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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. APHIS-2015-0050]

RIN 0579-AE21

Importation of Bone-In Ovine Meat From Uruguay

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations governing the importation of certain animals, meat, and other animal products by allowing, under certain conditions, the importation of bone-in ovine meat from Uruguay. Based on the evidence in a risk assessment that we have prepared, we believe that bone-in ovine meat can safely be imported from Uruguay provided certain conditions are met. This proposal would provide for the importation of bone-in ovine meat from Uruguay into the United States, while continuing to protect the United States against the introduction of foot-and-mouth disease.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to

<http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0050>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2015-0050, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0050> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Stephanie Kordick, Import Risk Analyst, Regional Evaluation Services, National Import Export Services, VS, APHIS, 920 Main Campus Drive Suite 200, Raleigh, NC; (919) 855-7733; Stephanie.K.Kordick@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) prohibit or restrict the importation of certain animals and animal products into the United States to prevent the introduction of various diseases, including rinderpest, foot-and-mouth disease (FMD), African swine fever, classical swine fever, and swine vesicular disease. These are dangerous and destructive communicable diseases of ruminants and swine. Section 94.1 of the regulations contains criteria for recognition by the Animal and Plant Health Inspection Service (APHIS) of foreign regions as free of rinderpest or free of both rinderpest and FMD. Section 94.11 restricts the importation of ruminants and swine and their meat and certain other products from regions that are declared free of rinderpest and FMD but that nonetheless present a disease risk because

of the regions' proximity to or trading relationships with regions affected by rinderpest or FMD. Regions APHIS has declared free of FMD and/or rinderpest, and regions declared free of FMD and rinderpest that are subject to the restrictions in § 94.11, are listed on the APHIS Web site at http://www.aphis.usda.gov/import_export/animals/animal_disease_status.shtml.

APHIS considers rinderpest or FMD to exist in all regions of the world not listed as free of those diseases on the Web site. APHIS considers Uruguay to be free of rinderpest. However, APHIS does not consider Uruguay to be free of FMD because Uruguay vaccinates cattle against FMD. With few exceptions, the regulations prohibit the importation of fresh (chilled or frozen) meat of ruminants or swine that originates in or transits a region where FMD is considered to exist. One such exception is beef and ovine meat from Uruguay and specified regions of Argentina and Brazil. The regulations in § 94.29 allow the importation of fresh beef and ovine meat into the United States from these regions provided that the following additional conditions have been met:

- The meat is beef from animals born, raised, and slaughtered in the exporting regions of Argentina or Brazil, or is beef or ovine meat from animals born, raised, and slaughtered in Uruguay.
- FMD has not been diagnosed in the exporting region within the previous 12 months.
- The meat comes from bovines or sheep that originated from premises where FMD had not been present during the lifetime of any bovines or sheep slaughtered for the export of beef and ovine meat to the United States.
- The meat comes from bovines or sheep that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.

- The meat comes from bovines or sheep 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 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 and 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 the regulations as free of rinderpest and FMD.
- 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.
- An authorized veterinary official of the government of the exporting region certifies on the foreign meat inspection certificate that the above conditions have been met.
- The establishment in which the bovines and sheep are slaughtered allows periodic on-site evaluation and subsequent inspection of its facilities, records, and operations by an APHIS representative.

In response to an official request from the Government of Uruguay that APHIS allow the importation of fresh (chilled or frozen) bone-in ovine meat into the United States from Uruguay, we have conducted a risk analysis of their proposed select lamb program, which can be viewed on the Regulations.gov Web site or in our reading room.¹ The Government of Uruguay has proposed an exemption from the FMD deboning mitigation required in § 94.29(g) for ovine meat from a select group of lambs that would be subject to additional mitigations, including individual animal testing for FMD virus, individual animal identification with both visual and radio frequency identification (RFID) ear tags, and segregation of selected lambs from other FMD-susceptible animals following testing. For the risk analysis, we evaluated information provided by Uruguay's Ministry of Livestock, Agriculture, and Fisheries (MGAP), reviewed scientific literature, and conducted a site visit to the proposed exporting region. We concluded that Uruguay possesses the necessary barriers to introduction of FMD, as well as the ability to detect an introduction, prevent its spread, and eradicate FMD, should it occur. We further concluded that, because of the measures in place in Uruguay, the likelihood that lambs selected for exemption from the deboning requirement would be exposed to FMD from susceptible Uruguayan livestock or wildlife is very low. When subjected to the proposed select lamb measures, including multiple tests for FMD virus, individual identification, and segregation in a protected facility, followed by maturation of carcasses, we conclude that the likelihood that bone-in meat derived from the selected lambs would be contaminated with FMD virus is negligible. Based on the evidence documented in our risk assessment, we believe that fresh (frozen or chilled) bone-in ovine meat can be safely imported from Uruguay, provided certain

¹ Instructions on accessing Regulations.gov and information on the location and hours of the reading room may be found at the beginning of this document under ADDRESSES. You may also request paper copies of the risk analysis by calling or writing to the person listed under FOR FURTHER INFORMATION CONTACT.

conditions are met. Accordingly, we are proposing to amend the regulations in § 94.29 to allow the importation of fresh bone-in ovine meat from Uruguay under certain conditions.

Risk Analysis

Drawing on information provided by the Government of Uruguay and observations from our site visit, we have conducted a risk analysis that evaluates the likelihood of entry of FMD as a result of importing fresh (frozen or chilled) bone-in ovine meat from Uruguay derived from lambs subjected to the measures included in Uruguay's proposed select lamb program. A summary of the evaluation is discussed below.

The risk analysis was conducted in accordance with World Organization for Animal Health (OIE) standards for import risk analysis. Under OIE standards, the first step of an import risk analysis is hazard identification, which is the identification of pathogenic agents associated with the commodity that could result in adverse consequences if imported with the commodity. FMD virus is the only hazard considered in this analysis.

Following the hazard identification step, a risk assessment is conducted. The risk assessment evaluates the likelihood of entry, establishment, and spread of the specified hazard as a result of importing the commodity, and the consequences of exposure to the hazard. It usually consists of four parts: entry assessment, exposure assessment, consequence assessment, and risk estimation. However, if the likelihood of entry of, or exposure to, the hazard is determined to be negligible, the assessment may be concluded. Because the entry likelihood for the commodity under evaluation in this assessment was determined to be negligible, exposure and consequence assessments were not necessary and the risk assessment was concluded with an estimation of negligible risk.

Based on our analysis, we have determined that fresh (frozen or chilled) bone-in ovine meat can be safely imported into the United States from Uruguay under certain conditions.

Entry Assessment

The entry assessment estimates the likelihood of an imported commodity being infected or contaminated with a hazard. For the purpose of our risk analysis, entry refers to the introduction of live FMD virus into the United States through imports of fresh, maturated ovine meat from Uruguayan lambs that have not been vaccinated against FMD and have been subjected to the proposed mitigations as described below, in addition to restrictions specified in 9 CFR 94.29 with the exception of deboning.

The entry assessment is divided into two sections. First, we conducted a review of Uruguay's overall FMD status and FMD program. This review was based on APHIS' 2002 and 2007 evaluations in combination with updated information from 2014. Second, we provide additional information about, and an evaluation of the proposed select lamb program.

Previous Evaluations of Uruguay's FMD Program

APHIS has evaluated Uruguay's FMD control measures in beef (in 2002) and ovine meat (in 2007). As part of those evaluations, we reviewed and analyzed various components essential to the exclusion, detection, and control of FMD for their ability to constitute an effective FMD program. This program includes entry controls at Uruguay's border, national surveillance in susceptible species, traceability systems, as well as other measures. As a result of those evaluations, and with the inclusion of updated information from 2014, we concluded that Uruguay has the veterinary and regulatory infrastructure to adequately monitor and control the possible incursion of FMD.

Proposed Select Lamb Program

The Government of Uruguay has requested an exemption from the FMD deboning mitigation required in 9 CFR 94.29(g) for ovine meat. They have piloted and presented to APHIS an alternative that involves three main elements: Individual animal testing for FMD, individual identification (visual and RFID) that is part of the national traceability system, and separation of select lambs from other FMD-susceptible animals. This program exists within the framework of Uruguay's national FMD program, which includes entry controls at Uruguay's borders, routine serologic surveillance, clinical surveillance, an effective movement and traceability system, a competent diagnostic laboratory, vaccination of its cattle population, a robust official veterinary services agency with knowledgeable personnel, and an effective preparedness and response system for FMD.

Uruguay's animal health authority, the General Directorate of Livestock Services (DGSG), is responsible for general oversight and auditing of the select lamb program and also has a direct role in some aspects of the program, including approval of source farms, application of identification devices, and collection and submission of blood for FMD testing. However, officials with the Uruguayan Wool Secretariat (SUL) are responsible for most of the day-to-day activities at the facility where the select lambs are housed.

Uruguay would only be permitted to export bone-in ovine meat from select lambs provided that FMD is not introduced into the country and the rest of the requirements in § 94.29 are met.

Sourcing of Select Lambs

Only sheep that have never been vaccinated against FMD would be considered for participation in the select lamb program. Although Uruguay vaccinates its cattle population

against FMD as part of a nationwide systematic campaign, vaccination of sheep has been prohibited in Uruguay since 1988.

Source farms for the select lamb program are member establishments of SUL. They must maintain records demonstrating a history of good production practices with good animal health standards, animal welfare standards, and environmental measures. Only a few farms are used to source lambs for each season. Lambs are purchased from the farms by SUL. Once SUL has selected the source farms, they inform DGSG and request approval for movement to the select lamb facility. DGSG verifies that there are no movement restrictions or animal health concerns in the proposed source farms. If approved, DGSG registers the farms as providers to the select lamb facility in Uruguay's Animal Health Information System (SISA). SISA is a comprehensive electronic database that incorporates data from public and private sources at the local, regional, and national levels.

Requiring DGSG approval of source farms and only selecting farms with good animal health and welfare standards reduces the likelihood that FMD is present in source flocks for the select lamb facility. In combination with national FMD control measures, including routine national serosurveillance, awareness programs and notification requirements for FMD, and import controls at Uruguay's border, the likelihood that FMD virus-infected lambs are selected for inclusion in the proposed program is very low.

Identification of Select Lambs

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 to 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

(SNIG) and SISA, 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 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 in SISA, allowing verification of each animal's health status upon entry into the select lamb facility and again at the slaughter plant. Incorporation of the animals' identification tag numbers into SNIG also helps ensure that the final product can be traced back to the source farm of each lamb exempted from the deboning requirement.

Testing of Select Lambs

Individual testing of select lambs for antibodies to FMD virus is done prior to movement off the source farm. Veterinarians with the local animal health division of DGSG collect blood samples from select lambs at the source farm, apply identification tags, and record data in SNIG. Samples are sent to the central laboratory of the Veterinary Laboratories Division of DGSG 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 entire group of lambs would be held while follow-up testing is conducted in the test-positive animals. If these follow-up test results are negative, the remaining lambs would be released to the select lamb facility; however, lambs that tested positive to the screening test (but negative on subsequent testing) would not be allowed to move to the facility. If the follow-up test is positive, then movement of any animals off of the source farm would be prohibited and an investigation conducted to determine if there is evidence of FMD virus circulation within the source farm.

Test results are reported within approximately 1 day of submission. Movement of FMD-test negative lambs to the select lamb facility must occur within 7 days after testing.

Following FMD sample collection and application of ear tags, select lambs are isolated from other animals at the source farm prior to movement to the select lamb facility. The lambs remain segregated from other FMD-susceptible animals from sampling through slaughter and after slaughter their carcasses remain in separate channels throughout processing.

The sensitivity of the FMD antibody test used to screen select lambs prior to entry to the segregated facility is greater than 99 percent. Because the lambs originate from a small number of farms, with several lambs selected from each farm, and due to the highly contagious nature of FMD, antibodies to FMD virus are expected to be present in more than one select lamb if the source farm were affected, increasing the likelihood of detection. Because cattle are vaccinated for FMD in Uruguay and routine surveillance for FMD is conducted in cattle and sheep, it is unlikely that source flocks would be affected with FMD, increasing the likelihood further that lambs testing negative to the screening test truly are negative.

After the lambs have entered the select lamb facility, the flock is subjected to a second round of testing at the herd level, using the same tests for screening and confirmation as in the individual testing. This is done to increase confidence that select lambs were not exposed to FMD on the source farm shortly before initial testing, when incubating FMD infection prior to production of antibodies might result in a false negative response to the first round of testing. Because it is possible that the production of antibodies to FMD virus following exposure of susceptible animals may take several days, the herd level test would be performed no sooner than 28 days after entry of the lambs to the select lamb facility, to allow time for production of antibodies in potentially infected animals. The second round of testing would have to be

conducted on a sample of lambs large enough to allow for detection of FMD if it were present in at least 5 percent of the animals in the flock, at a confidence level of 95 percent. As above, because of the highly contagious nature of FMD, it is likely that the disease would spread within the flock to greater than 5 percent of the lambs if FMD were introduced from one of the source flocks; therefore, this level of sampling should provide for an additional level of safety in assuring that FMD is not present in the select lamb population.

Management of Lambs Within the Select Lamb Facility

The select lamb facility is located in Cerro Colorado, in the interior of Uruguay. The facility is owned by SUL and has been used for research in the past for projects such as crossbreeding for more productive wool and meat-type sheep and improved fertility.

The facility is approximately 315 hectares in size and is surrounded by a double wire fence system, with 5 feet separating the 2 fences. The external fence is approximately 6 feet high, and the internal fence is approximately 4 feet high and electrified. The area around the fence line is clear cut and herbicide is regularly applied along the fence line. The voltage of the internal fence is checked daily; if fewer than 3,000 volts are measured, the entire fence line is checked and the low-voltage problem is identified and resolved. The property is divided into 30 pastures separated by single fencing. Each pasture can hold approximately 300 lambs.

There is a single point of entry into the facility, allowing for application of biosecurity measures. Authorization and registration is required for entry of all animals, personnel, vehicles, and equipment. Tires and undercarriages of vehicles are disinfected upon entry in the facility. Visitors are required to use footbaths and wear coveralls and booties in order to access the facility.

The property has facilities dedicated to working with sheep. There are facilities for loading and unloading of animals, isolation, introduction of material and equipment, storage of food and veterinary products, waste and carcass disposal, water supply, etc. The isolation facilities are used for each newly introduced group of select lambs. Lambs from different source flocks may enter the facility over a period of a few days; however, the facility operates on an all-in, all-out basis, and once the lambs within a production group have been assembled, the facility is closed to new entries.

Two employees of SUL work exclusively at the facility, evaluating the lambs and checking the fence line on a daily basis. They receive training in animal health, hygiene, and biosecurity. Technical supervision is provided by a DGSG-accredited veterinarian employed by SUL and dedicated to the facility.

Once every 30 days each lamb is weighed and receives an individual visual inspection. The employees check that the ear tags are in place, and re-sort the lambs based on changes in weight, if necessary. If lambs are moved to a different pasture, the SUL veterinarian is informed and he or she, in turn, notifies DGSG of the change so that SNIG can be updated.

The select lambs are sheared 1 month prior to slaughter. Shearing equipment is dedicated to the facility and remains on-site. All work vehicles and working animals (two herding dogs, one guard dog, and one horse) used within the facility remain on the facility.

Each lamb that dies prior to slaughter is necropsied by the SUL veterinarian. At the time of our site visit in 2014, the cohort of lambs at the facility had less than 3 percent mortality. Mortality is usually due to Pasteurella pneumonia and weather-related issues. If there is any question or concern about the diagnosis, the carcass is sent to the regional DGSG laboratory for additional evaluation.

There are no livestock adjacent to the facility; surrounding farms are mostly used for timber. If movement of livestock into these areas were proposed, MGAP would not allow it (they have the authority and ability to control all livestock movement in the country).

The select lamb facility provides housing for the lambs in a manner that prevents commingling with other livestock. Facility biosecurity measures, particularly the electrified fencing, reduce, but do not eliminate the potential for contact with wild animals. Free-roaming deer and peccaries, which are FMD-susceptible animals, are present in Uruguay. Because of measures in Uruguay to prevent the entry of FMD into the country and to detect it if it were present, APHIS considers the facility's biosecurity measures to be adequate to preserve the identity, traceability, and health status of the select lambs. If FMD were to be detected anywhere in Uruguay, meat exports from animals housed in the facility would be halted immediately. The intense management practices at the select lamb facility would also allow for ample opportunity to detect signs of FMD in the select lambs, even if the signs were subtle.

Processing of Select Lambs at the Slaughter Facility

All lambs at the select lamb facility are processed at the San Jacinto slaughter plant. The plant has two separate slaughter lines, one for beef and one for sheep. Staff at the plant are trained to work both lines, but only one line – either beef or sheep – is run per day. The sheep capacity is 4,200 per shift. All lambs from the select lamb facility are processed in a single day and no other animals are processed at the plant on that day. This significantly reduces the possibility that a non-select lamb would be exempted from deboning. Additionally, the only sheep in Uruguay that have ear tag identification devices are the select lambs, and each ear tag is electronically read at the slaughter plant to ensure it belongs to a select lamb that has been housed at the SUL facility and tested negative for FMD.

Lambs in each lot are assigned a sequential number at the slaughter plant corresponding to the order of slaughter. This number and the date of slaughter are linked to the animals' individual tag number to allow trace back of each carcass and the products produced from it to the farm of origin and test results of the lamb.

When the select lambs arrive at the plant, the accompanying transport documents are examined before off-loading occurs, and seals are inspected by DGSG officials to ensure that they are intact and match the paperwork. Then the lambs are unloaded, checked to ensure ear tags are in place, and moved into pens where ante-mortem inspection is conducted. If any physical abnormalities are observed a notation is made on the pen card. Ante-mortem inspection is relatively cursory; however, post-mortem inspection is much more thorough, with up close visual inspection of each lamb's oral cavity, interdigital spaces, and coronary band. Any animals that die prior to slaughter are necropsied on-site by an official veterinarian and disposed of through rendering. If any discrepancies with respect to the identification of the select lambs are noted, all of the meat from the entire lot would be diverted to the domestic market or would be required to be deboned prior to export.

Following slaughter, carcasses of select lambs are kept in chilling rooms with only carcasses of other select lambs for the duration of maturation. To ensure that the temperature inside the chilling room remains within the desired range throughout the maturation process, the chamber temperature is measured several times: When staff begins loading the carcass into the chamber, when loading has been completed, and every 30 minutes until the chamber is opened after 24 hours have passed. All temperature data points are captured on a chart that becomes part of the official record. If the temperature falls outside of the required zone (between 4 and 10 °C)

at any point in the process, all of the carcasses in the chamber are rejected for export and redirected to domestic consumption.

At the conclusion of the maturation period, a DGSG veterinary inspector checks the pH of the longissimus dorsi muscle of every carcass. If the pH is 6.0 or higher, the carcass is rejected for export. The pH meters are calibrated daily by the plant's internal laboratory.

Following processing, all meat products derived from the select lambs are affixed with labels identifying those products as having been derived from select lambs that are exempted from the deboning requirement. The labels contain sufficient information to be able to trace each package of meat to the date of slaughter and premises of origin of the animal from which it was derived.

Requiring identification of select lambs with uniquely numbered ear tags that are linked to the FMD test history and status of the lambs in the SISA database helps ensure that only meat from select lambs will be exempted from the deboning requirement prior to export to the United States. Prohibiting slaughter of other animals on the day that select lambs are processed at the San Jacinto slaughter plant will also contribute to this assurance. Additional procedures, such as the requirement that lambs pass a clinical examination from an accredited veterinarian prior to shipment to the slaughter plant and receive a thorough post-mortem examination by a DGSG veterinarian at the plant, and that the carcasses of the select lambs undergo maturation, which is verified through pH evaluation of every carcass, routine temperature checks in the maturation chamber, and daily checks of pH meters, further reduce the likelihood that meat produced from select lambs and exported to the United States would be contaminated with FMD virus to a negligible level. Accordingly, we are proposing to amend the regulations in § 94.29 to allow the importation of fresh bone-in ovine meat from Uruguay under certain conditions.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available by contacting the person listed under FOR FURTHER INFORMATION CONTACT or on the Regulations.gov Web site (see ADDRESSES above for instructions for accessing Regulations.gov).

APHIS is proposing to exempt ovine meat imported from Uruguay from the deboning requirement for a select group of lambs subjected to additional risk mitigating measures. These measures include testing for FMD with negative results, individual animal identification (both visual and radio frequency) and traceability, and segregation of selected lambs from FMD-susceptible animals following testing.

In 2013, the Food and Agriculture Organization of the United Nations estimated the sheep population in Uruguay to be 7.5 million head, generating income both from the sale of wool and sheep meat. With the exception of dairy farms, most of the livestock farms in Uruguay are mixed, running both beef cattle and sheep. There are approximately 15,000 farms with sheep, but income from sheep is only a minor proportion of total income.

Uruguay has requested the exemption from the deboning requirement specifically to export rack of lamb, which includes the rib bones, to the United States. These cuts are higher quality and command a higher price than lamb meat which has been deboned as currently required.

Given the additional risk mitigating measures, Uruguay expects to export bone-in meat from up to 6,000 lambs per year. These lambs would be between 6-8 months of age at the time of slaughter, producing a total carcass weight of lamb meat of about 100 tons per year. While all meat from these lambs would be eligible for import under this rule, the focus would likely be on rack of lamb, which represents about one quarter of this weight, or about 25 tons.

Over the last 3 years, the United States has imported an average of about 46,000 tons of bone-in lamb meat annually, valued at over \$419 million. The vast majority of these imports have been from Australia and New Zealand, with small quantities from Canada, Chile, and Iceland. Annual imports of 100 tons of bone-in lamb from Uruguay would be equivalent to less than 3/10 of 1 percent of total annual bone-in lamb imports into the United States.

Given the very small quantity of bone-in lamb meat expected to be imported from Uruguay, this action would not have a significant economic impact on domestic producers or importers, large or small.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS-2015-0050. Please send a copy of your comments to: (1) APHIS, using one of the methods described under ADDRESSES at the beginning of this document, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

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. Imported animals must also be officially identified and select animals tested. APHIS is proposing to amend 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 this information collection activity to ensure that ovine products from Uruguay pose negligible risk of introducing FMD among other diseases into the United States.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.5 hour per response.

Respondents: Federal animal health authorities in Uruguay and exporters of sheep and ovine meat from Uruguay to the United States.

Estimated annual number of respondents: 6,006.

Estimated annual number of responses per respondent: 3.

Estimated annual number of responses: 18,006.

Estimated total annual burden on respondents: 9,009 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

List of Subjects in 9 CFR part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR Part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, NEWCASTLE DISEASE, HIGHLY PATHOGENIC AVIAN INFLUENZA, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, SWINE VESICULAR DISEASE, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701-7772, 7781-7786, and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

2. In 94.29, paragraph (g) is revised to read as follows.

§ 94.29 Restrictions on importation of fresh (chilled or frozen) beef and ovine meat from specified regions.

* * * * *

(g) All bone and visually identifiable blood clots and lymphoid tissue have been removed from the meat; except that bone-in ovine meat from Uruguay may be exported to the United States under the following conditions:

(1) The meat must be derived from select lambs that have never been vaccinated for FMD;

(2) The select lambs must be maintained in a program approved by the Administrator.

Lambs in the program must:

(i) Be segregated from other FMD-susceptible livestock at a select lamb facility operated under the authority of the national veterinary authority of Uruguay;

(ii) Be subjected to an FMD testing scheme approved by the Administrator; and

(iii) Be individually identified with official unique identification that is part of a national traceability system sufficient to ensure that only the products of select lambs meeting all required criteria are exempt from the deboning requirement.

(3) Select lambs and their products must not be commingled with other animals and their products within the slaughter facility.

* * * * *

Done in Washington, DC, this _____ day of _____ .

Administrator, Animal and Plant Health Inspection Service.

[http://sp.we.aphis.gov/PPD/RAD/Dockets/Dockets/2015 Dockets/15-050-1.docx](http://sp.we.aphis.gov/PPD/RAD/Dockets/Dockets/2015%20Dockets/15-050-1.docx) smt 12/8/15

OGC changes made 3/1/16 smt

PRA information added 4/20/16 smt