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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2013-0105]

Notice of Determination of the Foot-and-Mouth Disease and Rinderpest Status of a Region of Patagonia, Argentina

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are adding a region of Argentina, consisting of the areas of Patagonia South and Patagonia North B, to the lists of regions that are considered free of rinderpest and foot-and-mouth disease (FMD). We are taking this action because we have determined that this region is free of rinderpest and FMD. We are also adding the Patagonia Region to the list of regions that are subject to certain import restrictions on meat and meat products because of their proximity to or trading relationships with rinderpest- or FMD-affected countries. These actions update the disease status of the Patagonia Region with regard to rinderpest and foot-and-mouth disease while continuing to protect the United States from an introduction of those diseases by providing additional requirements for any meat and meat products imported into the United States from the Patagonia Region of Argentina.

DATES: Effective Date: [Insert date 60 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Silvia Kreindel, Senior Staff Veterinarian, Regionalization Evaluation Services, National Import Export Services, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 851-3300.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of certain animals and animal products into the United States to prevent the introduction of various animal diseases, including rinderpest and foot-and-mouth disease (FMD). The regulations prohibit or restrict the importation of live ruminants and swine, and products from these animals, from regions where rinderpest or FMD is considered to exist.

Within part 94, § 94.1 contains requirements governing the importation of ruminants and swine from regions where rinderpest or FMD exists and the importation of the meat of any ruminants or swine from regions where rinderpest or FMD exists to prevent the introduction of either disease into the United States. We consider rinderpest and FMD to exist in all regions except those listed in accordance with paragraph (a)(2) of that section as free of rinderpest and FMD.

Section 94.11 of the regulations contains requirements governing the importation of meat of any ruminants or swine from 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. Such regions are listed in accordance with paragraph (a)(3) of that section.

The regulations in 9 CFR part 92, § 92.2, contain requirements for requesting the recognition of the animal health status of a region. If, after review and evaluation of the information submitted in support of the request, the Animal and Plant Health Inspection Service (APHIS) believes the request can be safely granted, APHIS will make its evaluation available for public comment through a notice published in the Federal Register. At the close of the comment

period, APHIS will review all comments received and will make a final determination regarding the request that will be detailed in another notice published in the Federal Register.

In accordance with that process, on January 23, 2014, we published in the Federal Register (79 FR 3775-3777, Docket No. APHIS-2013-0105) a notice of availability[1] in which we announced the availability for review and comment of our evaluation of the FMD status of the areas of Patagonia South and Patagonia North B, referred to below as the Patagonia Region of Argentina. Based on this evaluation, we determined that that the animal disease surveillance, prevention, and control measures implemented by Argentina in the Patagonia Region are sufficient to minimize the likelihood of introducing FMD into the United States via imports of FMD-susceptible species or products.

However, because of the Patagonia Region's proximity to and trading relationships with FMD-affected regions, we found that it is necessary to impose certain restrictions in accordance with § 94.11 on the importation of meat of any ruminants or swine from the Patagonia Region.

In the same notice we also made available an evaluation assessing the rinderpest status of South America for public review and comment. Rinderpest has never been established in South America. No South American country has ever reported the disease except Brazil, which had an outbreak in 1921 that was limited in scope and quickly eradicated. Furthermore, the global distribution of rinderpest has diminished significantly in recent years as a result of the Food and Agriculture Organization Global Rinderpest Eradication Program. The last known cases of rinderpest worldwide occurred in the southern part of the "Somali pastoral ecosystem" consisting

[1] To view the notice of availability, the assessments, and the comments we received, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0105

of southern Somalia, eastern Kenya, and southern Ethiopia. In May 2011, the World Organization for Animal Health (OIE) announced its recognition of global rinderpest freedom.

We solicited comments on the notice of availability for 60 days ending on March 24, 2014, and extended the comment period for an additional 30 days, ending April 23, 2014. We received 33 comments by that date, from State and national livestock associations and from private citizens. The commenters raised a number of issues about our proposed action. The comments are discussed below.

Five commenters specifically addressed our proposal to recognize South America as free of rinderpest. All of those commenters expressed support for that determination.

Many commenters raised concerns about the risk analysis for FMD. These concerns included concerns about the methodology, scope, hazard identification, release assessment, exposure assessment, risk estimation, and discussion of geographical details.

Several commenters stated that the specific methodology and measurements used during the site visits to support the qualitative risk analysis are not available for review. One commenter expressed concern that such documentation was not collected or recorded. That commenter also stated that APHIS should develop a protocol to be used for site visits so that reviewers' assessments can be analyzed and summarized more objectively, and then made available with APHIS' conclusions of the risk analysis.

The purpose of the site visit is to verify and complement the information previously provided by the country. APHIS site visits consist of an in-depth evaluation of the risk factors identified by APHIS in § 92.2 as factors to consider in assessing the risk of the relevant animal

disease posed by a region.[2] The animal disease risks are identified in the risk analysis from the information gathered on these factors during the site visits and APHIS' document review, and whenever mitigations are considered necessary, such mitigations are discussed in the risk analysis.

APHIS has also published guidance on our approach to implementing our regionalization process and the way in which we apply risk analysis to the decision-making process for regionalization. This document can be found on the APHIS Web site at http://www.aphis.usda.gov/import_export/animals/downloads/regionalization_process.pdf.

Site visit findings are thoroughly described throughout the risk analysis, including visits to local offices (pages 21-22), airports (pages 33-34), border controls (pages 37-38), farms (page 43), and laboratories (pages 60-64).

One commenter stated that APHIS should regard the eight factors as more than a simple checklist for reviewers and that consistent implementation of the factors should be completely verified.

APHIS agrees with the commenter. When conducting a site visit, APHIS verifies that all the factors related to the FMD control and eradication program, including prevention, controls, surveillance, and reporting, are in place and that the country has strong veterinary authority and infrastructure to carry out the FMD program.

[2] The risk analysis for the Patagonia Region includes an in-depth assessment of the 11 factors used by APHIS to evaluate the animal health status of a region prior to 2012. In 2012, APHIS consolidated the 11 factors listed in § 92.2(b) into 8 factors. APHIS introduced this simplification in order to facilitate the application process; however, since the evaluation of the Patagonia Region started before 2012, and the topics addressed by the 11 factors are encapsulated in the 8, this analysis follows the 11 factor format.

Some commenters stated that according to the risk analysis, APHIS only conducted three site visits to the Patagonia Region. The commenters stated that APHIS should maintain a more active and robust presence in the region.

APHIS believes that its site visits to the Patagonia Region, in conjunction with the other documentation and information APHIS has reviewed, provided APHIS with sufficient information to correctly determine the region's FMD status. As a member of the OIE, Argentina must immediately notify the OIE of any suspect cases of FMD that may occur in the future. In addition, under § 92.2, a region that is granted a specific animal health status may be required to submit additional information pertaining to that animal health status, or to allow APHIS to conduct additional information collection activities in order to maintain its animal health status.

One commenter stated that the hazard identification appears to be lacking information, and that APHIS seems to consider that FMD is the only hazard of concern. The commenter also stated that the risk analysis does not provide detailed information about the different serotypes of the FMD virus, does not discuss the efficacy of the FMD vaccination programs in regions surrounding Patagonia, and does not mention virus survival in commodities of concern, such as sheep and lamb embryos and semen. The commenter stated further that the risk analysis does not provide any details regarding the onset of clinical signs for the different species or focus on subclinical disease or the species, such as sheep, that may display mild clinical signs that can go unnoticed and undetected.

APHIS notes that Argentina requested FMD status recognition; therefore the risk analysis focuses on the FMD status of the region and not on other hazards. Appendix I of the risk analysis describes the different serotypes of the FMD virus. In the risk analysis APHIS also

describes the disease status of adjacent regions, including the FMD outbreaks that occurred in 2003 and 2006, and the eradication and control programs in adjacent regions.

The vaccination rates in the adjacent region of Northern Argentina reached over 99 percent between 2008 and 2012. In addition, the region of Northern Argentina has several overlapping controls to ensure compliance with vaccination calendars through matching vaccination records to movement permits and census data and through field inspections. We have updated the risk analysis to add the following to the discussion of the disease status of adjacent regions: "Vaccination of cattle is mandatory in the area north of the 42nd parallel with the exception of Patagonia North B (the area adjacent to Patagonia South, a region without vaccination) and recently, Patagonia North A and the summer pastures (zona veranadas) of Calingasta Valleys in the province of San Juan. The Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA) is the Government of Argentina's enforcement authority and regulating body for planning, implementing, and controlling actions to eradicate FMD. SENASA establishes the technical requirements for the vaccination program. Vaccination can only be performed by authorized personnel who are trained, registered, and accredited/audited by SENASA. Vaccination coverage rates have been over 97 percent in the region above the 42nd parallel (with the exception of Patagonia North B, and most recently Patagonia North A, in which vaccination is not conducted) since 2001."

On page 71 of the risk analysis, we described embryos as presenting a negligible risk of infecting an exposed recipient with the FMD virus, as the zona pellucida is an important barrier against pathogens, and only embryos with an intact zona pellucida may be imported into the United States under the provisions of § 98.3(h). On page 72 of the document we described semen as presenting a likelihood of exposure of susceptible animals to this virus if the semen is

collected from an infected animal. However, based on the conclusion of the release assessment that diseased animals are not likely to exist in the Patagonia Region or, if they do, are not likely to go undetected, APHIS considers it unlikely that U.S. animals would be exposed to infected semen from the Patagonia Region.

APHIS looked at clinical disease in all the relevant species, including those, like swine, that are not expected to be exported from the Patagonia Region. Clinical disease in sheep is discussed in Appendix I. APHIS has updated the risk assessment to add the following to the Appendix: "The incubation period in sheep is similar to that observed in bovines, and has been reported to be 1 to 12 days, with most cases appearing in 2-8 days." We understand that subclinical disease or species-specific symptoms may result in unnoticed and undetected viral infection. However, because no vaccination is carried out in the Patagonia Region, any cattle or swine in that region exposed to the FMD virus would act as good sentinels of an outbreak.

One commenter stated that the release (entry) assessment focuses on the factors in § 92.2 rather than providing a description of all the biological pathways necessary for an importation activity to introduce the disease into the United States. The commenter stated that this section could be strengthened by a detailed chronological list of FMD outbreak information for the Patagonia Region and the bordering regions to include the year of the outbreak, epidemiological disease spread information, risk factors, maps, and the controls implemented during the outbreak.

When preparing a risk analysis, APHIS evaluates the relevant pathways as described by the scientific literature and supported by the OIE. Therefore, on page 70 of the risk analysis, APHIS has described the biological pathway that it believes is most likely to result in the release of FMD into the United States, which is exposure through the importation of FMD-infected sheep meat. APHIS also discusses the history of FMD outbreaks in the Patagonia Region and

neighboring regions in sections 2 and 3 of the entry assessment. APHIS does not believe a description of all the biological pathways that could possibly introduce FMD into the United States is necessary or helpful in determining the likelihood of release because not all pathways will lead to the introduction of active virus through the importation of susceptible commodities.

In conducting an animal disease status evaluation in a foreign region, APHIS focuses on the likelihood that the region is free of the hazard(s) by evaluating, for example, the official veterinary capacity and authority, surveillance systems, and import controls, in place in the exporting country. APHIS believes that an analysis of these factors provides a robust analysis of the likelihood of release of FMD into the United States. Given that there is a very low likelihood that FMD is present in the Patagonia Region or would be introduced into Argentina without detection, the corresponding entry likelihood into the United States is considered also to be very low.

One commenter stated that the exposure assessment does not discuss the potential transmission of FMD within and from quarantine facilities.

We are confident that the exposure assessment appropriately describes the biological pathways necessary for exposure of animals and humans in the United States to FMD, and that APHIS' regulatory safeguards will provide effective protection against the risks associated with the importation of ruminants or their products from the Patagonia Region of Argentina. These safeguards include subjecting animals and animal products from the region to certain restrictions because of the region's proximity to FMD-affected countries (§ 94.11); certification that ruminants and swine have been kept in a region entirely free of FMD and rinderpest (for ruminants) for 60 days prior to export (§§ 93.405 and 93.505); and a minimum quarantine of 30

days from the date of arrival at the port of entry for most imported ruminants (§ 93.411), and 15 days for all imported swine (§ 93.510).

One commenter stated that sufficient data is lacking for the plausible risk exposure pathways mentioned in the exposure assessment.

In the risk analysis, the exposure pathways are defined for the importation of sheep meat, genetic materials, and susceptible live ruminants. We anticipate that these are the commodities that will be exported to the United States based on the information provided in Argentina's application, our knowledge of the livestock industry in the Patagonia Region, and what commodities are exported from the Patagonia Region now.

One commenter stated that there is a disparity in the risk levels for embryos in the exposure assessment with the documentation as negligible on page 71 and low on page 72.

The risk of transmission of FMD via embryos is negligible. APHIS will correct the wording on page 72.

The commenters stated that the risk analysis does not include sufficient detail for geographical landmarks outlining the Patagonia Region or maps with the necessary level of detail to be useful.

APHIS disagrees. The geographic landmarks outlining the Patagonia Region are described on page 27 of the risk analysis. This description also includes a discussion of the area and climate. Figure 1 is a map of Argentina showing different provinces (including oceans and neighboring countries) and Figure 2 shows the regionalization status as defined by the OIE after Patagonia North B was recognized as free without vaccination in May 2007.

One commenter stated that the risk analysis review and general assessment process do not seem to be completely transparent and are not documented satisfactorily for thorough outside analysis, but did not identify specific aspects of the process that seemed opaque.

APHIS is confident that the review and assessment process is appropriately explained and documented in the risk analysis document.

Several commenters stated that APHIS should prepare a quantitative risk analysis and make it available for public review. Some commenters stated that the qualitative format for the risk analysis is subjective and fails to objectively quantify the probability of risk and adequately assess the magnitude of the consequences. One commenter noted that APHIS prepared a quantitative risk analysis in 2002 for importation of beef from Uruguay and asked why APHIS chose to prepare a qualitative risk analysis for the Patagonia Region.

APHIS believes that a qualitative analysis is appropriate in this situation. APHIS' evaluations are based on science and conducted according to the factors identified in § 92.2, which include biosecurity measures, livestock demographics, and marketing practices. As explained in the risk analysis, we conducted an in-depth evaluation of the 11 factors used by APHIS to evaluate the animal health status of a region prior to 2012. The factors include: (1) The authority, organization, and infrastructure of the veterinary services organization in the region; (2) Disease status; (3) The status of adjacent regions with respect to the agent; (4) The extent of an active disease control program, if any, if the agent is known to exist in the region; (5) The vaccination status of the region; (6) The degree to which the region is separated from adjacent regions of higher risk through physical or other barriers; (7) The extent to which movement of animals and animal products is controlled from regions of higher risk, and the level of biosecurity regarding such movements; (8) Livestock demographics and marketing practices

in the region; (9) The type and extent of disease surveillance in the region; (10) Diagnostic laboratory capacity; and (11) Policies and infrastructure for animal disease control in the region. Neither the regulations in 9 CFR part 92 nor APHIS guidance documents require a quantitative risk analysis or indicate that one is needed here.

Most of APHIS' risk analyses have been, and continue to be, qualitative in nature. Over time, APHIS has come to use qualitative risk assessments given the limitations of quantitative models, although APHIS recognizes that quantitative risk analysis models can be useful in cases where the risk management questions or information cannot be addressed with a qualitative model. When coupled with site visit evaluations, APHIS believes that qualitative risk analyses provide the necessary information to assess risk of disease introduction through importation. Additionally, quantitative modes are resource-intensive and take a much longer time to complete. Quantitative models also tend to be data-intensive, and the types of data needs required by such models are often not available or adequate under most circumstances. At the same time that quantitative models are data-intensive, they are also necessarily developed using a set of assumptions that may not always adequately represent the biological situation in question, thus resulting in a wide range of uncertainty in interpretation of the model outcomes. Quantitative models also require constant updating, which is dependent on availability of current research and data, and thus these models may not always represent the current state of scientific information. Finally, uncertainty in the results or outcomes of quantitative models also arises from a large number of sources, including problem specification, conceptual or computational model construction and model misspecification, estimation of input values, and other model misspecification issues.

One commenter asked what types of training programs are given to SENASA personnel stationed at the border checkpoints and patrolling in the areas along the border.

The training of SENASA border personnel is described on page 30 of the risk analysis. The border personnel are trained on a number of topics, including legal framework, national and international zoosanitary status, epidemiological characterization of the region, and import and export procedures.

Two commenters expressed concern that Argentina's border control and security between the Patagonia Region and neighboring regions have not been adequately verified.

Border control and security in the Patagonia Region are discussed on pages 27 through 37 of the risk analysis. APHIS looked at these issues during all of its site visits. Based on those visits and other documents and information that APHIS has obtained and made available with the risk analysis, APHIS is confident that Argentina's border controls with respect to the Patagonia Region are sufficient to prevent the introduction of FMD into the region.

One commenter stated that in addition to assessing the risk of disease directly from animals and animal products from the Patagonia Region, it is also important to measure and address risk due to potential economic incentives to trans-ship animals and animal products. Two additional commenters expressed concern that because Argentina consumes a large portion of the meat that is produced in the country, and because there is transit between regions for access and delivery of beef and meat products, there is a greater risk of contamination and infection across regional boundaries.

As we explained above, APHIS has assessed the border controls and security of the Patagonia Region and we are confident that these are sufficient to prevent the introduction of FMD into the region. We also note that Argentina has effective and appropriate requirements for

the importation of susceptible commodities into the Patagonia Region. These are discussed on page 69 of the risk analysis.

One commenter asked what disinfection methods are used against the FMD virus at the border points.

As explained on page 38 of the risk analysis, disinfection methods include spraying vehicles with disinfectants that are effective against the FMD virus. Among other effective disinfectants, SENASA uses the following: 5.25 percent sodium hypochlorite, 3 percent acetic acid, 4 percent potassium peroxymonosulfate and 1 percent sodium chloride, and 4 percent sodium carbonate.

One commenter stated that SENASA reports that all producers, animal caretakers, and transporters were well-versed in recognizing clinical signs of FMD in livestock. The commenter asked how these individuals were trained to recognize clinical and subclinical signs of FMD, and if there is any accreditation or certification process for their training. The commenter also asked if there was any verification process for their reported FMD recognition skills.

APHIS notes that "subclinical disease" means that there are no observable clinical signs of the disease. The training requirements for official and non-official veterinarians are described on page 19 of the risk analysis, and the training requirements for SENASA personnel are described on page 20. In all cases the training is in line with the main strategies in Argentina's FMD National Eradication Plan. In addition, different components of FMD outreach and awareness programs (e.g., radio advertisement, presentations to industry, etc.) remind producers of vaccination campaigns, clinical signs compatible with the disease, and compulsory reporting of suspect cases.

With respect to verification of disease recognition skills, SENASA has a training and promotion program, which includes the performance of drills. The training is carried out by the Bureau of Epidemiology. In addition, the Field General Coordination holds meetings to provide updates on the information, methodology, and standards that the local veterinarians should know. Training records are maintained by the Bureau of Human Resources and Training in which official agents get credits for the various classes they attend. The credits are added up in a score that is used towards promotions in the organization. The Bureau of Human Resources and Training coordinates the training activities of each of the National Bureaus through training consultants. In the case of the National Bureau of Animal Health, two professionals work as consultants who lead the 22 training delegates of the provinces who coordinate, audit, and guide the process of teaching official veterinarians. This training program is described in the risk analysis on page 67.

Three commenters stated that over half the sheep in Argentina reside in the Patagonia Region. The sheep are generally raised in extensive management systems and since FMD clinical signs are relatively subtle in sheep, it is important that data be collected for public review on which specific diagnostic practices and risk mitigation measures are used at border crossings to prevent FMD from entering Patagonia. One commenter asked specifically how APHIS will ensure that there are enhanced surveillance systems in place that will preclude the virus circulating in the sheep population undetected.

The commenters are correct that sheep are the predominant livestock species in the Patagonia Region. Almost 60 percent of the sheep in Argentina reside in Patagonia. The livestock density is less than one animal per hectare. Due to extensive husbandry practices and low animal density, contact between sheep and other species and with other sheep is minimized,

reducing the risk of disease spread in the event that the FMD virus was introduced into the region. As we explained above, no vaccination is carried out in the Patagonia Region, so any cattle or swine in that region exposed to the FMD virus would act as good sentinels of an outbreak.

Border control and security in the Patagonia Region are discussed on pages 27 through 37 of the risk analysis. SENASA conducts serological surveillance (testing blood serum for viral activity) of sheep and cattle. This is an effective indicator of the FMD situation because the FMD susceptible species are not vaccinated against FMD. Furthermore, for sheep, premises identification is required, either by eartag, which includes the CUIG (Clave Unica de Identification Ganadera – Unique Holding Identification Code) number of the farm, or ear notch. The eartag color and shape may be selected by the farmer (the color is not specific to the FMD status of the region as in cattle). Ear notches are controlled by and registered with SENASA to ensure that they are unique. SENASA requires all premises with agricultural animal production to register with SENASA and obtain a RENSPA (Registro Nacional Sanitario de Productores Agropecuarios – National Sanitary Registry of Ag-Producers) number, an alphanumeric identifier that encodes information about individual premises. The RENSPA number is structured to identify the province, municipality, premises, and various details of the particular premises, such as ownership, rental status, or shared occupancy. In association with the RENSPA number, census information on all species on the premises and permit information showing animal movements are included in a database maintained by field officials. This information allows animals from an individual premise to be traced effectively, and we are confident that SENASA would be able to respond quickly in the event of positive or false positive results from serological testing.

Many commenters stated that Argentina has shown a trend of decreasing compliance in audits conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) between 2005 and 2009. One of the commenters stated that Argentina's history of compliance issues could influence their ability to consistently and successfully enforce control measures within the Patagonia Region in order to successfully mitigate the risk from the possible entry of FMD into this region from the surrounding higher-risk areas. One commenter asked if APHIS consulted with FSIS as part of our evaluation, and if so, what was FSIS' feedback.

The purpose of APHIS' evaluation was to assess the FMD situation in the Patagonia Region and to evaluate Argentina's ability to comply with the certification requirements for exporting specific FMD-susceptible commodities to the United States, including the certification requirements in § 94.11 for meat and other animal products imported from regions that are considered free of FMD and rinderpest but are subject to additional restrictions because of their proximity to or trading relationships with regions that are not free of FMD or rinderpest. Based on its site visits and other documentation and information, APHIS concluded that Argentina's legal framework, animal health infrastructure, movement and border controls, diagnostic capabilities, surveillance programs, and emergency response capacity are sufficient to detect, prevent, control, and eradicate FMD outbreaks within the boundaries of the Patagonia Region of Argentina. Moreover, with respect to the Patagonia Region, APHIS concluded that the Argentine veterinary authority is capable of complying with our requirements.

Nevertheless, based on the comments, APHIS has reviewed the last five FSIS audits conducted in Argentina at the slaughter level. The FSIS audits concluded that ante-mortem inspection processes, which are relevant to the detection of FMD during the slaughter process, were conducted satisfactorily.

One commenter stated that reviews of the European Commission's Food and Veterinary Office (EC FVO) audits identified points of concern in the areas of border controls, animal identification, vaccination controls, and other concerns. The audits evaluated animal health controls concerning FMD, related animal health control measures, and related certification procedures for fresh bovine and ovine meat intended for export to the European Union (EU).

The overall objective of the EC FVO audits was to assess the animal health controls in place in order to verify that guarantees provided by the competent authorities of Argentina, concerning the health status of the country with regard to FMD, continue to meet the requirements for the export of ovine and bovine meat from Argentina to the EU. In response to the comments, APHIS reviewed the latest reports. The most recent report, from 2012, concluded that the official FMD control system in place for Argentina is reliable and meets EU requirements.

One commenter stated that the 2012 EC FVO audit showed a less than satisfactory enforcement of some requirements of the sheep identification and movement registration system in the Patagonia Region. The commenter also stated that the same audit identified a weak official control system along the Bolivian border, which cannot ensure the adequate management of risks related to animal movements and sufficient verification of satisfactory implementation of vaccination campaigns for FMD. The commenter further stated that limited attention is being paid to official "on-the-spot" controls on FMD vaccination, which casts doubt on the adequate fulfillment of the vaccination coverage in all areas with an increased risk of FMD.

As discussed above, the 2012 EC FVO report concluded that Argentina meets the requirements set forth by the OIE and the EU for complying with both the EU's certification requirements for fresh bovine and ovine meat and Articles 8.5.4 and 8.5.5 of the OIE's

Terrestrial Animal Health Code recognizing an FMD zone where vaccination is not practiced and an FMD zone where vaccination is practiced. Furthermore, with regard to the commenter's concern that the lack of "on-the-spot" controls on FMD vaccination would lead to inadequate fulfillment of vaccination coverage, as we discussed on page 59 of the risk analysis, after the 2012 EC FVO audit, and in collaboration with external animal health experts, Argentina revised its surveillance sampling design in order to confirm adequate vaccination coverage in its territory. The revised sampling design focuses on the effectiveness of various vaccination campaign plans as implemented by the local offices. At the time of APHIS' November 2013 site visit, over 50 percent of samples had already been collected with only two reactors identified. APHIS notes that the reactor animals are not suspect for FMD or other diseases; the reaction could be related either to immunity as a result of vaccination or to the presence of proteins in the vaccine. On completion of the study, SENASA expects to be able to compare effectiveness of operational implementation of the National Vaccination Plan at the local level. Vaccination coverage rates in Northern Argentina have been reported at over 97 percent. In reference to the Bolivian border, APHIS recognizes that some borders in the northern part of Argentina might be porous, and that other mitigations might be required in such areas in the event Argentina would request to export a particular commodity into the United States. APHIS notes, however, that such borders are located over 2,500 miles from the region that is under consideration in this notice.

One commenter stated that the EC FVO audits showed a limited contribution of passive surveillance to the detection and notification of suspect cases of FMD. The commenter asked if the current system of passive surveillance in Argentina is really working, and asked how the system of passive surveillance could work effectively if it is not actively pursued.

The reporting of FMD suspect cases is infrequent in the Patagonia Region; APHIS believes that this is because FMD is not present in the region and other vesicular diseases are rare. As we noted on page 24 of the risk analysis, there were no reports of suspect vesicular diseases in 2012 or 2013 in the Patagonia Region. To assess the ability of veterinary officials at local offices to respond to a suspicious case of disease, the site visit team asked to view records of reports of a suspected notifiable disease (in this case, mange) during the 2009 site visit. The information shared revealed that a visit to the affected farm was made within 24 hours of the report, and all animals on the farm were inspected, with samples collected and submitted to the laboratory on the same day. The farm was immediately quarantined upon the report of the suspect case and the quarantine remained in place throughout the duration of the investigation. At the initial visit, neighboring farms were contacted to alert the owners of the disease suspicion, and the owners were told to make their animals available for inspection.

Finally, APHIS notes that the data provided in our risk analysis are more up-to-date than those provided by the EC FVO audits. Further surveillance efforts from 2001 to 2013 are described on page 57, surveillance efforts specifically in Patagonia North A are described on page 58, and other ongoing surveillance efforts on page 59. Based on those findings APHIS concluded that the design under which serological sampling is conducted in Argentina is both valid and efficient and the sampling coverage is adequate and that the serological sampling is adequate to detect disease and identify and measure viral activity (if any) in the area.

A commenter stated that the EC FVO audits present wildlife issues as a concern for the continued management of FMD risk. The commenter stated specifically that this issue required investigations to assess the risk associated with the presence of pigs and wild boars in the areas

neighboring Bolivia and Paraguay, and their possible exposure to feeding practices that may carry a risk of introduction of the FMD virus.

Although several South American wild animal species are susceptible to FMD, research into FMD in South America has determined that wildlife populations, including feral swine, do not play a significant role in the maintenance and transmission of FMD. During outbreak situations, wildlife may become affected by FMD; however, as we discussed on pages 15-16 of the environmental assessment, the likelihood that they would become carriers under field conditions is rare. Therefore, it is unlikely that FMD would be introduced into the Patagonia Region through movement of infected wildlife. The active surveillance on wild boars conducted in 2013 is described on page 58 of the risk analysis. In the serological study conducted in swine, a total of 462 samples were collected from 76 establishments in Patagonia North A. The wildlife surveillance consisted of a total of 21 samples. All porcine samples were tested using the LF ELISA test with negative results.

Furthermore, feeding garbage to animals is prohibited in Argentina unless specific products undergo a cooking process guaranteeing destruction of pathogenic organisms (pages 21 and 22 of the risk analysis). In the event that these laws were circumvented, other factors evaluated in the risk analysis, including biosecurity measures and response capabilities, would mitigate disease risks.

Two commenters stated that wildlife may move across traversable national boundaries and infect other wildlife and livestock. One of the commenters stated that while the environmental assessment seeks to address wildlife issues and FMD risk, there have not been enough wildlife studies or efforts to document the natural wildlife movements in Patagonia or the

surrounding regions. The commenter further stated that no ideas have been advanced to identify practical mitigation measures for wildlife species.

As we explained earlier, research into FMD in South America has determined that wildlife populations, including feral swine, do not play a significant role in the maintenance and transmission of FMD. During outbreak situations, wildlife may become affected by FMD; however, the likelihood that they would become carriers under field conditions is rare and it is unlikely that FMD would be introduced into the Patagonia Region through movement of infected wildlife.

One commenter stated that there are clear weaknesses within Argentina's standards of surveillance and management practices, specifically inadequate import controls and quarantine procedures, that could put the U.S. beef supply at risk.

APHIS disagrees with the commenter. We found no evidence of weakness in the import controls or quarantine procedures in the Patagonia Region and are confident that they provide effective protection against the introduction of FMD to the region.

One commenter stated that a November 2013 report confirmed that Brazil and Argentina were beginning a second round of vaccination for FMD. The commenter stated that this shows that Argentina had not previously made serious efforts to address its disease problem.

There is no vaccination for FMD in the Patagonia Region. APHIS does not recognize regions that vaccinate for FMD as free of the disease. The vaccination activities that occur in other regions of Argentina and in Brazil are part of the FMD control program in those regions.

One commenter asked how APHIS would monitor and verify compliance with the measures and restrictions that APHIS would place on the importation of animals and animal products into the United States. The commenter stated that in addition to monitoring processing

operations and sampling, and in addition to OIE reporting requirements, the responsible government agencies of the exporting region should be required to submit data and status review information regularly, as is done in the United States between APHIS and State animal health agencies. The commenter stated that these measures, in addition to follow-up site visits and risk monitoring, would further assure that the appropriate systems and procedures are being followed.

Under the provisions of § 92.2(g), regions that are granted animal health status may be required to submit additional information pertaining to animal health status or allow APHIS to conduct additional information collection activities in order to maintain that status. Specifically, we ask for additional information if they report suspect or known cases of disease to the OIE; if we receive public information about suspect or known cases of disease; if the region that was previously evaluated has been re-defined; if there are public reports stating changes in the veterinary authority, budgets, or controls in border areas; if there are outbreaks or suspect cases in border regions; or if there are changes in any of the other factors we consider when preparing a risk analysis. We do not require submission of additional information on a regular schedule because we are concerned primarily with events that could potentially affect the risk status of the region under consideration.

One commenter stated that there was no indication of ongoing verification of risk control measures other than APHIS personnel may inspect slaughter establishments periodically. The commenter stated that a more routine and rigorous system of verification should be established.

As we explained above, regions that are recognized for animal health status may be required either to provide or to allow APHIS to collect additional information in order to maintain their status if we have reason to believe that events in the region or in surrounding regions could affect the risk status of the region under consideration. We also note that APHIS

uses a wide variety of sources to conduct verification activities in the Patagonia Region. These sources include the U.S. Embassy, multilateral relationships with trading partners, and the OIE.

One commenter stated that, according to APHIS reports to the U.S. Animal Health Association's Transmissible Diseases of Swine Committee, from 2009 to 2013 a number of unlicensed garbage feeders were found in the United States each year by State and Federal animal health authorities. The commenter asked if APHIS has any supporting information that estimates the number of unlicensed garbage-feeding facilities.

Searches for non-licensed garbage feeding facilities are regularly conducted using several different techniques as part of the duties of APHIS animal health staff, as well as State animal health staff and staff with other State agencies. When unlicensed garbage feeding facilities are identified, the unauthorized activity is documented and the facility is brought into compliance. Depending on the State, all swine on the premises may be quarantined and tested for foreign animal diseases. Information on the number of inspections conducted to detect unlicensed garbage feeding facilities, the number of unlicensed facilities identified, and resolution of unlicensed facilities are captured at the State level and evaluated by APHIS on a regular basis. We do not find the number of unlicensed garbage-feeding facilities to be too large or their existence to pose a risk of FMD given the regular monitoring for them.

One commenter stated that according to the risk analysis, APHIS considers the most likely pathway of exposure of domestic livestock to FMD is through feeding of contaminated food waste to swine, but that APHIS considers the likelihood of exposure of susceptible swine to the FMD virus through inadequately processed food waste to be low. The commenter stated that this position is based on a 1995 risk analysis and a 2001 survey, and that the pork industry has undergone significant changes since then. The commenter asked what confidence APHIS has

that these sources adequately reflect the current risk to the U.S. pork industry, and if the 1995 work should be repeated with more current data.

APHIS acknowledges that the pork industry in general has undergone significant changes since 1995; however, the garbage-feeding industry in particular has not. APHIS is confident that the 1995 risk analysis and 2001 survey adequately reflect the current risk to the U.S. pork industry from contaminated food waste fed to swine.

One commenter stated that under the Swine Health Protection Act, licensed facilities are required to have two to four temperature checks of garbage cooking equipment every year. The commenter asked what records licensed facilities maintain in order to verify that they are meeting the time and temperature requirements on days when they are not inspected, and if those records are adequate to provide assurance to APHIS that times and temperatures are being met outside of normal inspections.

During regularly scheduled visits to licensed waste feeding operations, inspectors observe the cooking procedure to ensure the operator understands the proper procedures and is able to conduct them properly. If there are any suspicions that cooking is not being properly conducted, the inspector will make additional unscheduled visits to ensure that cooking procedures are sufficient to ensure inactivation of any pathogens, if present. APHIS believes that this approach helps to ensure proper cooking time and temperature even when inspectors are not present.

One commenter asked about APHIS' confidence that FMD would be detected early in licensed garbage feeding operations. The commenter also asked what we estimated the time for detection would be and if it would be adequate to meet the goals of the Foreign Animal Disease Preparedness and Response Plan (FAD PReP) for disease detection.

Because of the routine visits of inspectors to garbage feeding facilities, which provide opportunities for education on disease signs and requirements for reporting, as well as the opportunity for direct observation of signs of illness in animals, APHIS believes that the presence of FMD or other reportable conditions would be detected more quickly in these types of premises than in other, unregulated premises.

One commenter stated that effective surveillance for vesicular diseases relies on a high level of awareness by producers and veterinarians on what clinical signs are consistent with vesicular diseases and how to report suspected cases. The commenter asked if APHIS had current demographics on the level of biosecurity, security, veterinary care, routine health observations, and knowledge of disease reporting pathways in garbage-fed populations to meet the goal of a FAD PReP. The commenter also asked what level of confidence APHIS has regarding the education provided to licensed garbage feeders, whether biosecurity and veterinary care protocols are being followed; and whether disease reporting procedures are being followed.

Licensed garbage feeders are generally provided with education during routine inspections by animal health regulatory staff on topics including the importance of proper cooking, signs of foreign animal diseases, appropriate biosecurity measures, etc. Mandatory inspections provide confidence in the ability of licensed garbage feeding operations to maintain biosecurity and reporting requirement protocols. Demonstration of adequate facilities and equipment is a requirement for obtaining and maintaining licensure.

One commenter asked what level of confidence we have that FMD would be detected in unlicensed garbage-feeding operations, and what the estimated time for detection would be.

If FMD were to occur in an unlicensed garbage feeding facility, APHIS estimates that likelihood of detection would be no different than introduction into any swine herd.

One commenter asked if budget cuts to APHIS and State animal health staffs have had a negative effect on the ability to carry out the regulatory activities outlined in the Swine Health Protection Act, and if the reduction in regulatory activities had decreased the number of inspections and searches for unlicensed garbage-feeding operations to a level lower than what was used in the 1995 risk analysis.

While budget cuts to APHIS have resulted in reorganizing priorities within the Swine Health Program (SHP), our SHP activities remain at recommended levels. The changes made have resulted in shifting of lower-yield activities in favor of allowing SHP inspectors to spend more time interacting with swine producers. For instance, APHIS no longer supports State and Federal employees conducting regular trips to restaurants to inquire about garbage disposal. Instead, this activity has been passed to other State partners, including public health and environmental health employees, who routinely frequent restaurants as part of their daily activities. These individuals report to State cooperators when they uncover suspicions of unlicensed garbage feeding, which allows APHIS inspectors and State cooperators to focus on likely violations. This, in turn, allows inspectors to spend more time on swine farms, working with producers, providing education, and performing inspections, among other duties.

One commenter stated that according to the sixth edition (2013) of the OIE Tool for the Evaluation of Performance of Veterinary Services, stability of structures, sustainability of policies, and operational funding are listed as critical competencies for institutional and financial sustainability. The commenter asked how confident APHIS is that the short- and long-term levels of funding for SENASA are adequate to carry out their mission related to this proposed rule.

As described on page 17 of the risk analysis, SENASA reported that its 2013 budget was 1.3 billion pesos (approximately $200.7 million). SENASA officials described the system as self-sufficient because user fees are required for almost every service SENASA provides, including slaughter surveillance, issuances of certificates, and laboratory tests. The budget for the laboratory is 60 million pesos (approximately $12 million). APHIS finds no reason to believe that the funding will change, as stable funding for the FMD control and eradication programs in Argentina has been in place for over a decade.

One commenter asked whether APHIS' funding levels are adequate to carry out the agency's mission, especially verification of practices conducted in Patagonia.

While APHIS' funding levels have decreased in recent years, we are still confident in our ability to carry out our mission successfully. As we explained above, APHIS uses a wide variety of sources to conduct verification activities in the Patagonia Region, including the U.S. Embassy, multilateral relationships with trading partners, and the OIE.

Two commenters stated that some of the supporting documentation is in a foreign language and no official translation was provided. One commenter stated that while stakeholders could shoulder the cost burden to have the material translated, it would not constitute an official translation.

In addition to the risk analysis and other supporting documents, APHIS provided the public with documents that were referred to in the risk analysis. Some of these documents were provided by the Government of Argentina and are in Spanish. These documents include presentations that were done at the local offices. For the documents that have not been officially translated for the public, APHIS verified the data when conducting the site visit. This

information, including data analysis and conclusions, is thoroughly described throughout the risk analysis that was made available for public comment.

Many commenters noted that there was no economic impact analysis associated with this notice. One commenter stated that while an economic analysis is not required for risk evaluation notices, the economic analysis for the 2007 proposed rule had deficiencies. Others stated that infected beef entering the United States could have a negative impact on our domestic livestock supply and economy. The commenters stated the economic risk of an FMD outbreak to the U.S. livestock industry is too great to take any action that increases the risk to the domestic cattle herd. These commenters stated that a new economic analysis for animals and animal products should be prepared and made available to the public for review and comment.

The commenter is correct that an economic analysis is not required for risk evaluation notices. APHIS has determined that susceptible commodities imported from the Patagonia Region pose a very low risk of introducing FMD into the United States and that these products can be safely imported. This determination is based on the lack of FMD virus circulating in the Patagonia Region, the Argentine regulatory and industry safeguards that would likely arrest the spread of FMD should it be introduced into the region and prevent exports of infected commodities, and, APHIS' regulatory safeguards, including quarantine of live imported animals. As we explained above, we are confident that APHIS' regulatory safeguards will provide effective protection against the risks associated with the importation of ruminants or their products from the Patagonia Region of Argentina.

One commenter stated that even with a robust emergency management system in the United States, the mobility and demographics of susceptible livestock and products in the United States would allow for the probable spread of FMD to many States before it could be contained.

The commenter further stated that the accidental introduction of FMD into the United States would cost producers, consumers, and governments billions of dollars in lost revenue, response overhead, increased retail costs, and long-term loss of consumer confidence.

While we agree with the commenter that the expected consequences of an FMD outbreak in the United States would be severe, the likelihood of such an outbreak occurring due to exposure of the domestic livestock population to FMD-susceptible animals and products imported from the Patagonia Region of Argentina is very low. Therefore, the overall risk of FMD to U.S. animal health from imports of these commodities is also very low.

The commenter stated that the United States has defended its decision to reject beef from Argentina citing general sanitary issues. The commenter stated that Argentina demanded that the U.S. market be opened to their exports but have not taken appropriate action to address their sanitary issues.

APHIS disagrees with the commenter. Our evaluation shows that Argentina, as discussed in the risk analysis, has taken the necessary action to address FMD issues.

Based on the evaluation and the reasons given in this document in response to comments, we are recognizing the Patagonia Region of Argentina as free of FMD and rinderpest. The lists of regions recognized as free of these diseases can be found by visiting the APHIS Web site at http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/importexport and following the link to "Animal or Animal Product." Copies of the lists are also available via postal mail, fax, or email

upon request to the Regionalization Evaluation Services, National Import Export Services, Veterinary Services, Animal and Plant Health Inspection Service, 4700 River Road Unit 38, Riverdale, Maryland 20737.

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.

Done in Washington, DC, this 26th day of August 2014.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

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