Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. APHIS–2008–0085]

RIN 0579–AD17

Importation of 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 to allow, under certain conditions, the importation of fresh (chilled or frozen) ovine meat from Uruguay. Based on the evidence in a risk assessment that we have prepared, we believe that fresh (chilled or frozen) ovine meat can safely be imported from Uruguay provided certain conditions are met. These actions would provide for the importation of 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 April 25, 2011.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0085* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send one copy of your comment to Docket No. APHIS–2008–0085, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2008–0085.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room 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) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Silvia Kreindel, Senior Staff Veterinarian, Regionalization Evaluation Services Staff, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–8419.

SUPPLEMENTARY INFORMATION:

Background

Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture may prohibit the importation of any animal or article if the Secretary determines that the prohibition is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock.

Pursuant to this Act, 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 9 CFR part 94 (referred to below as the regulations) 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). These are dangerous and destructive communicable diseases of ruminants and swine.

Section 94.1 of the regulations lists regions of the world that are declared free of rinderpest and FMD. Section 94.11 lists regions that have been determined to be free of rinderpest and FMD, but that are subject to certain restrictions because of their proximity to or trading relationships with rinderpest- or FMD-affected regions.

In a final rule effective and published in the **Federal Register** on May 29, 2003 (68 FR 31940–31949, Docket No. 02–109–3), we amended the regulations to authorize the importation of fresh beef from Uruguay, a region of the world that we do not recognize as free of FMD, under certain conditions. Those conditions, found in § 94.22 of the regulations, require that the meat come from bovines that have been born, raised, and slaughtered in Uruguay, that the bovines have not been exposed to FMD on their premises of origin or through contact with bovines from other premises, that the bovines are subject to inspections and processing designed to detect FMD and remove potentially affected body parts, that the beef is subject to a maturation process designed to deactivate the FMD virus, that Uruguay is free of FMD for a year prior to the export of the beef, and that the beef has not come in contact with meat from FMD-affected regions.

In 2006, Uruguay's Ministry of Livestock, Agriculture, and Fisheries (MGAP) submitted information to APHIS in support of their request that we amend the regulations to allow the importation of fresh ovine meat into the United States.

In response to this request, APHIS prepared a risk assessment, which can be viewed on the Internet on the Regulations.gov Web site or in our reading room.[1] This assessment pays close attention, in particular, to the role sheep played in the last outbreak of FMD in Uruguay in 2001, and the likelihood that FMD has been introduced into the domestic ovine population within the country since that time. In addition, as part of our evaluation of the risks associated with Uruguay's request, APHIS conducted a site visit in Uruguay in March 2007.

Based on the risk assessment and the site visit, we have determined that it is not necessary to prohibit the importation of fresh (chilled or frozen) ovine meat from Uruguay, provided certain requirements, similar to those described above for fresh beef and discussed later in this document, are met. These requirements would be

[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 assessment by calling or writing the person listed under **FOR FURTHER INFORMATION CONTACT**.

nearly identical to the existing requirements for the importation of beef; hence we are proposing to revise § 94.22 to authorize the importation of both beef and ovine meat from Uruguay into the United States.

Mitigation Measures for the Importation of Ovine Meat From Uruguay

There are several risk factors associated with the importation of ovine meat from Uruguay. We discuss our proposed mitigation measures for these risk factors in the following paragraphs.

Uruguayan Origin of Ovine Meat; Restrictions on Contact With Meat of a Different Region of Origin

Currently, paragraph (a) of § 94.22 requires that beef from Uruguay must come from bovines that have been born, raised, and slaughtered in Uruguay. Likewise, paragraph (h) of § 94.22 currently requires that beef from Uruguay not have been in contact with meat from regions other than those listed in § 94.1(a)(2), which lists regions declared to be free of both rinderpest and FMD. We would subject ovine meat from Uruguay to these same requirements. As documented in our assessment, Brazil and Argentina, countries that border Uruguay, both experienced outbreaks of FMD as recently as 2006, and FMD is under control, but endemic, in the region of South America surrounding Uruguay.

FMD Status of Uruguay

Currently, paragraph (b) of § 94.22 requires that FMD not have been diagnosed in Uruguay within the previous 12 months before beef from Uruguay is exported to the United States. We would amend the paragraph so that it would state that, if FMD is detected anywhere in Uruguay, the export of beef and ovine meat from all of Uruguay 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 current provision could be construed to state that the 12 month prohibition begins following diagnosis of the last affected animal during an outbreak, while eradication, cleaning, and disinfection efforts are still ongoing. This is not the case; it is APHIS' policy that the 12 month prohibition begins only after all "stamping out" efforts cease.

Premises of Origin

Paragraph (c) of § 94.22 currently requires that beef from Uruguay exported to the United States come from bovines that originated from premises where FMD has not been present during the lifetime of any bovines slaughtered for the export of beef to the United States. We would modify paragraph (c) so that it would pertain to both bovines and sheep. This measure is necessary because sheep that have been exposed to FMD on their premises of origin pose an unacceptably high risk of spreading the disease.

Movement From the Premises of Origin

Paragraph (d) of § 94.22 currently requires that beef from Uruguay come from bovines that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals. We would also subject ovine meat from Uruguay to this requirement, which addresses the risk of cattle or sheep coming into contact with or commingling during transit to slaughter with animals from regions in which FMD is known to exist, or that have not been evaluated by APHIS with regard to their FMD status.

Ante- and Post-Mortem Inspections

Paragraph (e) of § 94.22 currently requires that beef from Uruguay come from bovines that received ante- and post-mortem veterinary inspections, paying particular attention to the head and feet, at the slaughtering establishment, with no evidence found of vesicular disease. Because FMD has a short incubation period, if animals were infected with FMD at a premises of origin, it is likely that lesions would be visible in at least a few of those animals at the slaughtering establishment prior to slaughter. Similarly, post-mortem inspection of carcasses would be likely to identify any lesions and vesicles in animals infected with FMD. Since the lesions associated with FMD occur primarily on the feet and in the mouth, particular attention must be paid to the head and feet during these inspections. Because ante- and post-mortem inspections are effective in reducing disease risk, we are proposing to also require ante- and post-mortem inspections for sheep slaughtered for the export of fresh (chilled or frozen) ovine meat from Uruguay to the United States.

Restrictions on Certain Ovine Parts

Paragraph (f) of § 94.22 currently requires that beef from Uruguay consist 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. Accordingly, the paragraph prohibits the importation of all parts of bovine heads, feet, hump, hooves, or internal organs.

We would apply this requirement to ovine meat from Uruguay, and would therefore authorize the importation into the United States 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. As a result, we would continue to prohibit the importation of ovine heads, feet, hooves, and internal organs into the United States; sheep have no humps.

While portions of a sheep's head, feet, hooves, and internal organs may reach the necessary pH level to inactivate the FMD virus during the required maturation process (*see* the section below titled "Maturation Process"), these items can contain lymph tissue, depot fat, and blood clots that may potentially harbor active FMD virus, even after that process; hence the need for this requirement.

Bone, Blood Clots, and Lymphoid Tissue

Paragraph (g) of § 94.22 currently requires all bone and visually identifiable blood clots and lymphoid tissue to be removed from beef from Uruguay prior to export to the United States. We would subject ovine meat from Uruguay to this same requirement.

The removal of bones and visually identifiable blood clots is necessary because any FMD virus these parts might potentially harbor may not be inactivated by the maturation process described later in this document. Although we consider the removal of these parts to be necessary, we recognize that meat may contain small portions of blood clots or lymphoid tissue that are not visually identifiable as such. Because such small parts are unlikely to harbor any FMD virus that is not inactivated by the maturation process, and because we recognize that it would be difficult, if not impossible, to remove parts of blood clots or lymphoid tissue that are not recognizable as such, we have specified that all visually identifiable blood clots and lymphoid tissue would have to be removed.

Maturation Process

Paragraph (i) of § 94.22 currently requires that beef from Uruguay come from bovine carcasses that were allowed to maturate 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. It further states that measurement of the pH must be taken at the middle of both *longissimus dorsi* muscles. Finally, it provides that any carcass in which the pH does not reach 5.8 or less may be allowed to maturate an additional 24 hours and be retested, and states that, 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. These requirements are based on the fact that the FMD virus in meat is inactivated by acidification, which occurs naturally during maturation. An acid environment of a pH of 5.8 or less destroys the virus quickly. Accordingly, we would subject ovine meat from Uruguay to these same requirements.

APHIS Inspection of Slaughtering Establishments

Paragraph (j) of § 94.22 currently requires that an authorized veterinary official of the Government of Uruguay certify on the foreign meat inspection certificate that the conditions for importation of the beef have been met. Similarly, paragraph (k) currently requires that the establishment in which the bovines are slaughtered allow periodic APHIS inspection of their facilities, records, and operations. We would subject ovine meat from Uruguay to these requirements. We believe that, in the great majority of cases, certification by an authorized veterinary official of Uruguay will be sufficient verification that the ovine meat has met the conditions for importation into the United States. However, because of the possibility of occasional differing interpretations of the regulations, we consider it advisable to have provisions within the regulations enabling APHIS representatives to have access to slaughtering establishments for periodic inspections.

Finally, we note that, in addition to the above provisions, any ovine meat imported from Uruguay would have to meet the additional certification requirements under § 94.11(c). That paragraph prohibits the export-approved slaughter establishment from receiving FMD-susceptible animals or animal products that originated, transported, or commingled with animals or animal products from regions that APHIS does not consider as FMD-free.

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.

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 fresh (chilled or frozen) ovine meat from Uruguay. Based on the evidence in a recent risk assessment, we believe that fresh (chilled or frozen) ovine meat can be safely imported from Uruguay provided certain conditions are met.

We have prepared an economic analysis for this proposed rule. The analysis, which considers the number of and type of entities that are likely to be affected by this action and the potential economic effects on those entities, provides the basis for the Administrator's determination that this action would not have a significant impact on a substantial number of small entities. The economic analysis may be viewed on the Regulations.gov Web site (*see* **ADDRESSES** above for instructions for accessing Regulations.gov). Copies of the economic analysis are also available from the person listed under **FOR FURTHER INFORMATION CONTACT**.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) No retroactive effect will be given to this rule and (2) 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–2008–0085. Please send a copy of your comments to: (1) Docket No. APHIS–2008–0085, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238, 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.

We are proposing to amend the regulations governing the importation of certain animals, meat, and other animal products to allow, under certain conditions, the importation of fresh (chilled or frozen) ovine meat from Uruguay. This action would provide for the importation of ovine meat from Uruguay into the United States, while continuing to protect the United States against the introduction of foot-and-mouth disease. Under the proposed regulations, APHIS would collect information, provided by an authorized certifying official of the Government of Uruguay, certifying that specific conditions for importation have been met.

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 1.6 hours per response.

Respondents: Animal health officials of the government of Uruguay.

Estimated annual number of respondents: 5.

Estimated annual number of responses per respondent: 1.

Estimated annual number of responses: 5.

Estimated total annual burden on respondents: 8 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 Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

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 Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with allowing the importation of ovine meat from Uruguay into the United States, we have prepared an environmental assessment. The environmental assessment was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment may be viewed on the Internet on the Regulations.gov Web site and is available for public inspection in our reading room. (Instructions for accessing Regulations.gov and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) In addition, copies may be obtained by calling or writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

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 proposing to amend 9 CFR Part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, EXOTIC NEWCASTLE DISEASE, 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, 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 94.1 is amended by revising paragraph (b)(4) and the introductory text of paragraph (d) to read as follows:

§ 94.1 Regions where rinderpest or foot-and-mouth disease exists; importations prohibited.

* * * * *

(b) * * *

(4) Except as provided in § 94.22 for fresh (chilled or frozen) beef and ovine meat from Uruguay.

* * * * *

(d) Except as otherwise provided in this part, fresh (chilled or frozen) meat of ruminants or swine raised and slaughtered in a region free of foot-and-mouth disease and rinderpest, as designated in paragraph (a)(2) of this section, and fresh (chilled or frozen) beef and ovine meat exported from Uruguay in accordance with § 94.22, which during shipment to the United States enters a port or otherwise transits a region where rinderpest or foot-and-mouth disease exists, may be imported provided that all of the following conditions are met:

* * * * *

3. Section 94.22 is revised to read as follows:

§ 94.22 Restrictions on importation of beef and ovine meat from Uruguay.

Notwithstanding any other provisions of this part, fresh (chilled or frozen) beef and ovine meat from Uruguay may be exported to the United States under the following conditions:

(a) The meat is beef and ovine meat from animals that have been born, raised, and slaughtered in Uruguay.

(b) If foot-and-mouth disease is detected anywhere in Uruguay, the export of beef and ovine meat from all of Uruguay to the United States is prohibited until at least 12 months have elapsed since the depopulation, cleaning, and disinfection of the last infected premises.

(c) The meat comes from bovines and sheep that originate from premises where foot-and-mouth disease has not been present during the lifetime of any bovines and sheep slaughtered for the export of beef and ovine meat to the United States.

(d) The meat comes from bovines and sheep that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.

(e) The meat comes from bovines and 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.

(f) The meat consists only of bovine parts and 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.

(g) All bone and visually identifiable blood clots and lymphoid tissue have been removed from the meat.

(h) The meat has not been in contact with meat from regions other than those listed in § 94.1(a)(2).

(i) The meat comes from carcasses that were allowed to maturate 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 maturate 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.

(j) An authorized veterinary official of the Government of Uruguay certifies on the foreign meat inspection certificate that the above conditions have been met.

(k) 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.

Done in Washington, DC, this 18th day of February 2011.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2011–4138 Filed 2–23–11; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 52

[NRC–2010–0131]

RIN 3150–AI81

AP1000 Design Certification Amendment

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or Commission) proposes to amend its regulations to certify an amendment to the AP1000 standard plant design. The purpose of the amendment is to replace the combined license (COL) information items and design acceptance criteria (DAC) with specific design information, address the effects of the impact of a large commercial aircraft, incorporate design improvements, and increase standardization of the design. Upon NRC rulemaking approval of its amendment to the AP1000 design, an