

**SUPPORTING STATEMENT - OMB NO. 0579-0449**  
**IMPORTATION OF BONE-IN OVINE MEAT FROM URUGUAY**

2017

**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 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 of the *Code of Federal Regulations* (CFR) part 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).

APHIS' animal import regulations in sections 94.1, 94.11, and 94.29 place certain restrictions on the importation of 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 is asking OMB to approve its use of these information collection activities to ensure that bone-in ovine products from Uruguay 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.**

APHIS will use the following information collection activities in conjunction with other information collection activities previously approved under 0579-0040 and 0579-0372 to ensure that bone-in ovine products from Uruguay pose negligible risk of introducing exotic animal disease into the United States.

### **9 CFR 94.22 - Foreign meat inspection certificate (Foreign Federal Government)**

Imported 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 ovine meat from animals that have been born, raised, and slaughtered in Uruguay.
- The meat comes from sheep maintained in a program approved by the APHIS Administrator, meeting the following requirements:
  - The meat comes from sheep that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.
  - 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.
  - The meat consists only of ovine parts that are, by standard practice, part of the animal's carcass that is placed in a chiller for maturation after slaughter. The 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 §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 24 hours after slaughter and that reached a pH of below 6.0 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 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 - Animal Identification (Business)**

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, in conjunction with information captured in Uruguay's National Livestock Information System, provide for traceability of 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 provide assurance that 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 verification of 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 would move to the select lamb facility. If any animal were to test positive to the screening test, the group of lambs would be held while follow-up testing is conducted. If these test results are negative, the remaining lambs would be released to the select lamb facility; however, lambs that tested positive would not be 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 verified by an authorized veterinary official of the government of Uruguay on the Foreign Meat Inspection Certificate (listed above).

**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, we will be accepting computer extracts of electronic health certification health certification data. These certificates are included in the governmentwide utilization of the International Trade Data System (ITDS) via the Automated Commercial Environment (ACE) to improve business operations and further Agency missions.

The Foreign Meat Inspection certificate employed in this program must physically accompany the shipment, and requires an original signature from the authorizing veterinarian to be valid; therefore, it is not a candidate for electronic transmission.

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.

**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 product imports from Uruguay. The veterinarians who complete the required information 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 exotic animal diseases from Uruguay ovine product imports. This 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;**  
Select lamb test results are reported within approximately 1 day of submission and movement must occur within 7 days after testing.
- **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 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 spoke to the following individuals concerning the information collection activities associated with this program:

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

Laurie Huenike, International Trade Specialist  
 122 C Street, N.W., Suite 875  
 Washington, DC 20001  
 202-347-3600

Robert L. Morris, Jr.  
 International LLC  
 8417 Amparan, El Portal Industrial Park  
 Laredo, TX 78045-1829  
 956-723-6492  
[norris@morrisintl.Jlc.com](mailto:norris@morrisintl.Jlc.com)

The proposed rule, Docket Number APHIS-2015-0050, was published in the Federal Register on July 1, 2016, with a 60-day comment period. During this time, 17 comments were received by interested members of the public, which included producers, importers, exporters, industry and professional associations, specialty food retailers, and representatives of local and foreign

governments. Ten commenters were generally supportive of the proposed rule. Four commenters were opposed to the proposed rule but did not address specific provisions. The remaining commenters raised questions or concerns about the proposed rule and the risk analysis.

There were no changes made to the proposed rule in response to the comments and it is being adopted as a final rule, without change.

**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 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. Burden estimates were developed from discussions with Uruguay Federal animal health authorities.

- **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 Uruguay and producers in Uruguay. APHIS estimates the total annualized cost to these respondents to be \$162,162. APHIS arrived at this figure by multiplying the total burden hours (9,009 hours) by the estimated average hourly wage of the above respondents (\$18).

The hourly rate was determined through discussions with International contacts based in Uruguay.

**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 \$215, 661. (See APHIS Form 79.)

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

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	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	18,006	0	18,006	0	0	0
Annual Time Burden (Hr)	9,009	0	9,009	0	0	0
Annual Cost Burden (\$)	0	0	0	0	0	0

This is a new information collection resulting in 9,009 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.**

NA. There are no Agency forms included in 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.