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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: Final rule.

SUMMARY: We are amending 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 prepared, we believe that bone-in ovine meat can safely be imported from Uruguay provided certain conditions are met. This final rule will 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: Effective [Insert date 30 days after date of publication in the Federal Register].

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. 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.

On July 1, 2016, we published in the *Federal Register* (81 FR 43115-43120, Docket No. APHIS-2015-0050) a proposal¹ to amend the regulations to allow the importation of fresh bone-in ovine meat from Uruguay under certain conditions.

We solicited comments concerning our proposal for 60 days ending August 30, 2016. We received 17 comments by that date. They were from 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. The comments are discussed below.

¹ To view the proposed rule, the supporting documents, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0050>.

Risk Analysis

One commenter stated that previous risk assessments, conducted in 2002 and 2012, are too old and should not be used to support this action. The commenter also stated that the 2014 site visit appears to be an update of the 2012 visit.

The 2014 risk assessment focused on evaluation of factors related to the system of mitigations proposed for the select lambs. While specific conclusions reached in previous evaluations were not necessarily revisited, information collected during the 2014 evaluation substantiated our previous conclusions.

Two commenters stated that before action is taken on this matter, an updated and comprehensive quantitative risk analysis should be conducted and the results made available to the public for review and comment.

Most of APHIS' risk analyses for FMD have been, and continue to be, qualitative in nature. APHIS believes that, when coupled with site visit evaluations, qualitative risk analyses provide the necessary information to assess the risk of the introduction of FMD through importation of commodities such as fresh ovine meat. Quantitative risk analysis models may not be the best tool to use to assess the risk of FMD posed by exports from a country, such as in cases where the types of data required by such models are either unavailable or suffer from a high level of parameter uncertainty. In these instances, APHIS' approach is to characterize the risk of outbreak qualitatively in order to determine what appropriate measures to implement in order to mitigate the risk posed to the United States in the event of an outbreak in the exporting country (e.g., maturation and pH of meat, no diagnosis of FMD in the previous 12 months).

One commenter stated that a transparent review process for the recognition of the animal health status for export countries, to include documented management controls and written

reporting of site visits, would provide livestock stakeholders in the United States with the assurance of a rigorous, scientific decisionmaking process for assessing and minimizing animal disease risks associated with the trade of animals and animal products.

The risk analysis document, which was made available at the time the proposed rule was published, includes all relevant information collected during the evaluation process, including during the site visit. APHIS encouraged review and comment on this document, especially if additional scientific information is available that informs the risk determination.

In the past, site visit reports and other relevant documents have either been made available as part of the supporting documentation accompanying the proposed rule or upon request. Going forward, these documents will routinely be made available at the time of publication.

One commenter stated that when a product has increased value -- in this case bone-in lamb meat sales to the United States from Uruguay -- and there are like products in other zones, regions, or areas of lower value because they cannot export their products, there is an opportunity for transshipment or smuggling. The commenter stated that such risk should be measured and included in a quantitative risk analysis.

APHIS notes that this comment could be understood in different ways. If the commenter is referring to the potential for illegal importation of ovine meat not derived from select lambs from Uruguay, we note that the risk of direct smuggling of ovine meat into the United States is outside the scope of the risk analysis.

If the commenter's concern is that animals or their products could be smuggled into Uruguay and represented as Uruguayan lambs (or ovine meat), we note that all lambs selected for inclusion in the select lamb facility originate from source flocks that have been certified by

the national veterinary authority of Uruguay. Each lamb that enters the facility receives an official ear tag by the government authority and once the cohort is complete the flock is closed to new entries. The national veterinary authority of Uruguay is responsible for oversight and audit of the select lamb facility. Traceability is maintained from the source flock to the finished, labeled product at the slaughter plant.

Surveillance and Testing

One commenter stated that more information is needed on the specific procedures used by the Veterinary Laboratories Division of Uruguay (DILAVE). The commenter stated that information should be published on the laboratory quality control procedures, the proper use of positive and negative controls, and other procedures in place to routinely assess the quality and accuracy of the current diagnostic testing procedures used. The commenter also stated that while FMD test kits are validated by laboratories approved by the World Organization for Animal Health (OIE), the labs using the test kits should provide evidence of annual or more frequent blind testing for accuracy by an independent agency.

Information about laboratory procedures and practices at DILAVE were evaluated as part of the 2002 and 2012 evaluations. These procedures were determined to be satisfactory as a result of those evaluations. Updated information was provided as part of the current evaluation; DILAVE has since updated its quality assurance program, hiring a quality manager and achieving International Organization for Standardization (ISO) 9001:2008 certification and ISO/IEC17025-2005 accreditation, which help ensure compliance with laboratory standards. DILAVE continues to use OIE-validated test kits for its FMD testing. Therefore, APHIS maintains confidence in Uruguay's laboratory capacity for the detection of FMD virus.

One commenter expressed concern about the serological surveillance conducted in Uruguay. The commenter stated that the term “systematic sampling” is used but not well-defined. The commenter also stated that depending on the type of “systematic sampling” used, significant bias could be introduced that would lessen the likelihood of selecting and detecting an FMD infected animal. As an example, the commenter stated that the assumption of a 0.5 percent prevalence among herds means that a sampling scheme could miss testing an infected herd or flock for every 200 herds sampled and that a very large number of herds would have to be sampled to ensure that the population does not include a few infected herds. The commenter noted that APHIS states that since FMD is a highly contagious disease, most animals in a herd would be infected. The commenter stated that this assumption may not be true for sheep raised in a country with a reasonably aggressive vaccination program being practiced in cattle.

Uruguay’s national serologic surveillance program for FMD has been addressed in prior evaluations. The active surveillance component of the program has included herd level testing within the bovine and ovine populations, using both systematic and random selection of animals, depending on the study and the year. APHIS determined that the overall sampling scheme was rigorous. Furthermore, under the proposed system of mitigations, additional FMD testing is conducted in 100 percent of lambs upon entry into the select lamb facility followed by herd level testing within the facility prior to slaughter.

Two commenters stated that the claims of sensitivity of the FMD virus antibody test for sheep are not supported by the studies, as cited. The Sharma study² cited in the risk analysis did not examine sheep, and therefore, there is no scientific basis in that study to support that the

² Sharma, G. K., J. K. Mohapatra, et al. (2014). "Comparative evaluation of non-structural protein-antibody detecting ELISAs for foot-and-mouth disease sero-surveillance under intensive vaccination." *Journal of Virological Methods* 207: 22-28.

assay would have a 99 percent sensitivity in sheep. The commenters stated that the Brocchi study³ cited in the risk analysis did examine sheep but reported in the abstract a 99 percent sensitivity only for cattle.

Although the number of sheep tested in the Brocchi study was too small to derive statistical conclusions, because results in sheep mirrored those in cattle, with a detection rate of 100 percent 20 days post-infection, the authors concluded that the findings of the study indicated “performances [for sheep were] similar to those observed for cattle,” which was 99 percent overall. In addition, many peer-reviewed articles have demonstrated that the 3ABC non-structural protein (NSP) enzyme-linked immunosorbent assay (ELISA) has adequate diagnostic sensitivity when used in sheep, including both those with clinically apparent and subclinical disease.⁴

³ Brocchi, E., I. Bergmann, et al. (2006). “Comparative evaluation of six ELISAs for the detection of antibodies to the non-structural proteins of foot-and-mouth disease virus.” *Vaccine* 24(47): 6966-6979.

⁴ Armstrong, R.M., Cox, S.J., Aggarwal, N., Mackay, D.J., Davies, P.R., Hamblin, P.A., Dani, P., Barnett, P.V. and Paton, D.J., 2005. “Detection of antibody to the foot-and-mouth disease virus (FMDV) non-structural polyprotein 3ABC in sheep by ELISA.” *Journal of Virological Methods*, 125(2): 153-163.

Blanco, E., Romero, L.J., El Harrach, M. and Sánchez-Vizcaíno, J.M., 2002. “Serological evidence of FMD subclinical infection in sheep population during the 1999 epidemic in Morocco.” *Veterinary Microbiology*, 85(1): 13-21.

Bruderer, U., Swam, H., Haas, B., Visser, N., Brocchi, E., Grazioli, S., Esterhuysen, J.J., Vosloo, W., Forsyth, M., Aggarwal, N. and Cox, S., 2004. “Differentiating infection from vaccination in foot-and-mouth-disease: evaluation of an ELISA based on recombinant 3ABC.” *Veterinary Microbiology*, 101(3): 187-197.

Lu, Z., Cao, Y., Guo, J., Qi, S., Li, D., Zhang, Q., Ma, J., Chang, H., Liu, Z., Liu, X. and Xie, Q., 2007. “Development and validation of a 3ABC indirect ELISA for differentiation of foot-and-mouth disease virus infected from vaccinated animals.” *Veterinary Microbiology*, 125(1): 157-169.

Sørensen, K.J., Madsen, K.G., Madsen, E.S., Salt, J.S., Nqindi, J. and Mackay, D.K.J., 1998. “Differentiation of infection from vaccination in foot-and-mouth disease by the detection of antibodies to the non-structural proteins 3D, 3AB and 3ABC in ELISA using antigens expressed in baculovirus.” *Archives of Virology*, 143(8): 1461-1476.

One commenter stated that in the executive summary of an audit report carried out by the European Commission (EC) in March 2012 concerning the animal health controls for FMD in Uruguay, three outstanding issues were noted as weakening the system of FMD controls in Uruguay. The first of these was insufficient attention paid to targeting official on-the-spot controls on FMD vaccination and deficient official reporting of those controls. Without appropriate targeting, adequate vaccination coverage in all areas with an increased risk of FMD cannot be ensured.

As we explained in the proposed rule, Uruguay vaccinates cattle against FMD, but does not vaccinate sheep. APHIS evaluated factors related to the proposed system of mitigations for sheep in the 2014 risk assessment. The cattle vaccination program was not re-evaluated at this time; however, in our previous evaluations we determined that the vaccination program for cattle in Uruguay was robust. Additionally, the report cited in this comment determined that the observed deficiencies were compensated by the high level of cooperation observed among farmers, and that annual surveys demonstrated that immunity levels in the national cattle population clearly exceeded the OIE recommended target of 80 percent, demonstrating adequate vaccine coverage.

The commenter noted that the second issue identified in the EC report was a very limited contribution of passive surveillance to the detection and notification of suspect cases of vesicular diseases.

APHIS evaluated the contribution of passive surveillance to the overall national surveillance program in Uruguay in its 2012 evaluation, concluding that the measures were “effective and rigorous.” Although national surveillance was not re-evaluated in the October 2015 risk assessment, documents provided by Uruguay support these conclusions, demonstrating

the continued legal requirements for notification of suspicious cases of FMD on the part of all livestock owners and workers and an ongoing awareness program. In addition to these requirements for animal owners and handlers, clinical inspection of livestock is conducted by official personnel during routine farm visits, at points of animal concentration such as auctions and at sanitary posts within the country, resulting in inspection of over 1 million head per year. APHIS also notes that passive surveillance within the population of lambs designated for slaughter for export is carried out within the select lamb facility by the two full time employees assigned to the facility, as described in the risk analysis. APHIS believes that surveillance activities carried out in the national livestock population of Uruguay and the select lamb facility are sufficient to detect FMD if present.

The third issue noted by the commenter in the EC report was non-validated sensitivity of the combination of diagnostic tests used to carry out the sero-epidemiological checks conducted since 2007 aimed at proving the absence of virus circulation in cattle and ovine populations.

APHIS notes that the EC report addressed Uruguay's use of the ELISA 3A and 3B tests to detect NSP, rather than the 3ABC NSP test, as recommended by the Pan American Foot and Mouth Disease Center. As described in the risk assessment, Uruguay is currently using the 3ABC NSP ELISA, the recommended screening test, in this cohort of lambs. In addition, although APHIS did not re-evaluate the national FMD surveillance program in the current risk assessment, documentation received from Uruguay demonstrate that the recommended protocol was put in place beginning in late 2012, after the conclusion of the report.

One commenter stated that a readily available and up-to-date FMD vaccine bank for the United States with the capacity to meet the demands of a type 3 or greater FMD outbreak should be a priority action for the agency.

We recognize that, depending on the size and scope of an FMD outbreak, the production and distribution of vaccines could prove challenging. While we do have a resource in the North American Foot-and-Mouth Disease Vaccine Bank (NAFMDVB), which stores many types of inactivated FMD virus antigens, this resource might be overwhelmed in the face of a large and expanding outbreak. APHIS continues to discuss this issue and engage our stakeholders in planning and preparation for any response, including identification of options and potential funding sources for expansion of the bank. In the event that the United States experiences an FMD outbreak in which a specific strain is identified, the United States Department of Agriculture will notify the NAFMDVB, which will request the manufacturing of finished vaccine from approved suppliers, based on the stockpiled antigens.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

Executive Orders 12866 and 13771 and Regulatory Flexibility Act

This final 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. Further, because this final rule is not significant, it is not a regulatory action under Executive Order 13771.

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 on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

With this rule, APHIS will exempt sheep 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 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 that 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 will be between 6-8 months of age at the time of slaughter, producing a total carcass weight of lamb meat of about 100 metric tons (MT) per year. While all meat from these lambs will be eligible for import under this rule, the focus will likely be on rack of lamb, which represents about one quarter of this weight, or about 25 MT.

From 2012 through 2015, the United States imported an average of about 43,300 MT of bone-in lamb meat annually, valued at over \$427 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 MT 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 will 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 will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings 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 final rule, which were filed under 0579-0449, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the *Federal Register* providing notice of what action we plan to take.

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 rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

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 are amending 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. Section 94.29 is amended as follows:

- a. By revising paragraph (g); and
- b. By revising the OMB citation at the end of the section.

The revisions 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.

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(Approved by the Office of Management and Budget under control numbers 0579-0372, 0579-0414, 0579-0428, and 0579-0449)

Done in Washington, DC, this 6th day of September 2017.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

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