DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. APHIS–2014–0032]

RIN 0579–AD92

Importation of Beef From a Region in Argentina

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 to allow, under certain conditions, the importation of fresh (chilled or frozen) beef from a region in Argentina located north of Patagonia South and Patagonia North B, referred to as Northern Argentina. Based on the evidence in a recent risk analysis, we have determined that fresh (chilled or frozen) beef can be safely imported from Northern Argentina, subject to certain conditions. This action provides for the importation of beef from Northern Argentina into the United States, while continuing to protect the United States against the introduction of foot-and-mouth disease.

DATES: Effective September 1, 2015.

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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 animal diseases, including rinderpest, foot-and-mouth disease (FMD), African swine fever, classical swine fever, and swine vesicular disease. These are dangerous and destructive communicable diseases of ruminants and swine. Section 94.1 of the regulations contains criteria for recognition by the Animal and Plant Health Inspection Service (APHIS) of foreign regions as free of rinderpest or free of both rinderpest and FMD. Section 94.11 restricts the importation of ruminants and swine and their meat and certain other products from regions that are declared free of rinderpest and FMD but that nonetheless present a disease risk because of the regions' proximity to or trading relationships with regions affected with rinderpest or FMD. Regions APHIS has declared free of FMD and/or rinderpest, and regions declared free of FMD and rinderpest that are subject to the restrictions in § 94.11, are listed on the APHIS Web site at *http://www.aphis.usda.gov/import_export/animals/animal_disease_status.shtml*.

Because vaccination for FMD may not provide complete protection to livestock, and because it can be difficult to quickly detect FMD in animals vaccinated for FMD, APHIS does not recognize regions that vaccinate animals for FMD as free of the disease. Although there has not been a major outbreak of FMD in Argentina since 2001/2002, we do not consider Northern Argentina to be free of FMD because of Argentina's vaccination program in that region. With few exceptions, the regulations prohibit the importation of fresh (chilled or frozen) meat of ruminants or swine that originates in or transits a region where FMD is considered to exist. One such exception is beef and ovine meat [1] from Uruguay, which is allowed to be imported into the United States under certain conditions that mitigate the FMD risks associated with these products. The conditions are set out in § 94.29 of the regulations.

In a proposed rule [2] published in the **Federal Register** (79 FR 51508–51514, Docket No. APHIS–2014–0032) on August 29, 2014, we proposed to also allow the importation of fresh (chilled or frozen) beef from Northern Argentina under those conditions found in § 94.29 of the regulations. The proposed conditions were as follows:

- The beef is from animals born, raised, and slaughtered in Northern Argentina.
- FMD has not been diagnosed in Northern Argentina within the previous 12 months.
- The meat comes from bovines that originated from premises where FMD had not been present during the lifetime of any bovines slaughtered for the export of beef to the United States.
- The meat comes from bovines that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.
- The meat comes from bovines that received ante-mortem and post-mortem veterinary inspections, paying particular attention to the head and feet, at the slaughtering establishment, with no evidence found of vesicular disease.
- The meat consists only of bovine parts that are, by standard practice, part of the animal's carcass that is placed in a chiller for maturation after slaughter. The bovine parts that may not be imported include all parts of the head, feet, hump, hooves, and internal organs.
- All bone and visually identifiable blood clots and lymphoid tissue have been removed from the meat.
- The meat has not been in contact with meat from regions other than those listed in the regulations as free of rinderpest and FMD.
- The meat comes from carcasses that were allowed to maturate at 40 to 50 °F (4 to 10 °C) for a minimum of 24 hours after slaughter and that reached a pH of below 6.0 in the loin muscle at the end of the maturation period. Measurements for pH must be taken at the middle of both *longissimus dorsi* muscles. Any carcass in which the pH does not reach less than 6.0 may be allowed to maturate an additional 24 hours and be retested, and, if the carcass still has not reached a pH of less than 6.0 after 48 hours, the meat from the carcass may not be exported to the United States.
- An authorized veterinary official of the Government of Argentina certifies on the foreign meat inspection certificate that the above conditions have been met.
- The establishment in which the bovines are slaughtered allows periodic on-site evaluation and subsequent inspection of its facilities, records, and operations by an APHIS representative.

We solicited comments concerning our proposal for 60 days ending October 28, 2014. We reopened and extended the deadline for comments until December 29, 2014, in a document published in the **Federal Register** on October 31, 2014 (79 FR 64687–64688, Docket No. APHIS–2014–0032). We received 295 comments by that date. They were from producers, trade associations, veterinarians, representatives of State and foreign governments, and individuals. Of those, 62 comments were non-substantive in nature, with 44 supportive of APHIS' proposal and 18 opposed. Two commenters requested an extension of the comment period, which was granted as detailed above. The remaining comments are discussed below by topic.

General Comments

In May 2007, the World Organization for Animal Health (OIE) recognized

[1] The provisions allowing the importation of ovine meat from Uruguay were added in a final rule published in the **Federal Register** (78 FR 68327–68331) on November 14, 2013, and effective on November 29, 2013.

[2] To view the proposed rule, the supporting risk analysis, economic analysis, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0032*.

Northern Argentina as being an area free of FMD where vaccination is practiced. One commenter stated that OIE recognition of a certain status was not sufficient reason for U.S. recognition of that status.

As a member of the OIE, the United States recognizes OIE guidelines, including guidelines on regionalization. OIE's Terrestrial Animal Health Code provides internationally accepted guidelines to protect animal health by limiting the spread of animal diseases within and between countries without unnecessarily restricting international trade. APHIS evaluates all requests from countries or regions requesting recognition of disease freedom or to export a particular commodity consistent with OIE guidelines. In this particular case, the request was to export fresh (chilled or frozen) beef. APHIS' evaluation of this request was based on science and conducted according to the factors identified in 9 CFR 92.2. We did not automatically accept OIE recognition of Northern Argentina's disease status as the basis for changes to our regulations; rather, we conducted our own evaluation, which is detailed in the proposed rule and its accompanying risk analysis.

One commenter said that the definition of Northern Argentina as ''North of Patagonia South and Patagonia North B'' is vague. The commenter added that the proposed rule's subsequent claim that ''Northern Argentina is bordered by the Atlantic Ocean and shares land borders with Bolivia, Brazil, Chile, Paraguay, Uruguay, and the Province of Río Negro, Argentina'' is confusing as Patagonia is not bordered by Bolivia, Brazil, Paraguay, or Uruguay. The commenter suggested that the definition of the proposed region be more clearly designated by the use of degrees of latitude.

Figure 12, which is located on page 52 of the risk analysis, is a map showing the various regions in Argentina, including Northern Argentina. The region under consideration is located north of the Patagonia Region; the Patagonia Region includes the region located south of the 42nd parallel known as Patagonia South, and the region immediately north of the 42nd parallel known as Patagonia North B.[3] The limits of the Patagonia North B region are as follows: In the west along the Andes Mountains (international border with the Republic of Chile) in the Province of Neuquén; in the north along the Barrancas River at the border with the Province of Mendoza; in the east, the border with the Province of Río Negro; and in the south, the 42nd parallel and the southern border with the Province of Chubut. The region within the country of Argentina, north of Patagonia North B as described above is known as Northern Argentina.

It is true that Patagonia is not bordered by Bolivia, Brazil, Paraguay, or Uruguay, as Patagonia is located in the south of Argentina. Northern Argentina, however, shares land borders with those countries as well as being north of the Patagonia Region.

One commenter stated that the Country of Origin Labeling (COOL) law should cover any imports of fresh (chilled or frozen) beef from Argentina.

Under COOL, which is administered by the U.S. Department of Agriculture's (USDA) Agricultural Marketing Service, retailers, such as full-time grocery stores, supermarkets, and club warehouse stores, are required to notify their customers with information regarding the source of certain food, including muscle cut and ground meats. Any fresh (chilled or frozen) beef imported from Argentina would be subject to such requirements.

Another commenter said that the risks posed by possible unregulated beef potentially entering the country far outweigh any short-term solutions to consumer demand issues that would result from allowing any type fresh (chilled or frozen) beef to be imported from Argentina.

In accord with the Animal Health Protection Act (AHPA, 7 U.S.C. 8301 *et seq.*) and consistent with our international agreements, APHIS has analyzed the FMD risks associated with allowing for the importation of fresh (chilled or frozen) beef from Northern Argentina. APHIS is confident that the required sanitary safeguards will allow fresh (chilled or frozen) beef to be imported safely into the United States.

One commenter stated that APHIS must ensure that cattle from Northern Argentina are held to the same health standards as cattle from the United States.

We are confident in our assessment of the capabilities of the Argentine sanitary system in maintaining the health of herds in Northern Argentina to the standards set out in this rule. Argentina may be required either to provide or to allow APHIS to collect additional information in order to maintain its authorization to export fresh (chilled or frozen) beef if we have reason to believe that events in the region or in surrounding regions could affect the risk profile of the region under consideration. We also note that APHIS uses a wide variety of sources to conduct verification activities in Northern Argentina. These sources include the U.S. Embassy, multilateral relationships with trading partners, and the OIE.

We received a number of comments from Argentine beef trade organizations. One domestic commenter stated that comments from those organizations should not be given any consideration. The commenter further stated that American cattle associations should be given the power to approve or deny any trade agreements reached by the United States and other countries.

We disagree. Federal agencies must accept and respond to comments from all interested parties. The comment regarding international trade agreements falls outside the scope of this final rule, as APHIS is not entering into a trade agreement with Argentina.

One commenter said that the importation of fresh (chilled or frozen) beef from Northern Argentina was contrary to the recommendation put forward by the U.S. Dietary Guidelines Advisory Committee that Americans eat more plant-based foods.

The dietary guidelines released yearly by the U.S. Department of Health and Human Services' Office of Disease Prevention and Health Promotion and the USDA's Center for Nutrition Policy and Promotion are irrelevant to APHIS' mission to protect the nation's animal and plant health and to APHIS' determination regarding whether fresh (chilled or frozen) beef may be safely imported from Northern Argentina. These guidelines are intended for individual use on a voluntary basis; they are not broad policy statements or trade directives.

Comments on the Impetus for Rulemaking

One commenter stated that they believe the motivation for the publication of the proposed rule and APHIS' ongoing privileging of Argentine interests is tied to Argentina's WTO complaint against the United States over our ban of Argentina's animal and meat exports. The commenter found it troubling APHIS would place trade

[3] In 2002, Argentina divided the country into four major parts: Patagonia South, Patagonia North A, Patagonia North B, and Northern Argentina. While the OIE recognized Patagonia North A as FMD free without vaccination in 2014, APHIS has made no similar determination. For export purposes, APHIS includes Patagonia North A in the Northern Argentina region and any fresh (chilled or frozen) beef exported from that area would be required to be treated in the same manner as beef exported from the smaller, OIE-recognized region of Northern Argentina. Northern Argentina as it is discussed in this document and the supporting documentation accompanying this final rule includes Patagonia North A.

considerations ahead of food safety and animal health. Another commenter postulated that the proposed action is intended to decrease the cost of beef for the American consumer at the risk of the United States livestock industry.

We undertook this rulemaking at the request of Argentina and in accordance with APHIS' regulations, the United States' obligations under its international trade agreements, and the findings of our risk analysis that fresh beef could safely be imported into the United States from Northern Argentina under certain conditions. Our decision was based on a scientific evaluation of the disease situation in Northern Argentina, which we conducted in accordance with § 92.2. We would not propose to allow for the importation of a commodity from any region unless our evaluation of the region's disease situation and sanitary capabilities supported it, consistent with our statutory responsibility under the AHPA.

Another commenter wanted to know if the importation of fresh (chilled or frozen) beef from Argentina would result in a benefit to another portion of the American economy via the export of products to Argentina.

We do not believe this rule favors one portion of the American economy over another and the commenter did not provide evidence suggesting that such an effect would occur.

Under the agreements reached in the GATT was a provision that, upon approval of the USDA, Argentina would be authorized to ship an additional 20,000 metric tons (MT) of fresh (chilled or frozen) beef to the United States under the U.S. import quota system. One commenter said that the quota reached during the Uruguay Round is insignificant when compared to the existing security and financial stability of the U.S. beef market as a whole and that security and stability should not be jeopardized via the importation of fresh (chilled or frozen) beef from Argentina.

The commenter's point regarding import quotas reached at the GATT is beyond the scope of the rulemaking. APHIS evaluates the sanitary or phytosanitary risk of importing a given commodity independent of considerations of existing import quotas.

One commenter cited Argentina's willingness to export meat to Russia as problematic since the United States and the European Union (EU) member nations currently have trade sanctions in place against that country. The commenter said that APHIS should not be allowing for trade with a country openly mitigating the effects of those food sanctions.

Another commenter postulated that the importation of fresh (chilled or frozen) beef represents a quid pro quo arrangement between the Democratic Party and its financial backers. The commenter stated that the rule would serve to benefit these parties monetarily and is not scientifically substantiated. The commenter concluded that scientific evidence contrary to the proposed action has been ignored by APHIS.

Under the AHPA and its predecessor statutes, APHIS' primary responsibility with regard to international import trade has always been to identify and manage the sanitary risks associated with importing commodities. When we determine that the risk associated with the importation of a commodity can be successfully mitigated, it is our obligation under the international trade agreements to which the United States is signatory to make provisions for the importation of that commodity. Under our international trade agreements, APHIS considers market access requests from countries and regions. Approval or denial of these requests, as mandated by the AHPA and consistent with our Nation's trade agreements, are not and cannot be made along political lines. They must be made as a result of sound science. A detailed discussion of the scientific basis for this rule may be found in the risk analysis and in this document. Additionally, the commenter provided no examples or evidence to support the claim that APHIS has ignored any contrary scientific findings regarding FMD in Northern Argentina.

Many commenters said that no trade is worth jeopardizing the safety of U.S. livestock and wildlife. The commenters pointed to the trade deficit as proof that the United States should not prioritize importation of commodities and concluded that APHIS should be investing in domestic rather than foreign agriculture.

As stated above, our principal task related to international trade is to identify and manage the risks associated with importing commodities. Moreover, under the international trade agreements to which the United States is signatory, APHIS' decisionmaking regarding the safe importation of commodities must be based on scientific sanitary considerations. APHIS has determined that the import of the commodity at issue does not jeopardize U.S. animal health.

Comments on U.S. Production

Several commenters questioned why the rulemaking was necessary if those existing imports are not problematic and there is no increased demand for beef by U.S. consumers. Another commenter stated that APHIS should focus on domestic agriculture, national animal identification, and labeling of all food products instead of international trade.

Consistent with our international obligations, APHIS considers market access requests from countries and regions. U.S. demand for these products is not a part of the consideration of such requests. Before such requests are granted, we must first assess the animal disease risks to U.S. herds posed by imports by evaluating the requesting country's or region's disease status and the efficacy of its risk mitigation measures. The United States and many other member countries are a part of the rules-based international trading system, which has benefitted all those countries through the maintenance of open international markets. Regarding the comment that APHIS focus on domestic activities, APHIS and other Federal agencies currently operate programs in the areas of focus specified by the second commenter, namely domestic agriculture, national animal identification, and food product labeling.

One commenter characterized the proposed rule as an attempt by APHIS to remedy short-term beef price increases. The commenter stated that the U.S. cattle herd needs to be rebuilt, but the rulemaking may discourage producers from restocking.

As noted in our previous responses, APHIS' consideration of Argentina's market access request is a scientific inquiry into whether fresh (chilled or frozen) beef from Northern Argentina can be safely imported. APHIS does not consider the impact on short-term beef prices. The commenter's second statement is a hypothetical one based on an unsupported presumption and, as such, difficult to evaluate. We did not receive any data from this or other commenters that would suggest that the rulemaking would discourage U.S. cattle producers from restocking.

Another commenter said that American cattle are not fed animal proteins, which are prohibited in ruminant feeds.

Although bovine spongiform encephalopathy (BSE)-related concerns were not within the scope of the FMD risk-specific risk analysis completed regarding the importation of beef (chilled or frozen) from Northern Argentina, we do note that Argentina also bans the feeding of ruminant proteins to ruminants in line with OIE guidelines concerning BSE.

Comments on APHIS Oversight

One commenter said that APHIS does not appear to have a mitigation plan in place if FMD were to be introduced into the United States as a result of this proposal or otherwise. Two other commenters stated that there is no FMD vaccine currently available in the United States.

In carrying out our safeguarding mission, APHIS works to ensure the continued health and welfare of our Nation's livestock and poultry. One important aspect of this work is making sure we can readily detect foreign animal diseases, such as FMD, and respond efficiently and effectively when faced with an outbreak. APHIS partners with other Federal, State, and local government agencies and private cooperators to expand the pool of available resources we can draw on in an emergency. Specifics of our FMD response plan may be found in a document entitled ''USDA APHIS Foot-and-Mouth Disease (FMD) Response Plan: The Red Book'' (September 2014), which is designed to provide strategic guidance on responding to an FMD outbreak. The plan gives direction to emergency responders at the local, State, Tribal, and Federal levels to facilitate FMD control and eradication efforts in domestic livestock in the United States and may be found on the Internet at *http://www.aphis.usda.gov/animal_health/emergency_management/downloads/fmd_responseplan.pdf.*

As to the commenters' point regarding availability of the FMD vaccine, 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. In the event that the United States experiences an FMD outbreak in which a specific strain is identified, the USDA will notify the NAFMDVB, which will request the manufacturing of finished vaccine from approved suppliers, based on the stockpiled antigens.

One commenter recommended that APHIS conduct annual audits of the Argentine system as we do domestically in order to continually verify split-state disease status and regional disease programs. Another commenter stated that the USDA's Food Safety and Inspection Service (FSIS) must determine Argentina's equivalency to U.S. food safety standards in order for specific processing facilities to be eligible to export fresh (chilled or frozen) beef to the United States; any imported beef must follow FSIS labeling regulations; and shipments of fresh (chilled or frozen) beef from Northern Argentina is subject to examination by U.S. inspectors before being allowed to enter the country.

Under the provisions of § 92.2(g), APHIS may require Argentina to submit additional information pertaining to animal health status or allow APHIS to conduct additional information collection activities in order to maintain its authorization to export to the United States. 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 we receive reports or evidence of smuggling from neighboring countries; 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.

FSIS makes determinations of equivalence by evaluating whether foreign food regulatory systems attain the appropriate level of protection provided by our domestic system. Thus, while foreign food regulatory systems need not be identical to the U.S. system, any imported meat is subject to the inspection, sanitary, quality, species identification, and residue standards applied to products produced domestically. FSIS evaluates foreign food regulatory systems for equivalence through document reviews and on-site audits. Imported meat is subject to reinspection at the port of first entry into the United States.

Comments on Argentine Oversight

One commenter stated that we did not adequately address the significance of the Argentine Government's failure to provide prompt notification of its widespread FMD outbreaks in 2000. The commenter suggested that Argentine officials were not subject to any type of sanctions that would prevent the recurrence of a similar failure to notify APHIS of any future FMD outbreaks. Another commenter, citing what they characterized as Argentina's spotty record of compliance with safety standards, recommended that APHIS consider the development of an ongoing oversight protocol, beyond the usual port-of-entry testing, to monitor Argentina's compliance with our required risk mitigation measures. Two commenters further stated that APHIS has not adequately described how it will continue to provide oversight and/or monitor Argentina's animal health infrastructure indefinitely, to ensure that the country will maintain adequate controls to prevent the spread of FMD from other regions of Argentina or from neighboring countries to the exporting area.

The regulations in § 92.2 provide for monitoring of regions after APHIS authorizes imports from such regions. If we determine that necessary measures have not been fully implemented or maintained, we will take appropriate remedial action to ensure that the importation of fresh (chilled or frozen) beef from Northern Argentina does not result in the importation of FMD into the United States. Contrary to the commenter's assertion, the consequence of Argentina's failure to notify APHIS of the FMD outbreak in 2000/2001 was a provisional suspension of the beef trade with Argentina. In the future, indications of noncompliance may result in similar actions. Incidents would be evaluated by APHIS on a case-by-case basis.

Many commenters stated that Argentina has shown a trend of decreasing compliance in audits conducted by FSIS between 2005 and 2009. The commenters stated that Argentina's history of compliance issues could influence its ability to consistently and successfully enforce control measures within Northern Argentina in order to successfully mitigate the risk from the possible entry of FMD into this region from the surrounding higher-risk areas. The commenters asked if APHIS consulted with FSIS as part of its evaluation, and if so, what was FSIS' feedback. Several commenters asked that the comment period on the proposed rule be extended until FSIS posted its most recent audit report for review by stakeholders.

The purpose of APHIS' evaluation was to assess the FMD situation in Northern Argentina and to evaluate Argentina's ability to prevent, detect, control, report, and manage FMD within its borders. 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 Northern Argentina. Moreover, with respect to Northern Argentina, APHIS concluded that the Argentine veterinary authority is capable of complying with our requirements. Nevertheless, based on the comments, APHIS has reviewed the last six FSIS audits conducted in Argentina at the slaughter level, including the most recent audit, which was finalized in July 2014. The FSIS audits concluded that ante-mortem inspection processes, which are relevant to the detection of FMD during the slaughter process, were conducted satisfactorily. We did not extend the comment period pursuant to the release of any future FSIS audit reports. As stated previously, the initial 60-day public comment period was extended by 60 days, providing stakeholders with a total of 120 days to share information relevant to the rule. In addition, given the contents of the last six reports, APHIS has no reason to believe that additional reports would be inconsistent.

One commenter said that little is known about the Argentine beef industry, including such factors as animal care standards, antimicrobial use, and environmental protection issues. The commenter said that we may be unintentionally supporting practices in these areas that have been determined to be harmful.

Contrary to the commenter's assertion, we thoroughly examined the infrastructure and efficacy of the Argentine bovine production and export system and detailed all aspects in our risk analysis. We subsequently determined that it is robust and capable of meeting the standards for exportation set forth by APHIS. Results of the environmental assessment we conducted to evaluate the possible environmental impacts of the rulemaking did not suggest that the rule would lead to adverse environmental impacts and the commenter provided no evidence to the contrary. FSIS's last six audits of the Argentine system at the slaughter level, which include a review of food safety practices, animal care standards, and antimicrobial use, concluded that the system is satisfactory.

Another commenter expressed concern about the financial stability of Argentina, which the commenter proposed could compromise the Servicio Nacional de Sanidad y Calidad Agroalimentario's (SENASA) ability to provide adequate sanitary surveillance and support a rigorous food safety inspection system. The commenter said that recent news reports speculating as to whether Argentina will default on its international loans suggest that the Argentine Government may not be able to adequately fund its own operations.

As described in 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 said that it is unrealistic to expect that Argentine beef will be uniformly processed and inspected under ideal circumstances as required by the standards set out in the proposed rule. The commenter viewed it as unrealistic to expect that the APHIS-approved criteria for sanitary safety to be foolproof. Another commenter said that Argentina has participated in a regional plan to eradicate FMD in all of South America since 1987 and APHIS should encourage Northern Argentina and neighboring countries to continue in their efforts and commitment to eradication of the disease so that vaccination is no longer necessary. The commenter said that, after this milestone is reached, Argentina's request to export fresh (chilled or frozen) beef to the United States could then be considered. The commenter concluded that if trade is permitted from a country or area of higher risk (*e.g.,* FMD free with vaccination) to a country or area of lower risk (*e.g.,* FMD free without vaccination), then there is little incentive for the vaccinating country or area to take the extra effort required to truly eradicate the disease, and global eradication is likely to be delayed.

We have determined that the Argentine production and export system is robust and capable of meeting the standards for exportation set forth by APHIS. APHIS does not adopt a zero tolerance for risk for international trade in meat products. Our risk analysis process is designed to determine whether a product may be imported safely into the United States. If, based on our risk analysis, we conclude that the production system in the country in question is insufficient to provide an appropriate level of protection, then we will not authorize the importation of the particular commodity. As described in the risk analysis, APHIS concluded that the surveillance, prevention, and control measures implemented by Argentina are sufficient to minimize the risk of introducing FMD into the United States for the purpose of beef imports. Since 2002, Argentina has taken a targeted approach to eradicating FMD one region at a time and harmonizing FMD-related regulations with neighboring countries. We therefore disagree with the commenter's conclusion that there is little incentive to eradicate the disease, as Argentina gives us no reason to believe that this targeted approach will not continue in the future. Any risk of FMD introduction into the exporting region is mitigated by this approach due to local regulations, standardized vaccination schedules, and other harmonization measures involved in regionalization. Consistency of approach allows for effective surveillance and monitoring.

One commenter suggested that APHIS conduct further surveillance of the Argentine program prior to any consideration of allowing for the importation of fresh (chilled or frozen) beef from Argentina. The commenter stated that three site visits made to the region in question are inadequate to fully understand the Argentine production system.

APHIS evaluated the information provided by Argentina since the application was first submitted in 2003, and conducted site visits as part of the verification process. We do not make our determinations based solely on site visits but rather on all the information gathered during the evaluation process, which, in the case of Argentina, lasted over 10 years. We are confident in our conclusion that the system in Northern Argentina is robust and that fresh (chilled or frozen) beef produced under the conditions stipulated may safely be imported into the United States.

Comments on General Disease Risk

One commenter claimed that it would be a poor decision to allow beef to be imported from Northern Argentina into the United States due to the risk associated with FMD, rinderpest, African swine fever, classical swine fever, and swine vesicular disease. The commenter observed that these diseases can be transferred from infected animals or meats from Argentina to animals in the United States.

The commenter's categorization of APHIS' proposed action is incorrect insofar as we only proposed to import fresh (chilled or frozen) beef from

Northern Argentina and not any species of live animal. Further, no South American country has ever reported an outbreak of rinderpest 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 of southern Somalia, eastern Kenya, and southern Ethiopia. In May 2011, the OIE announced its recognition of global rinderpest freedom. Finally, African swine fever, classical swine fever, and swine vesicular disease are diseases only associated with pigs and not transmissible to cattle or other bovine species. A detailed discussion of FMD in Argentina may be found in the risk analysis and in this final rule under the subheading ''Comments on FMD Risk.''

Another commenter stated that the United States would put all cloven hoofed animals in the United States, both domestic and wild, at risk for diseases not controlled in Northern Argentina.

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 and the commenter provided no evidence or specifics concerning any other diseases.

Comments on FMD Risk

Many commenters, citing the highly contagious nature of FMD, expressed the view that we should not allow fresh beef to be imported from any country where the disease is present because regionalization is not likely to mitigate the risks associated with imports effectively.

One commenter noted that Argentina's last significant FMD outbreak, which caused the loss of its countrywide FMD free status in 2001, was linked specifically to the movement of cattle across its northern borders with Bolivia and Paraguay, which were not free of FMD. The commenter added that cattle from Bolivia and Paraguay were sold in Argentine markets at a discount due to their inability to be sold legally in Argentina and this practice allowed for the spread of FMD into the Argentine domestic cattle population. Another commenter said that the acknowledgement of a risk of reintroduction of FMD from exporting regions into the export area as mentioned in the risk analysis is cause for concern.

Our evaluation is centered on the safety of a particular commodity—fresh (chilled or frozen) beef, not live animals—in terms of potential introduction of FMD into the United States. However, most of the countries in South America have been recognized by the OIE as being FMD free with (Uruguay) or without vaccination (Chile and Guyana) or with free regions with vaccination (Argentina, Bolivia, Brazil, Colombia, and Peru) or without vaccination (Argentina, Bolivia, Brazil, Colombia, and Peru). No outbreaks have been reported in Brazil since 2006, Paraguay since 2012, or Bolivia since 2007. In that regard, the risk of introduction from neighboring countries is low. Any risk of introduction is mitigated by the coordinated regional approach to FMD eradication among those countries. In our risk analysis, we also detail the many enhancements enacted by SENASA in its border control activities along the northern borders with Bolivia, Paraguay, and Brazil.

As stated in the risk analysis accompanying the proposed rule, we considered the epidemiological characteristics of FMD that are relevant to the risk that may be associated with importing beef from the export region of Northern Argentina. Based on our assessment, we concluded that beef from Northern Argentina could safely be imported into the United States, subject to certain mitigation requirements, which include removal of bones and certain tissue as well as chilling of carcasses until they reach a pH level of under 6.0. We evaluated information submitted by SENASA and verified the accuracy of that information through site visits. As detailed in the risk analysis, SENASA underwent extensive reorganization in the wake of the FMD outbreak in 2001. The new structure was designed to increase the efficiency and effectiveness of the existing system. Based on our assessment of this system, we concluded that Argentina has the legal framework, animal health infrastructure, movement and border controls, diagnostic capabilities, surveillance programs, and emergency response capacity to prevent FMD outbreaks within the boundaries of the export region and, in the unlikely event that one should occur, to detect, control, and eradicate the disease. Argentina's active and passive surveillance system would allow for rapid detection. In the event of an outbreak, in the exporting region, Argentina would promptly report findings to the OIE, and the United States would stop importing beef from Northern Argentina. Our findings regarding Argentina's disease-control capabilities give us confidence that the mitigation methods required under this rulemaking will be effective in preventing the introduction of FMD into the United States via the importation of fresh beef from Northern Argentina.

Another commenter stated that the risk analysis does not provide detailed information about the level and efficacy of the FMD vaccination programs in Northern Argentina.

The vaccination rates in 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. As detailed in the risk analysis, 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 technical requirements for the vaccination program are established by SENASA and 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. In the unlikely event that unvaccinated susceptible animals are exposed to the FMD virus, these animals will develop clinical signs that will be easily detected in the field and during ante-mortem and postmortem inspection. This will trigger a response that includes epidemiological investigation, movement restrictions, and submission of samples for laboratory analysis. If the laboratory reports the case as positive for FMD, Argentina will notify the international authorities and its trading partners, and trade will cease.

One commenter claimed that the regionalization process has eroded the sanitary safety of the United States with regard to FMD. The commenter stated that a blanket prohibition on the importation of meat from countries that have experienced outbreaks of FMD is by far the more effective option. The commenter concluded that the change from APHIS' previous policy involving such a prohibition to our current

regionalization approach was motivated by trade pressures.

Regionalization recognizes that pest and disease conditions may vary across a country as a result of ecological, environmental, and quarantine differences, and adapts import requirements to the health conditions of the specific area or region where a commodity originates. This final rule is predicated on a risk analysis document that provides a scientific basis for potential importation of chilled (fresh or frozen) beef from Northern Argentina. Without this document, APHIS would not have proposed this action. Political and economic interests may stimulate consideration of the expansion of trade of agricultural commodities between countries, but all APHIS decisionmaking concerning sanitary restrictions on trade is based on sound science, not on trade pressures.

Many commenters stated that the last FMD outbreak in Argentina was detected in February 2006 in an area near the border with Paraguay and that this area of Paraguay continues to have active virus present that can serve as a source of new outbreaks in cattle. According to officials in Argentina, illegal movement of animals from neighboring countries, as well as mechanical transmission of the virus, introduced the FMD virus into Argentina during the 2000/2001, 2003, and 2006 outbreaks. These officials acknowledge that even where there are barriers or checkpoints, people, cars, and animal products can cross both domestic and international borders illegally. The commenters concluded that the potential for the FMD virus to cross the border, particularly by passenger car or foot traffic, remains. Another commenter said that the risk analysis did not adequately describe the degree to which the region is separated from high risk regions by physical and other barriers.

In the risk analysis, we discussed the disease status of regions adjacent to the export region, the separation of those regions from the export region, and border controls. As noted in both the risk analysis and the environmental assessment, Northern Argentina has many natural barriers, such as large rivers, mountains, forests, and semiarid areas, along its international and internal borders. Even in relatively remote frontier areas, where there may be less surveillance and monitoring than in more populous ones, those geographic barriers restrict animal movement and human traffic, thereby preventing the spread of disease. In addition, Argentina collaborates with neighboring countries to harmonize FMD-related programs and restrictions. Mechanisms have been established to provide for immediate notification between these countries if an outbreak occurs. High-risk surveillance areas have been established on Argentina's borders with Bolivia, Paraguay, and Brazil. Border control and security in Northern Argentina are discussed in detail in the risk analysis. APHIS examined 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 Northern Argentina are sufficient to prevent the introduction of FMD into the region.

Some commenters questioned the efficacy of the Argentine system in controlling illegal entry of livestock and wildlife interactions, specifically citing potential transmission via feral swine populations in the northern border regions with Bolivia and Paraguay. Several commenters stated that reviews of European Commission Food and Veterinary Office (EC FVO) audits identified points of concern in the areas of border control, particularly those along the border with Bolivia, animal identification, vaccination controls, and other concerns. Another commenter stated that Argentina has demonstrated non-compliance in the course of routine USDA and EC FVO audits in the past.

We do not agree that wildlife-livestock interactions in Argentina play a significant role in the transmission of FMD. 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 discussed in the environmental assessment and the risk analysis, the likelihood that they would become carriers under field conditions is rare. Therefore, it is unlikely that FMD would be introduced into Northern Argentina through movement of infected wildlife. Further, Argentina's biosecurity measures, surveillance activities, and response capabilities, which we evaluated in our risk analysis, would mitigate the already low risk of the FMD virus spreading from wildlife to livestock in the exporting region of Northern Argentina.

We have made additions to the risk analysis that address the commenters' point regarding the EC FVO audits.[4] As described in the updated risk analysis, at the time the risk analysis that accompanied the proposed rule was finalized, no FMD outbreaks had been reported in South America for over 3 years. Based on the history of the disease in the continent, Argentina's veterinary infrastructure, and SENASA's prompt response to the FMD outbreaks that occurred in neighboring countries (Brazil 2006, Bolivia, 2007, and Paraguay 2011/12), APHIS concluded that it is unlikely that the disease could be reintroduced from adjacent areas into the export region. Our review of the most recent EC FVO report, from 2014, revealed that the EC FVO had concluded that the official FMD control system in place for Argentina is reliable and meets EU requirements. APHIS has also concluded that the veterinary infrastructure, surveillance, prevention, and control measures implemented by Argentina are sufficient to minimize the risk of introducing FMD into the United States for the purpose of beef imports. Further, the 2012 EC FVO report specifically states that, ''the FMD vaccination programme covers more than 80% of the susceptible population.''

In terms of the specifically mentioned Argentine border with Bolivia, local veterinarians in the Bolivian border region, as coordinated and supervised by the SENASA Coordinator of Animal Health, have instituted additional measures to strengthen sanitary controls in that area, including:

- Enhancing controls concerning transhumant animals (*i.e.,* animals moved from one grazing ground to another, usually seasonally), which include periodic visits to areas with higher likelihood of transhumance and the application of sanitary measures (*e.g.,* compulsory vaccinations, frequent visits with owners to discuss health-related issues).
- Revising and updating the registry of subsistence producers to improve the vaccination controls and animal movements in the region.
- Increasing the frequency of vaccinator audits, and implementing additional sanitary measures such as movement restrictions in irregular cases (*e.g.,* an animal lacking paperwork or an animal whose ownership is unknown).
- Increasing animal movement controls on roads, which include both fixed and mobile checkpoints.
- Identifying risk areas related to the possible presence of swine in rubbish

[4] A full account of Argentina's response to the 2012 EC audit may be found on the Internet at *http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=3099.*

dumps and other places of exposure to sources of irregular feeding, and implementing responsive sanitary measures according to those findings.

• Continuing awareness campaigns and education for the community on FMD and animal health in general, in order to minimize the risk of introduction of the FMD virus in the region.

As stated previously, the regulations in § 92.2 provide for monitoring of regions after APHIS authorizes imports. If we determine, via audit or other means, that the required measures have not been fully implemented or maintained, or that SENASA is unable to certify that the specific certification requirements are met, we will take appropriate remedial action to ensure that the importation of fresh (chilled or frozen) beef from Northern Argentina does not result in the importation of FMD into the United States.

Several commenters said that APHIS had concluded in the risk analysis and the proposed rule that there is a risk of reintroduction of FMD from adjacent areas into the export region, as long as the disease is endemic in the overall region in South America. The commenters stated that even though the risk of introducing FMD to the United States is low, if all of the conditions are met as outlined in the proposed rule, the risk is still present and must be viewed in light of the devastation it would cause to the U.S. beef industry if an FMD outbreak were to occur.

We took this information into account in our risk analysis and determined that the Argentine production and export system is robust and capable of meeting the standards for exportation set forth by APHIS. APHIS does not adopt a zero tolerance for risk for international trade in meat products. Our risk analysis process is designed to determine whether a product can be imported safely into the United States. If, based on our risk analysis, we conclude that the production system in the country in question is insufficient to provide an appropriate level of protection, then we will not authorize the importation of the particular commodity. That is not the conclusion we reached regarding the importation of fresh (chilled or frozen) beef from Northern Argentina.

Several commenters questioned the efficacy of Argentina's internal animal movement controls. One commenter claimed that there is no required branding program or other animal identification program. The commenter further stated that non-symptomatic carriers of FMD exist in South America and therefore a qualified laboratory is required to identify these carriers. Another commenter stated that in a large, diverse nation such as Argentina, it is quite possible for FMD virus to have been circulating among various species in various regions undetected for long periods of time. A third commenter said that it is common practice in the beef industry to ship livestock from place to place and, as a result, the risk of cattle from outside the designated area being transshipped through the area then to the United States is tremendous. The commenter asserted that all imports cannot be inspected and tested. Another commenter stated that greater market opportunities and the resulting higher prices offered in the export region might foster illegal animal movements into that region from the surrounding countries.

We do not agree with these comments. Based on our review of the veterinary infrastructure in Argentina, we determined that SENASA, which oversees animal movement within the country, has the legal authority, technical capabilities, and personnel to implement the FMD program within Argentina. Movement controls in Argentina are stringent. We evaluated these controls and concluded that cattle movements follow particular requirements, which are described in detail in the risk analysis, and that cattle whose beef is destined to be exported to the United States are required to be accompanied by documentation at slaughter showing that they were born and raised in the Northern Argentina region. APHIS evaluated the system and concluded that SENASA has the ability to certify that this requirement has been met.

As described in the risk analysis, in 2007, Argentina instituted a compulsory cattle identification program, requiring that all calves born after September 2007 carry official tags (Resolution 754/2006). Resolution 563/2012 requires that bovines from the older age groups be individually identified. At the time of the 2013 site visit, SENASA reported that the entire Argentine herd was individually identified. Individual identification of bovines is unique and permanent. The number of tags needed is requested by the animal owner and is crosschecked at the local office to the inventory in the integrated management system for animal health (Sistema Integrado de Gestión en Sanidad Animal—SIGSA). The animals' owner is responsible for applying the tags and then notifying the local office as to which tags have been used. The color of tags issued to cattle holders is determined by the FMD status of the region in which the cattle reside. Green tags are used in regions that are FMD-free without vaccination, yellow for regions that are FMD-free with vaccination, red in buffer areas, and blue tags are used for tag replacement purposes only. SENASA requires that all premises with agricultural animal production register with SENASA and obtain a RENSPA (Registro National Sanitario de Productores Agropecuarios or National Sanitary Registry of Agricultural Producers) number. The local SENASA office must issue an animal movement permit (DT-e), which is required whenever animals are moved. The local SENASA office is responsible for verifying that the vehicle transporting the animals has been cleaned and disinfected as required by law. Any inspection associated with animal movement involves checking the documents and verifying the animal information, as well as clinical observation of animal health.

Argentina's surveillance system includes active surveillance (which involves ongoing laboratory-based testing). We are confident that the SENASA laboratory, which is responsible for the screening and confirmatory diagnosis of FMD, is fully capable of carrying out those responsibilities.

Any beef product that is imported into the United States from Argentina must be certified by SENASA as meeting all requirements set out in the regulations. This certification must accompany each shipment and is subject to review by the U.S. Customs Border and Protection (CBP) officials that cover each port of entry into the United States. Any shipments not meeting that requirement are refused entry and CBP reserves the right to question documentation or packaging at the port of entry based upon inspection. Imported meat products are then forwarded to an FSIS Inspection House for re-inspection. We are confident that these measures supply the necessary level of inspection required to minimize the risk of introducing FMD into the United States.

Some of the commenters did not believe the requirement for chilling the carcass after slaughter would be an effective mitigation against the FMD virus. One commenter stated that chilling beef may be inadequate for eliminating the virus, since that virus can remain active in blood clots. Two commenters said that research shows that the FMD virus can survive in frozen bone for up to 6 months.

APHIS agrees that chilling alone may not be adequate to eliminate the virus. Other tissues, organs, etc., that may harbor FMD virus, such as blood clots,

heads, feet, viscera, bones, and major lymph nodes, do not undergo acidification, allowing the virus to survive the maturation process and subsequent low-temperature storage. Under this rulemaking, however, as noted previously, these tissues, bones, and organs must be removed from the carcasses prior to export to the United States. We have also added a more detailed discussion of viral inactivation to the risk analysis.

Two commenters noted that, in the past, APHIS has characterized other countries, *e.g.,* Argentina, Japan, and South Korea, as low-risk countries for FMD, and that, soon after we did so, outbreaks of the disease occurred in those countries.

Because disease situations are fluid and no country, not even the United States, can guarantee perpetual freedom from a disease, APHIS' risk analyses consider whether a country can quickly detect, respond, and report changes in disease situations. In our evaluation, conducted according to the factors identified in § 92.2, ''Application for recognition of the animal health status of a region,'' we concluded that Argentina has the legal framework, animal health infrastructure, movement and border controls, diagnostic capabilities, surveillance programs, and emergency response systems necessary to detect, report, control, and manage FMD outbreaks.

As a member of OIE, Argentina is obligated to immediately notify the organization of any FMD outbreak or other important epidemiological event. The notification must include the reason for the notification, the name of the disease, the affected species, the geographical area affected, the control measures applied, and any laboratory tests carried out or in progress.

Upon notification of an FMD outbreak in the exporting region of Argentina, APHIS would implement critical prevention measures to respond to the outbreak, including alerting CBP inspectors at all ports of entry. Because § 94.29(b) of this final rule requires that FMD must not have been diagnosed in the exporting region within the past 12 months, fresh beef from the region would no longer meet our requirements, and we would immediately stop allowing it to be imported.

One commenter said that Argentina is surrounded by FMD positive countries and inquired about the disease status of southern Argentina. Another commenter stated that reliance on natural barriers to protect against FMD is an inadequate prevention tool for a region that shares multiple borders with countries known to have FMD or are FMD free with vaccination.

No FMD outbreaks have been reported in South America since 2012. Most South American countries have been recognized by the OIE as being FMD free with vaccination (Uruguay) or without vaccination (Chile and Guyana) or with free regions with vaccination (Argentina, Bolivia, Brazil, Colombia, Peru) or without vaccination (Argentina, Bolivia, Brazil, Colombia, Peru). No outbreaks have been reported in Brazil since 2006, in Paraguay since 2012, and in Bolivia since 2007. In that regard, the risk of introduction from neighboring countries is low. Any risk is of introduction is mitigated by following a regional approach to FMD eradication. APHIS acknowledges many enhancements in border control activities along the northern borders with Bolivia, Paraguay, and Brazil.

Further, Argentina does not solely rely on natural barriers to protect the export region from FMD; rather, it is one of many elements that contribute to Argentina's overall sanitary security. As long as FMD is considered endemic only in small areas of South America, there is a very low risk of reintroduction of FMD from those small, adjacent affected areas into the export region and therefore a low likelihood that beef destined for the United States could originate from or be commingled with animals or animal products from affected neighboring areas.

In the event FMD were to be introduced into the northwest of Argentina, the consequences would not be major (as demonstrated in the Tartagal outbreak, 2003) mainly due to the low animal density, low animal movements, and effective veterinary infrastructure in the area. The FMD outbreak that occurred in 2006 shows that SENASA is able to immediately notify and contain the disease, even before confirming diagnosis. APHIS acknowledges that SENASA has adopted several measures to prevent the introduction of the FMD virus from the south of Brazil, Bolivia, and Paraguay. Both Argentina and the OIE divide the areas south of Northern Argentina into three major parts: Patagonia North A, Patagonia North B, and Patagonia South. Patagonia North A was recognized by the OIE as FMD free without vaccination in 2014, however, as stated in footnote 3, APHIS has made no similar determination. For export purposes, APHIS includes Patagonia North A in the Northern Argentina region and any fresh (chilled or frozen) beef exported from that area would be required to be treated in the same manner as beef exported from the slightly smaller region known to Argentina and the OIE as Northern Argentina. On August 29, 2014, we published in the **Federal Register** (79 FR 51528–51535, Docket No. APHIS–2013–0105) [5] a notice that we were adding Patagonia North B and Patagonia South to the list of regions that APHIS considers free of FMD.

One commenter specifically cited the feral swine population of Texas as a potential vector for the rapid spread of FMD if it were to enter into the United States via the importation of fresh (chilled or frozen) beef from Argentina.

FMD susceptible scavengers, such as feral swine, might ingest discarded FMD-contaminated meat, such as raw meat trimmings, and become infected. The frequency of scavenging incidents is similar to risk factors analyzed in connection with the waste feeding pathway (*e.g.,* the amount of imported, contaminated, uncooked meat in household garbage). Therefore, we consider the risk of the scavenging pathway to be equivalent to or lower than that of the waste feeding pathway. We have updated the exposure assessment section of the risk analysis to include further discussion of the risk related to susceptible scavenger and waste feeding of swine.

Another commenter cited the practice of some cowboys in the Patagonia Region who capture and sell feral cattle stating, that cattle of this type are not tested and therefore could be carriers of FMD.

Feral cattle that are captured and enter the Argentine beef production system must come into compliance with the Argentine FMD program requirements, including compulsory vaccination and identification, as is necessary for cattle from any other source in Argentina. Vaccination campaigns take special consideration of the distribution and reach of feral populations.

Comments on the Risk Analysis Development Process

The risk analysis for Northern Argentina includes an in-depth evaluation of the 11 factors used by APHIS to evaluate the animal health status of a region prior to 2012. In August 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 Northern Argentina started before 2012, and the topics

[5] To view that notice and its supporting documentation, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0105.*

addressed by the 11 factors are encapsulated in the 8, this analysis follows the 11 factor format. One commenter objected to our use of the 11 factor format. The commenter characterized the reason for the change as the fact that ''the list of 11 factors can be confusing.'' The commenter said that the use of the 11 factor analysis is arbitrary and contrary to APHIS' current regulations and should not be permitted.

We disagree. As stated in the proposed rule, the topics addressed by the 11 factors are encapsulated in the 8. Appendix II of the risk analysis describes the correspondence between the 8 and 11 factors. The commenter's assertion that APHIS amended its evaluation factors because they were confusing is an incomplete assessment of the situation at the time of the August 2012 rule. Specifically, we said that the 11 factor list could be confusing because the information requested in some of the factors overlapped with information requested in other factors. We therefore amended the list so as not to receive redundant information from requesting countries. Given that the development of our risk analysis took years and given that the 11 factors are included in the 8 factors, rewriting the analysis in the way the commenter suggests would involve a time-consuming, non-substantive consolidation process, which is not warranted under the circumstances.

Some commenters questioned the methodology we employed for the site visits to Argentina. It was claimed that there is no obvious evidence of any established protocol or methodology to allow for consistency and assurance in the quality of the APHIS site visit reviews and that documentation pertaining to the visits was lacking or unavailable for public review. According to one commenter, documents pertaining to the specific methodology and measurements used during the site visits to support the qualitative risk analysis should have been available for the public to review. It was stated that without sufficient documentation, there was no way to distinguish between data obtained from the site visits and data supplied by the Government of Argentina. It was recommended that APHIS develop a protocol, which it should make available to the public, to be used for site visits so that our assessments can be analyzed and summarized more objectively.

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 to consider in assessing the risk of the relevant animal disease posed by a region. The animal disease risks identified in the risk analysis come from the information gathered pertaining to 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 decisionmaking 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.

Two other commenters stated that a request for information had been made under the Freedom of Information Act (FOIA) to APHIS related to the site visits to Argentina and documented reporting procedures and established methodology used to conduct those site visits. The commenters said that the rule should not be finalized until the commenters receive, review, and have the opportunity to make additional comments based on the information obtained through FOIA.

We disagree with the commenter's suggestion. As stated previously, the initial 60-day public comment period was extended by 60 days, providing stakeholders with a total of 120 days to share information relevant to each rule. FOIA requests are processed and fulfilled separately from the regulatory process.[6]

Two commenters said that some citations in the risk analysis, such as references to APHIS internal publications or unpublished reports, did not seem credible because those sources were not readily available to stakeholders for review. The commenters added that each of the primary supporting documents included with the rule on Regulations.gov should have been explicitly referenced in the risk analysis.

We disagree. The information referenced and the conclusions reached are thoroughly described in the risk analysis. In addition, the final risk analysis includes further discussion and references regarding some of the issues about which other commenters had questions.

Two commenters raised issues regarding the scope of our risk analysis. It was stated that the release assessment, exposure assessment, and consequence assessment appeared to be incomplete with regard to the necessary steps and requirements described in the OIE Terrestrial Animal Health Code.

We conducted the risk analysis in accordance with chapter 2.1 of the OIE Terrestrial Animal Health Code, ''Import Risk Analysis.'' The Code recommends that risk analyses include four steps: An entry assessment, an exposure assessment, a consequence assessment, and an overall risk estimation based on the data compiled in the previous three steps. A description of each of those steps is included. In conducting our risk analysis of Northern Argentina, we followed the steps listed in the OIE Terrestrial Animal Health Code. Where there are differences, they have more to do with terminology than methodology. For example, we refer to what the OIE terms the entry assessment as a release assessment.

Comments on the U.S. Governmental Accountability Office Audit

Many commenters stated that the U.S. Government Accountability Office (GAO) has accepted a request submitted by several members of Congress to review the APHIS country review and verification process and the risk analysis used to formulate this proposed rule. The commenters said that no further action on the rule should be taken until the GAO review is completed. One commenter stated that a USDA Office of the Inspector General (OIG) review is also a possibility and that APHIS should wait for the reports from both bodies before proceeding with further action.

While an audit has been requested, that request has not been processed by the GAO. The GAO is an independent agency and, as such, its audit process exists independently of the APHIS regulatory process. If, in the future, the GAO conducts such an audit and releases findings and recommendations, APHIS will review them and adjust our process accordingly. As for the OIG audit referenced by the commenter, at this time such a request has not been submitted. If it is submitted in the future, the OIG will conduct the audit independently of APHIS, and we will take any findings into consideration at the time they are released.

[6] For more information on the APHIS FOIA process you may visit *http://www.aphis.usda.gov/wps/portal/aphis/resources?1dmy&urile=wcm%3apath%3a/aphis_content_library/sa_resources/sa_laws_and_regulations/sa_foia/ct_foia.*

Comments on the University of Minnesota Report

Several commenters made reference to a report released by a third-party scientific review team from the University of Minnesota College of Veterinary Medicine, Center for Animal Health and Food Safety, and the Center for Veterinary Population Medicine which evaluated the APHIS risk analysis. The commenters stated that the report found limited or lacking scientific methodological approaches in performing the risk analysis, poorly defined scope regarding the specific animal types and products for the risk analysis, lack of sufficient detail for geographical landmarks outlining the region, and maps lacking the necessary level of detail to be useful to determine the region.

We have not been made privy to this report and therefore cannot provide a detailed response to topics beyond those cited by the commenters. Both APHIS and the OIE support the use of a qualitative risk analysis model for the purpose of animal health status evaluation. In the OIE's ''Handbook on Import Risk Analysis for Animal and Animal Products,'' qualitative risk analyses, such as the one that informs our decision to allow for the importation of fresh (chilled or frozen) beef from Northern Argentina, are cited as both an appropriate and the most common type of assessment used to support import decisions. The risk factors evaluated by APHIS and described in detail in the risk analysis are almost identical to those evaluated by the OIE.[7] Additionally, we disagree that the specific animal types and products are undefined. The sole product under consideration for importation in the risk analysis is fresh (chilled or frozen) beef that has been matured and deboned in accordance with the regulations. We also disagree with the claims regarding lack of geographical detail. As described previously, figure 12, which is located on page 52 of the risk analysis, is a map showing the various regions in Argentina, including Northern Argentina. The region under consideration is located north of the Patagonia Region, which includes the region located south of the 42nd parallel known as Patagonia South, and the region immediately north of the 42nd parallel known as Patagonia North B. The full description of the area is found earlier in this document. We have also added further description of the area to the risk analysis.

Comments on the Risk Analysis

Some commenters stated that APHIS should prepare a quantitative risk analysis for beef from Northern Argentina and make it available for public review. Commenters took the position that the qualitative risk analysis methodology that we employed is too subjective because it fails to quantify objectively the probability of risk and adequately assess the magnitude of the consequences of a disease outbreak. Noting that APHIS prepared a quantitative risk analysis in 2002 in support of the rulemaking allowing the importation of fresh beef from Uruguay, commenters questioned why APHIS chose to prepare only a qualitative risk analysis for Northern Argentina.

One commenter stated that although the commenter recognized that the analysis was qualitative, some categories that define what USDA considers ''low'' risk would be helpful and are necessary for a clear understanding of the risk associated with importation of a given commodity.

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 properly assess the risk of the introduction of FMD through importation of commodities such as fresh beef. Quantitative risk analysis models are not the best tool to use to assess the risk of FMD posed by exports from a country where the types of data required by such models are unavailable or inadequate. In these instances, APHIS characterizes the risk of potential 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 beef, no diagnosis of FMD in the previous 12 months).

Contrary to the assertion that a qualitative analysis should define an explicit level of risk or a range of risk, the relative flexibility afforded by a qualitative analysis allows us to evaluate commodity import programs in a holistic manner.

Some commenters viewed the documentation supporting our risk analysis as insufficient. It was further noted that some of those supporting documents were in Spanish. As a result, according to the commenters, transparency was lacking regarding our research methodology and the manner in which we arrived at our conclusions. It was also claimed that the documents we did make available lacked consistency and evidence of verification of our findings.

APHIS acknowledges that some of the documents used as references in the risk analysis were submitted to APHIS in Spanish; APHIS personnel were able to read and evaluate these documents without the necessity of translation into English. In most instances, the same or related data were provided in English in other documents or verbally presented to APHIS during site visits. However, the information provided by Argentina and the conclusions reached are thoroughly described in English in the risk analysis that was made available for public review and comment.

As stated in the proposed rule, although there has not been a major outbreak of FMD since 2001/2002, APHIS does not consider Northern Argentina to be free of FMD because of the vaccination program in that region. One commenter stated that the sanitary security of the United States would be more effectively protected by continuing only to allow for importation from countries that are certified as FMD free without vaccination.

We disagree with the commenter. Our conclusion regarding the decision to allow for the importation of fresh (chilled or frozen) beef from Northern Argentina was reached based upon our understanding of the disease situation in that region and the efficacy of mitigation measures for beef. It has been 9 years since the last FMD detection of any size in Northern Argentina; and the changes in SENASA's infrastructure following earlier outbreaks, as detailed in the risk analysis provide adequate protection against the importation of FMD into the United States via fresh (chilled or frozen) beef from Northern Argentina.

Another commenter observed that the source for APHIS' report that SENASA had officially inspected over 31 million cattle and sheep in 2009 was noted as being a discussion between APHIS and SENASA officials during APHIS' 2005 site visit. The commenter questioned the reliability of this source.

The date of the discussion regarding inspection that took place during the site visit was incorrect in the risk analysis that accompanied the proposed rule. We have corrected the reference in the updated risk analysis to indicate that the discussion occurred during APHIS' 2009 site visit.

Another commenter asked that APHIS address the impact of FMD on the economy and individuals, the duration

[7] You may find a detailed list of the OIE factors on the Internet at *http://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/2010/en_chapitre_selfdeclaration.htm.*

of the disease, meat inspection procedures, and uncertainties about Argentine sanitary security.

These topics and more are covered by the risk analysis. Further, we would note that in 2003 APHIS authorized the importation of fresh (chilled or frozen) beef under the same conditions that are found in this rule from Uruguay, a region that, like Northern Argentina, is free of FMD with vaccination. Since that time, importation of Uruguayan beef has not been associated with an increased risk of FMD.

Some of the commenters expressed reservations about the efficacy of the maturation requirements contained in the proposed rule, which included chilling the carcass after slaughter for a minimum of 24, and a maximum of 48, hours to ensure that the pH in the loin muscle will be below 6.0. One commenter observed that the risk analysis and the environmental assessment that accompanied the proposed rule were inconsistent concerning whether the FMD virus is totally inactivated as stated in the risk analysis, or whether a small proportion of the virus particles that are relatively resistant to the effects of heat and pH in most populations would remain, as stated in the environmental assessment. The commenter concluded that, if the latter situation were true, the presence of even a small number of virus particles undermined APHIS' claim that the risk posed by the importation of chilled (fresh or frozen) beef from Northern Argentina is low since the virus would not be truly inactivated.

Based on the existing scientific literature, it is generally accepted that FMD virus is inactivated at pH 6.0 or below after maturation at a temperature of 4 °C. Acidification of skeletal muscle that takes place during carcass maturation is normally sufficient to inactivate FMD virus in this tissue, even when cattle are killed at the height of viremia. Because it is known that the required level of acidification cannot be guaranteed under all circumstances, measuring of the pH level of the carcass muscle can be used to ensure that it has occurred. This rule requires that measurements for pH be taken at the middle of both *longissimus dorsi* muscles; any carcass in which the pH does not reach less than 6.0 may be allowed to maturate an additional 24 hours, and if the carcass still has not reached a pH of less than 6.0 after 48 hours, the meat from the carcass may not be exported to the United States. We have updated the risk analysis and the environmental assessment based on this comment to include further references and explanation of the issue.

One commenter noted that both the rate of pH fall and the ultimate pH achieved in the muscle tissue are influenced by factors such as species, type of muscle in an animal, genetic variability between animals, administration of drugs which affect metabolism, environmental factors prior to slaughter such as feeding or stress, and post-mortem temperature. The commenter stated that therefore a precise protocol must be followed, and expressed doubt that Argentine producers would be capable of adhering to this protocol.

Contrary to the commenter's point regarding different muscle types reaching varying pH levels, we have specified that pH readings must be taken from the *longissimus dorsi* muscle. Additionally, transportation and carcass resting both influence the likelihood that the muscle tissue will reach the required pH level since, as stated previously, acidification of the skeletal muscles takes place during this time. Even if one or more of the various influencing factors were to affect the pH of the muscle tissue, any carcasses that do not reach the required pH level will not be allowed to be exported into the United States, regardless of how that level was reached. As stated previously, we have added more discussion on the maturation process and the effectiveness of the process in FMD virus inactivation to the final risk analysis.

Two commenters said that the proposed mitigations involving the maturation of the fresh beef and deboning appeared inconsistent with the OIE guidelines for FMD risk mitigation. The commenters stated that the proposed requirements established deboning and maturation as two separate and unrelated mitigations, but the OIE recommendations clearly state that deboning should occur after the meat has matured and reached a pH less than 6.0 at the middle of both *longissimus dorsi* muscles.

While it was always our intention—and is our practice concerning importation of fresh (chilled or frozen) beef from Uruguay—that deboning occur after the meat had matured and reached the required pH level, we have amended, for clarification purposes, the language in this final rule describing this process.

The same commenters pointed out that neither the proposed rule nor the risk analysis provided information regarding freezing procedures, even though the product proposed for import was chilled or frozen beef.

Both chilling and freezing of meat after maturation are standard industry practices, crucial for food safety and quality regardless of the final destination of the meat. The procedure is as follows: After slaughter, beef carcasses are kept in the chilling rooms at appropriate refrigeration temperatures (carcasses will begin chilling within 1 hour from bleed-out). As previously stated, bovine carcasses are then required to maturate at 40 to 50 °F (4 to 10 °C) for a minimum of 24 hours and must reach a pH below 6.0 in the loin muscle at the end of this period. Measurements for pH must be taken at the middle of both *longissimus dorsi* muscles. The maturation process critical for FMD virus inactivation via pH drop is temperature dependent, which is why we specified the required temperature range in the proposed rule.

The process of carcass fabrication begins immediately after a carcass leaves the chilling room and takes place in the deboning room where beef cuts are obtained and blood clots and lymph nodes are removed under environmental refrigeration temperatures. These temperatures vary but are generally less than 50 °F (10 °C). Carcass temperature (usually between 4 and 7 °C) and pH are controlled before the carcass enters the deboning room in order to ensure compliance with SENASA authorities and the specifications of importing countries. After the carcass is processed into cuts of meat, those cuts are packed and stored either in a chiller separate from the chiller used for carcass maturation, or in a freezer. A description of the inactivation process has been added to the final risk analysis.

Another commenter observed that, unlike the risk analysis APHIS completed concerning the importation of fresh (chilled or frozen) beef from Brazil, the risk analysis for Northern Argentina does not disclose the number of practicing veterinarians in Argentina, instead stating that SENASA employs 1,054 veterinarians. The commenter said that the absence of the total number of veterinarians in Argentina made a true picture of the veterinarian-to-livestock ratio in Argentina impossible. The commenter further stated that the SENASA-employed veterinarian-to-livestock population ratio of approximately 1 government-employed veterinarian for each 54,080 head of cattle suggests that Argentina lacks an adequate number of veterinarians to effectively monitor the health of Argentina's cattle herd. The commenter said that APHIS should explain the discrepancy in approach between the risk analyses for Brazil and Northern Argentina.

In conducting our evaluation of any animal health program, APHIS is mainly concerned with the veterinary authority

of the responsible organization and its available resources for conducting emergency response, vaccination, enforcing movement restrictions, etc. We evaluate the veterinary infrastructure and authority in the context of detection and prevention of FMD, which includes the ability of the veterinary authority to certify that the required mitigations are met. That evaluation may or may not include number of veterinarians. Brazil provided that number with its application and Argentina did not. As in the United States, many veterinarians in Argentina operate mixed veterinary practices that encompass care of both large and small animals in varying proportion. Therefore, any information provided regarding total number of veterinary practices in Argentina would be misleading. Consequently, we do not consider the number to be a significant aspect of a country's sanitary infrastructure; however, we do provide such information in the risk analysis if it is included in the information provided to us.

The same commenter stated that, in the risk analysis accompanying APHIS' proposal to declare the State of Santa Catarina, Brazil, free of FMD, APHIS disclosed the type and quantity of high-risk imports that were known to enter Santa Catarina, the numbers and origins of FMD-susceptible animals that had entered Santa Catarina for breeding purposes, swine movement into and within the State of Santa Catarina, and imports of animals and products from FMD-susceptible animals into the State of Santa Catarina. The commenter said that these data enabled reviewers to evaluate the risk and formulate opinions regarding the specific import practices of the state that had requested to export FMD-susceptible animals and products to the United States and observed that APHIS provided no comparable data in the risk analysis accompanying the Argentine proposed rule.

The commenter specifically cited a statement from the risk analysis that ''an area near the border with Paraguay [is] considered endemic for FMD [and] [t]his endemic area appears to have active virus present in restricted niches or patches, which could potentially lead to outbreaks in cattle populations with low FMD immunity,'' and concluded that APHIS knows that it is likely, if not highly likely, that an active FMD virus is present in Northern Argentina.

As described in the two risk analyses, both the State of Santa Catarina, Brazil, and the region of Northern Argentina follow OIE guidelines for the importation of FMD-susceptible commodities. The particular imports as well as the guidelines followed are different since both regions have different status. Argentina is a net exporter of cattle, and the number of imported cattle is insignificant. According to SENASA, the last importation of cattle from Paraguay (which was for breeding purposes only) occurred in 2010 (11 head), no cattle imports have been reported from Brazil or Bolivia since 2010, and Argentina's imports from Uruguay are generally less than 200 head of cattle per year. The primary imports of beef into Argentina are from Uruguay under the same type of conditions that are currently in place for the importation of fresh (chilled or frozen) beef from Uruguay into the United States.

The risk analysis we performed pursuant to declaring the State of Santa Catarina free of FMD specifically evaluated the disease situation for four swine diseases, including FMD. The State of Santa Catarina is a major swine-producing state, and an assessment of swine movements was critical to our analysis. In the case of Northern Argentina, swine imports into the region are negligible as Argentina is not a major swine-producer. According to SENASA, 1,521 swine were imported into Argentina in 2014, all of which were from Brazil.

Further, the commenter has taken the statement about the Paraguay-Argentina border out of its original context in the risk analysis. The statement refers to the situation in Argentina in a particular area at the time of the most recent FMD outbreak in Argentina, which was 9 years ago. The current epidemiological situation and evidence supports APHIS' conclusion that either the disease does not exist in that region or that the vaccination coverage is high and the disease is under control. At the time the State of Santa Catarina, Brazil, risk analysis was finalized in August 2010, there were other regions of South America experiencing outbreaks. As a result, our consideration of risk for the State of Santa Catarina, Brazil, was based in part on the disease situation in the surrounding region, which differs here since there has been no outbreak of FMD reported in South America for the past 3 years.

One commenter stated that farmers who own property spanning the borders between Argentina and Paraguay and Argentina and Bolivia are of particular concern as this increases the potential for animal movements across the borders. The commenter added that nomadic people in the area would also be likely to move animals without proper documentation. Another commenter specifically cited the border with Paraguay as being of continuing concern given that the risk analysis identified illegal movement of livestock from Paraguay as a likely source of historical FMD introduction to Argentina.

Argentina collaborates with neighboring countries to harmonize FMD-related programs and restrictions. Mechanisms have been established to provide for immediate notification between these countries if an outbreak occurs. High-risk surveillance areas have been established on Argentina's borders with Brazil, Paraguay, and Bolivia. This program includes: Strengthening infrastructure of the veterinary services; harmonizing procedures for control, prevention, and eradication of FMD; harmonizing vaccination procedures in areas of geographic contiguity; and conducting vaccinations under APHIS supervision. That being said, in response to the comment we are adding a clarifying statement to both the risk analysis and the environmental assessment to emphasize that if FMD exists at all in South America, it likely does so only in very small regions as evidenced by the lack of reports of the disease over the past 3 years.

One commenter said that the nature of the border control and biosecurity measures in place between the Northern Argentina region and neighboring countries was not clearly described in the risk analysis. Another commenter stated that while APHIS described enhancements to the border control activities and infrastructure in the Provinces of Formosa, Salta, and Jujuy, we failed to explain what enhancements were made in the Provinces of Misiones, Chaco, and Corrientes.

As stated in the risk analysis, border control activities include, but are not limited to, vaccinations, surveillance, animal census, education, and animal identification. Contrary to the second commenter's assertion, enhancements made to border control activities, which include activities that occur in the Provinces of Misiones, Chaco, and Corrientes since they are located on the border of Argentina, are described in the risk analysis as follows: Following the recommendations of the OIE mission that visited Argentina, Brazil, and Paraguay in December 2006, the heads of the veterinary services and the Pan American Foot-and-Mouth Disease Center defined an area of high-level surveillance within the border regions of Argentina, Brazil, Paraguay, and Bolivia. Initially the program was intended to last 2 years and be subjected to periodic reviews and evaluations. During the 2009 and 2013 site visits,

SENASA reported that the program was still effectively operating, with a redefinition of the high surveillance area in 2013 to include the border regions of Argentina, Paraguay, and Bolivia. Most of the financing has been obtained from the World Bank and the Inter-American Development bank. Among others, the general actions include:

- Strengthening infrastructure of the veterinary services;
- Harmonizing procedures for control, prevention, and eradication of FMD;
- Harmonizing vaccination procedures in areas of geographic contiguity; and
- Conducting vaccinations under APHIS supervision.

The same commenter observed that APHIS included data on the buffalo population in our risk analyses for both the State of Santa Catarina, Brazil, and for the 14 additional Brazilian States that have requested to export fresh (chilled or frozen) beef to the United States, as buffalo are an FMD-susceptible species. The commenter noted that there is no mention of buffalo in the Northern Argentina risk analysis despite the existence of Internet advertisements for hunting water buffalo in Argentina. The commenter concluded that, for such advertisements to exist there must be a significant population of water buffalo in the region, which represent a risk of FMD transmission.

In 2014, the buffalo population in Argentina was less than 94,000 head [8] and vaccination and movement requirements for those buffalo are identical to those for cattle. We have added an explanation to this effect in the final risk analysis.

The same commenter stated that APHIS provides no discussion regarding the likelihood that wildlife in Argentina has developed a natural immunity to the FMD virus. The commenter posited that, with such immunity, wildlife could serve as asymptomatic carriers of the disease and because Argentina has been vaccinating cattle for FMD for a considerable period of time, the transmission of the FMD virus between wildlife and domestic livestock would not be expected to result in a symptomatic response.

Other commenters also took issue with the release assessment for suggesting that wildlife does not play a significant role in the transmission of FMD. It was claimed that the statement lacked support in the scientific literature. One commenter specifically cited the feral swine population in the Gran Chaco region and the endangered and protected Chacoan peccary that are allowed to move freely within the Gran Chaco as a potential source of wildlife transmission for FMD between Northern Argentina, Bolivia, Paraguay, and Brazil.

The first commenter provided no evidence to support the supposition that species of wildlife are likely to become asymptomatic carriers of the FMD virus in the particular region under consideration and there is no epidemiological data supporting such a claim. As stated previously, research into FMD in South America has determined that wildlife populations 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. Therefore, it is unlikely that FMD would be introduced into Northern Argentina through movement of infected wildlife.

The epidemiology of the disease in South America over time and the information provided in the surveillance section of the risk analysis clearly demonstrate that the role of wildlife in disease transmission in the area under consideration is insignificant. Many decades of experience with the disease have shown no consistent relationship between outbreaks in domestic animals and coexistence of susceptible wild animals in South America. In addition, results of repeated serological testing focusing on cattle as the most susceptible species do not reveal evidence of viral activity in domestic ruminants that are likely to contact wild animals. If wild animals were carriers or reservoirs of FMD, evidence of viral activity would be expected in domestic species coexisting in the same regions as infected wild animals.

A commenter said that, while the APHIS risk analysis states that, as of 2006, there were 52 eligible plants in Argentina certified to export meat to the United States, the most recent FSIS audit of the Argentine meat industry states that there are only 14 such establishments. The commenter said that APHIS' assessment of risk associated was therefore wrongly assuming that the volume of potentially export-eligible beef per plant was lower; a situation which would allow for more careful oversight within those plants than is actually the case given the FSIS data.

All plants approved by SENASA are federally inspected. Prior to the finalization of this rule, only cooked or cured beef was eligible for export from Northern Argentina under the regulations in 9 CFR 94.4, due to that region's FMD status. In response to the comment we are deleting the number of plants since that number will be updated after FSIS conducts its equivalence determination. Moreover, the number of eligible plants is subject to relatively frequent change, most likely due to ongoing compliance cost assessments made by individual owners in Argentina. Regardless, we do not make assumptions regarding how much beef a plant will produce; rather we evaluate the likelihood that FMD could be introduced into the United States via the importation of beef. It is unlikely, given the expected low import volume, that beef will be imported from Argentina at levels that will overwhelm the existing processing infrastructure.

The same commenter pointed out that the endnote citation listed in the risk analysis as supporting an assertion regarding the rate of pH change in the *longissimus dorsi* muscle referred to an FSIS report on Argentine plants eligible to export meat to the United States and not to any scientific literature.

The commenter correctly pointed out that our reference number was mistaken and we have corrected it in the final risk analysis.

Comments on the Economic Analysis

One commenter said that the underlying assumption in APHIS' entire economic model is that U.S. cattle are grain fed and, therefore, of higher quality, while imports from Argentina will be beef from grass fed cattle. The commenter characterized these assumptions as false, citing the USDA Foreign Agricultural Service's (FAS's) September 2014 GAIN report, which states that most of the beef currently consumed in Argentina is grain fed. The commenter concluded that therefore beef from Argentina will be comparable to high-quality U.S. beef and, therefore, more competitive in the U.S. market.

We acknowledge the fact that a large percentage of beef cattle in Argentina now complete their feeding regimen in feedlots. It is true that the grain fed beef imported from Argentina will be more directly competitive with U.S. sourced beef, but the overall conclusion of our analysis remains the same: The relatively small quantity of Argentine beef expected to be imported will not significantly impact the U.S. market. In 2013, Argentina exported approximately 7 percent of its total production and consumed the remaining 93 percent. Given Argentina's production capacity and its promotion of domestic consumption of beef, it is unlikely that

[8] SENASA, official communication with APHIS, January 23, 2015.

Argentina's beef will strongly compete in the U.S market. In terms of value, the EU continues to be the main destination for Argentina's beef exports, as it is able to enter the EU market under the Tariff Quota regulated by EC Regulation No. 936/97 of 27 May 1997. Argentina has been recently approved by the EU to access the quota for premium quality (Beef 481) with no fee. Other countries already authorized under this quota are the United States, Australia, Canada, New Zealand, and Uruguay. This quota differs from the Tariff Quota regulated by EC Regulation No. 936/97 described earlier in this document in that it is not allotted by portions to each of the participant nations, but it is a general quota for which all the countries involved must compete. Argentina's beef exports will therefore most likely be intended for multiple locations, not only for the U.S. market.

The same commenter said that in 2012, the price for heavy fed steers in Argentina was $8.80 pesos per live kilo (approximately $0.47 U.S. dollars per pound) and the price for heavy fed steers in the United States in that year was approximately $1.23 U.S. dollars per pound. The commenter observed that Argentine cattle are priced at about one-third of the price of U.S. cattle and this price differential will create incentive for multinational corporations to source beef from Argentine cattle and therefore quickly increase supplies of beef comparable to U.S. beef in the U.S. market.

Argentina's proposed export quantity represents less than 1 percent of U.S. beef production and is unlikely to have a major impact on the U.S. domestic market. In addition, Argentine beef will be exported to the United States under a quota, and quantities over that quota will be assessed an import duty of 26.4 percent. The EU is the largest market for Argentina's beef. Given projected import levels, above-quota duties, and existing market patterns, the economic impact of Argentine beef imports is likely to be small.

The same commenter stated that the economic analysis likely ignores the extreme sensitivity of U.S. cattle prices to changes in supply. The commenter cited studies that show that farm level elasticity of demand for slaughter cattle is such that a 1 percent increase in supply can reduce prices by up to 2.5 percent. The commenter observed that domestic cattle prices jumped $26 per hundredweight after trade restrictions were imposed on imports of cattle and beef from Canada in 2003, thus demonstrating the sensitivity of the market.

The economic analysis uses a partial equilibrium model for which more details can be found in Paarlberg et al.[9] In mapping interactions among the grain, livestock, and livestock product sectors, the model assumes price-taking economic decisionmakers who maximize well-defined objective functions. Utility maximization for consumers yields a set of per capita demand functions. Three sets of parameters drive the model: The livestock feed-balance calculator, the revenue shares for all industries, and elasticities used in the model solution. The livestock feed-balance calculators are critical because they relate the stocks and flows of animals for each quarter to the feed supplies available, forming the critical vertical linkage between the animal agriculture component and the crop component. Elasticities are critical parameters and are grouped into several sets. Most own- and cross-price elasticities of retail demand are based on estimates from econometric models. Cross-price elasticities are non-negative, implying that the commodities involved are substitutes. Substitution elasticities describe derived demand behaviors and affect supplies of the output commodities in the equation from which they are derived. Substitution elasticities are either obtained from the literature or generated consistent with commonly accepted supply elasticity values.

The percentage change in cattle and beef prices in 2003, which was because of trade restrictions due to the discovery of BSE in Canada, were significantly greater than the percentage price changes expected as a result of the importation of fresh (chilled or frozen) beef from Argentina. Immediately following the discovery of BSE in Canada in May 2003, the United States closed its border to imports of Canadian feeder cattle, fed cattle, cull cows, and beef. Later in 2003, the United States reopened its border to imports of Canadian boneless beef obtained from animals less than 30 months of age. Prior to May 2003, almost half of the cattle sold in Canada were exported as either live animals or meat. In 2002, about 90 percent of Canadian beef exports went to the United States and accounted for 55 percent of U.S. beef imports.

In contrast to the relatively sudden loss of such a large traded volume of beef in 2003, expected annual imports from Argentina of 20,000 MT of fresh beef would be the equivalent of less than 2 percent of average annual U.S. beef imports and less than 0.2 percent of the U.S. beef supply, 2009–2013.

The commenter cites studies indicating that a 1 percent increase in the supply of beef can reduce slaughter cattle prices by up to 2.5 percent. Other studies, such as Marsh et al. (2005), find a coefficient closer to 1.5 (beef price flexibility coefficient at the slaughter-wholesale market level).[10] When this coefficient is multiplied by the percentage increase in the U.S. beef supply expected with this rule (20,000 MT, when assuming no displacement of beef imports from other sources), the percentage impact on slaughter cattle prices, 0.25 percent, is found to be essentially the same as shown in the last row of table 3 of the economic analysis.[11]

A commenter expressed the view that the rulemaking would depress markets for U.S. producers.

The commenter did not present data that would support the proposition that Argentina's beef exports are likely to increase so precipitously as a result of this rulemaking that U.S. producers would experience negative effects.

One commenter stated that the rule did not represent any benefit to U.S. producers.

Using a partial equilibrium model and considering three scenarios of 16,000, 20,000 and 24,000 metric tons, there are net welfare gains in each scenario. Under the 20,000 MT import scenario, producers would experience a decline in surplus of $7.63 million or 0.42 percent, while consumers would benefit from the decrease in price by an increase in their surplus of $130.24 million or 0.30 percent. The overall impact would be a net welfare gain of $122.61 million or 0.27 percent for U.S. beef consumers. The net welfare gain for the beef sector would be $0.61 million or 0.002 percent.

In the initial regulatory flexibility analysis prepared in connection with the proposed rule regarding the economic effects of the rule on small entities, we stated that the primary entities affected by the rule would be

[9] Paarlberg, Philip L., Ann Hillberg Seitzinger, John G. Lee, and Kenneth H. Mathews, Jr. Economic Impacts of Foreign Animal Disease. Economic Research Report Number 57. USDA ERS, May 2008.

[10] Marsh, J.M., G.W. Brester, and V.H. Smith. ''The Impacts on U.S. Cattle Prices of Re-Establishing Beef Trade Relations.'' Agricultural Marketing Policy Center, Briefing No. 74, February 2005.

[11] The average annual U.S. fresh beef supply (production minus exports plus imports), 2009–2013, was 11.85 million MT. Expected imports from Argentina in comparison to the U.S. fresh beef supply: 20,000 MT/11,850,000 = 0.17 percent. Effect on slaughter cattle prices of fresh beef imports from Argentina assuming a flexibility coefficient of 1.5: (0.17 percent)(1.5) = 0.25 percent.

cattle producers, feedlots, and slaughter facilities, the majority of which were considered to be small businesses. We also stated that there could be other categories of small entities affected and invited commenters to supply us with any information we might be lacking on the number and nature of those entities. Two commenters cited this as evidence that APHIS did not adequately prepare for the publication of this proposed rule by presenting a full list of potentially affected small entities.

The economic analysis for the proposed rule considered the entities that may be directly affected. Under the Regulatory Flexibility Act, agencies are required to consider impacts on small entities and request additional information if it is not readily available. We estimate that cattle (steer) prices and wholesale beef prices are likely to decline between about 0.2 and 0.3 percent due to beef imports from Argentina. These measures of price effects are industry-wide. How reductions in producer surplus because of these price declines may be distributed among livestock operations and other affected entities cannot be determined from the information available.

Many commenters expressed concern about the potentially devastating economic effect an outbreak of FMD in the United States could have on U.S. cattle producers. It was stated that the potential economic risks greatly outweigh the benefits of this rulemaking, and that the economic analysis accompanying the August 2014 proposed rule failed to take into account those potential costs. Some commenters recommended that we revise the economic analysis to account for those potential costs. It was suggested that we should perform a comprehensive, up-to-date economic analysis to identify consequences for all U.S. commodity groups potentially affected by an FMD outbreak.

It is true that an outbreak of FMD in the United States, whatever its source, could have very serious effects on the U.S. cattle industry. In the economic analysis accompanying the August 2014 proposed rule, we modeled expected benefits and costs of annual imports of fresh (chilled or frozen) beef from Northern Argentina for three scenarios: Importation averaging 16,000 MT, 20,000 MT, and 24,000 MT, and found that the expected changes in U.S. beef production, consumption, and exports would be inconsequential. We have added a discussion of the potential impacts of an FMD outbreak for the U.S. economy to the final economic analysis. We also note that we examined the potential economic and other consequences of an FMD outbreak in the United States at some length in the consequence assessment section of our risk analysis.

Several commenters cited the ''Site-Specific Biosafety and Biosecurity Mitigation Risk Assessment'' [12] conducted for the Department of Homeland Security's National Bio and Agro-Defense Facility and the economic impact models used to estimate the impact of an outbreak of FMD, suggesting that APHIS consult those models in our own analyses.

The report referenced by the commenters shows the cumulative impact on the entire industry for a worst case disease scenario. Given the risk mitigation measures in place, it is highly unlikely that FMD would be introduced into the United States via fresh (chilled or frozen) beef from Argentina.

Comments on Economic Effects

While specific comments on the initial regulatory flexibility analysis are addressed above, we also received a number of comments concerning the overall economic effect of the rule as it relates to potential costs to U.S. consumers.

Several commenters stated that an analysis of the long term costs to consumers and the livestock industry resulting from an outbreak of FMD in the United States was not included in the proposed rule.

While we agree with the commenters that the 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 chilled (fresh or frozen) beef imported from Northern Argentina is low. Therefore, the overall risk of FMD to U.S. animal health from imports of these commodities is also low.

A commenter stated that allowing imports of beef from Northern Argentina may cause a loss of consumer confidence in other types of meat in addition to beef, resulting in a loss of profits for U.S. producers.

This is a hypothetical statement for which the commenter presents no supporting evidence.

Comments on the Environmental Assessment

One commenter stated that the environmental assessment accompanying the proposed rule marginalized empirical evidence demonstrating FMD spread in domestic wildlife by relying upon cursory studies.

There has been no confirmed spread of FMD in wildlife in the United States. Due to the lack of epidemiological data on FMD in U.S. wildlife, FMD research has had to rely on experimental infections or mathematical modeling. While experimental data indicates that many U.S. wildlife species are susceptible to FMD, transmission by persistently infected livestock or wildlife to susceptible animals has not been proven despite decades of worldwide research.

The same commenter said that the environmental assessment cited an 11-year-old study to assert that ''experts generally consider the transfer of FMD from wildlife to domestic animals to be unlikely,'' while, according to FMD disease notifications submitted to the OIE, the Republic of South Africa attributed its 2009 outbreak of FMD to contact with wild species as did Botswana.

Apart from the African buffalo (*Syncerus caffer*) in sub-Saharan Africa, wildlife has not been demonstrated to play a significant role in the transmission of FMD. More often, wildlife are passively infected when outbreaks of FMD occur in domestic livestock, and, in some wild ungulates, infection results in severe disease. Efforts to control FMD in wildlife may not be successful when the disease is endemic in livestock and may cause more harm to wildlife, human livelihoods, and domestic animals. Currently in sub-Saharan Africa, the complete eradication of FMD on a subcontinental scale in the near term is not possible, given the presence of FMD-infected African buffalo and the existence of weak veterinary infrastructures in some FMD-endemic countries.

The same commenter reasoned that since the environmental assessment states that likely results of an outbreak of FMD in the United States would include loss of livestock, rare species, and habitat due to the culling process, and the pollution of the environment from mass carcass disposals, then APHIS must initiate a Section 7 Consultation with the U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service (the Services) for a determination by the appropriate Service as to whether APHIS' proposed action is likely to adversely affect a listed species or its designated critical habitat under the Endangered Species Act.

[12] You may view this report on the Internet at *http://www.dhs.gov/xlibrary/assets/nbaf_ssra_final_report.pdf.*

APHIS is not required to consult with the Services if we determine that an action will not immediately affect listed species or critical habitat. As stated previously, in our risk analysis, APHIS concluded that Argentina's legal framework, animal health infrastructure, movement and border controls, diagnostic capabilities, surveillance programs and emergency response systems are adequate to detect and control any future FMD outbreaks within the national boundaries of the export region of consideration. Although consequences of an FMD outbreak in the United States are potentially substantial, the likelihood of an outbreak occurring via exposure of the domestic livestock population to fresh (chilled or frozen) beef imported from Northern Argentina under the required conditions is low. In addition, the environmental assessment also concluded that the potential for infection of wildlife from the proposed action is unlikely. The United States has retained an FMD-free status since 1929, and APHIS is very effective at assessing and implementing necessary mitigations to prevent FMD outbreaks in this country. In the unlikely event that FMD was discovered in the United States (most likely from an illegal importation of FMD-infected products or animals) and APHIS were to implement an eradication program, we would immediately enter into an emergency Section 7 consultation with the Services' offices to implement necessary protection measures for federally listed species and critical habitat in the eradication area.

One commenter objected to the environmental assessment's description of SENASA's sanitary enhancements as ''adequate'' and stated that the level of monitoring must be more than merely ''adequate.''

By ''adequate'' monitoring, we mean that APHIS has determined that Argentina has established the necessary controls that would allow for rapid detection, restrictions, quarantine, and reporting to the international community. In the event of such an event, the United States could impose the necessary restrictions on potentially affected products in a timely manner.

One commenter asked about the impact of the proposed action on the environment in Argentina given that the number of cattle raised in Argentina will increase significantly upon finalization of the rule.

While Executive Order 12114, ''Environmental Effects Abroad of Major Federal Actions'' furthers the purpose of the National Environmental Policy Act with respect to the environment outside of the United States, APHIS' proposed action is importation of fresh (chilled or frozen) beef from Northern Argentina into the United States. Therefore, the focus of the environmental assessment is to evaluate the potential impacts of allowing for the importation of fresh, maturated, and deboned beef from Northern Argentina into the United States, and not on the sustainability of cattle ranching in Argentina. The commenter's presumption regarding increased production may not be correct, in that the export of beef from Argentina may result in changes to the destination of product rather than substantial increases in domestic production.

Comments on Bioterrorism

Two commenters stated that the importation of fresh (chilled or frozen) beef would allow terrorists to intentionally introduce a foreign animal disease into the United States.

Another commenter observed that U.S. Department of Homeland Security has classified FMD as a national security issue. The commenter said that a terrorist with the intention of crippling the U.S. economy might use FMD as a mechanism to do so if the materials were made available.

This is a hypothetical statement for which the commenters presented no supporting evidence. Importation of a veterinary select agent or toxin such as FMD, which is among those agents and toxins that have been determined to have the potential to pose a severe threat to animal health or animal products, is strictly regulated by APHIS and the Centers for Disease Control and Prevention. With respect to the possibility of obtaining FMD virus from imported beef from Northern Argentina, as we have detailed elsewhere, we are confident that the conditions Argentina will be required to meet in order to import fresh (chilled or frozen) beef into the United States will preclude the importation of FMD.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the change discussed in this document.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This final rule has been determined to be economically significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides a final regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic 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**.

This analysis examines potential economic impacts of a final rule that will allow fresh (chilled or frozen) beef from a region in Northern Argentina to be imported into the United States provided certain conditions are met. Economic effects of the rule for both U.S. producers and consumers are expected to be small. Producers' welfare will be negatively affected. Welfare gains for consumers will outweigh producer losses, however, resulting in a net benefit to the U.S. economy. APHIS has concluded that the risk of exposing U.S. livestock to FMD via fresh beef imports from Argentina is sufficiently low such that imports are safe.

The United States is the largest beef producer in the world, and yet still imports a significant quantity. Annual U.S. beef import volumes from 1999 to 2013 averaged 0.9 million MT or roughly 11 percent of U.S. production. Much of the beef imported by the United States is from grass-fed cattle, and is processed with trimmings from U.S. grain-fed cattle to make ground beef. Australia, Canada, and New Zealand are the main foreign suppliers of beef to the United States.

Effects of the final rule are estimated using a partial equilibrium model of the U.S. agricultural sector. Economic impacts are estimated based on intra-sectoral linkages among the grain, livestock, and livestock product sectors. Annual imports of fresh (chilled or frozen) beef from Argentina are expected to range between 16,000 and 24,000 MT, with volumes averaging 20,000 MT. Quantity, price, and welfare changes are estimated for these three import scenarios. The results are presented as average annual effects for the 4-year period, 2015–2018.

A portion of the beef imported from Argentina will displace beef that would otherwise be imported from other countries. The model indicates that the net annual increase in U.S. fresh beef imports will be 12,955 MT (81 percent of 16,000 MT) under the 16,000 MT scenario; 15,895 MT (79 percent of 20,000 MT) under the 20,000 MT scenario; and 19,458 MT (81 percent of 24,000 MT) under the 24,000 MT scenario.

If the United States imports 20,000 MT of beef from Argentina, total U.S. beef imports will increase by 1.3 percent. Due to the supply increase, the wholesale price of beef, the retail price of beef, and the price of cattle (steer) are estimated to decline by 0.32, 0.12, and 0.35 percent, respectively. U.S beef production will decline by 0.01 percent, while U.S. beef consumption and exports will increase by 0.1 and 0.4 percent, respectively. The 16,000 MT and 24,000 MT scenarios show similar quantity and price effects.

The fall in beef prices and the resulting decline in U.S. beef production will translate into reduced returns to capital and management in the livestock and beef sectors. Under the 20,000 MT import scenario, beef producers will experience a welfare decline of $13.86 million or 0.4 percent, while consumers will benefit from the decrease in price by a welfare gain of $190.97 million or 0.6 percent. Cattle producers will experience decline in welfare of $107.05 million or 4 percent. The overall impact will be a net welfare gain of $177.11 million or 0.5 percent for producers and consumers in the beef processing sector. For the combined beef and cattle sectors, there will be a $70.06 million net welfare gain (0.18 percent net benefit).

The 16,000 MT and 24,000 MT scenarios show similar welfare impacts, with net benefits increasing broadly in proportion to the quantity of beef imported. The largest impact will be for the beef sector; consumers of pork and poultry meat will benefit negligibly. While most of the establishments that will be affected by this rule are small entities, based on the results of this analysis, APHIS does not expect the impacts to be significant.

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.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this final rule. The environmental assessment provides a basis for the conclusion that the importation of fresh beef from Northern Argentina under the conditions specified in this rule will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were 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 and finding of no significant impact may be viewed on the Regulations.gov Web site.[13] Copies of the environmental assessment and finding of no significant impact are also available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 799–7039 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

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 0579–0428, 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.

[13] Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0032.* The environmental assessment and finding of no significant impact will appear in the resulting list of documents.

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) 851–2727.

List of Subjects in 9 CFR Part 94

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

Accordingly, we 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 revised to read as follows:

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

Notwithstanding any other provisions of this part, fresh (chilled or frozen) beef from a region in Argentina located north of Patagonia South and Patagonia North B, referred to as Northern Argentina (the region sometimes referred to as Patagonia North A is included in Northern Argentina); fresh (chilled or frozen) beef from a region in Brazil composed of the States of Bahia, Distrito Federal, Espírito Santo, Goiás, Mato Grosso, Mato Grosso do Sul, Minas Gerais, Paraná, Rio Grande do Sul, Rio de Janeiro, Rondônia, São Paulo, Sergipe, and Tocantins; and 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:

(1) Beef from animals that have been born, raised, and slaughtered in the exporting regions of Argentina or Brazil; or

(2) Beef or ovine meat from Uruguay derived from animals that have been born, raised, and slaughtered in Uruguay.

(b) Foot-and-mouth disease has not been diagnosed in the exporting region of Argentina (for beef from Argentina), the exporting region of Brazil (for beef from Brazil), or in Uruguay (for beef or ovine meat from Uruguay) within the previous 12 months.

(c) The meat comes from bovines or sheep that originated 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 or 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 or sheep that received ante-mortem and post-mortem veterinary inspections, paying particular attention to the head and feet, at the slaughtering establishment, with no evidence found of vesicular disease.

(f) The meat consists only of bovine parts or ovine parts that are, by standard practice, part of the animal's carcass that is placed in a chiller for maturation after slaughter and before removal of any bone, blood clots, or lymphoid tissue. 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).

(i) The meat came from bovine carcasses that were allowed to maturate at 40 to 50 °F (4 to 10 °C) for a minimum of 24 hours after slaughter and that reached a pH below 6.0 in the loin muscle at the end of the maturation period. Measurements for pH must be taken at the middle of both *longissimus dorsi* muscles. Any carcass in which the pH does not reach less than 6.0 may be allowed to maturate an additional 24 hours and be retested, and, if the carcass still has not reached a pH of less than 6.0 after 48 hours, the meat from the carcass may not be exported to the United States.

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

(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.

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

Done in Washington, DC, this 26th day of June 2015.

Gary Woodward,

Deputy Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2015–16335 Filed 7–1–15; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE–2011–BT–TP–0042]

RIN 1904–AC53

Energy Conservation Program for Consumer Products and Certain Commercial and Industrial Equipment: Test Procedures for Residential and Commercial Water Heaters; Correction

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule; correction.

SUMMARY: On July 11, 2014, the U.S. Department of Energy published a final rule amending the test procedures for consumer water heaters and certain commercial water heaters. This correction addresses an error in one of the amendatory instructions for the regulatory text. Neither the error nor the correction in this document affects the substance of the rulemaking or any of the conclusions reached in support of the final rule.

DATES: *Effective* July 13, 2015.

FOR FURTHER INFORMATION CONTACT: Ms. Ashley Armstrong, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, Mailstop EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–6590. Email: *Ashley.Armstrong@ee.doe.gov.*

Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–9507. Email: *Eric.Stas@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Department of Energy (DOE) published a final rule in the **Federal Register** on July 11, 2014 (''the July 2014 final rule''), amending the test procedures for consumer and certain commercial water heaters. 79 FR 40542. In the rule, DOE incorporated by reference the American Society for Testing and Materials (ASTM) D2156–09, ''Standard Test Method for Smoke Density in Flue Gases from Burning Distillate Fuels,'' at 10 CFR 430.3(h)(1) for use in 10 CFR part 430, subpart B, Appendix E. The effective date for this rule is July 13, 2015.

On January 6, 2015, DOE published a final rule in the **Federal Register** (''the January 2015 final rule'') amending the test procedures for direct heating equipment and pool heaters. 80 FR 792. The January 2015 final rule incorporated by reference the same industry standard, ASTM D2156–09, at 10 CFR 430.3(i)(1) for use in 10 CFR part 430, subpart B, Appendix O. The effective date for this rule was February 5, 2015.

The July 2014 final rule instruction to incorporate by reference ASTM D2156–09 at 10 CFR 430.3(h)(1) conflicts with the January 2015 final rule instruction to incorporate by reference ASTM D2156–09 at 10 CFR 430.3(i)(1). The instruction in the July 2014 final rule would be in error if implemented as written, because it would needlessly duplicate the incorporation by reference of ASTM D2156–09, which was already incorporated by reference by the January 2015 final rule.

Amendatory instruction 8 on page 40567 of the **Federal Register** in the July 2014 final rule at 79 FR 40542 is, therefore, corrected to modify 10 CFR 430.3 to incorporate by reference ASTM D2156–09 for use in both Appendix E and Appendix O to subpart B. DOE notes that ASTM D2156–09 has already been approved for incorporation by reference for Appendix E (79 FR 40542) and Appendix O (80 FR 792), and, therefore, no additional action is necessary. The effective date of the July 2014 final rule at 79 FR 40542 remains July 13, 2015.

Correction

In FR Doc. 2014–15656 appearing on page 40542 in the issue of Friday, July 11, 2014, the following correction is made:

§ 430.3 [Corrected]

On page 40567, second column, § 430.3, amendatory instruction 8, is corrected to read as follows (and the text for paragraph (h) is removed):

§ 430.3 [Amended]

■ 8. In § 430.3, amend paragraph (i)(1) by removing the phrase ''appendix O'' and adding in its place the phrase ''appendices E and O''.