIS estimates the total cost to respondents to be \$424,995.53. APHIS arrived at this figure by multiplying the total burden hours (10,045) by the estimated average hourly wage of the above respondents (\$28.77) and then multiplying the result (\$288,994.65) by 1.4706 to capture benefit costs.

According to DOL BLS news release USDL-20-0451, dated March 2020 (see <https://www.bls.gov/bls/news-release/ecec.htm>), benefits account for 32 percent of employee costs, and wages account for the remaining 68 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.4706. The hourly rate was derived from the U.S. Department of Labor, Bureau of Labor Statistics March 2020 Report – Occupational Employment and Wages in the United States.

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.

The annualized cost to the Federal government is estimated at \$445,710.73. (See APHIS Form 79.)

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

	Requested	Program Change	Program Change	Change Due to	Change Due to	Previously Approved
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		Due to New Statute	Due to Agency Discretion	Adjustment in Agency Estimate	Potential Violation of the PRA	
Annual Number of Responses	19,458	0	+4,236	0	0	15,222
Annual Time Burden (Hr)	10,044	0	0	-4,758	0	14,802
Annual Cost Burden (\$)	0	0	0	0	0	0

Overall there is an increase of 4,236 responses and a decrease of 4,758 total burden hours. APHIS has seen a significant decrease in the amount of imported beef from Uruguay, however this renewal now includes burden from 0579-0449 *Importation of Bone-in Ovine Meat from Uruguay*, which has caused the total responses to increase due to adding animal identification and testing of select lambs.

Although this additional information has caused an increase in total responses, there has been decrease in the amount of imported beef from Uruguay, which has caused the number of responses per respondent to also decrease and result in an overall decrease in the total burden hours.

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.