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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. APHIS–2009–0017]

RIN 0579–AD41

Importation of Beef From a Region in Brazil

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of certain animals, meat, and other animal products by allowing, under certain conditions, the importation of fresh (chilled or frozen) beef from a region in Brazil (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). Based on the evidence in a recent risk assessment, we have determined that fresh (chilled or frozen) beef can be safely imported from those Brazilian States provided certain conditions are met. This action provides for the importation of beef from the designated region in Brazil into the United States while continuing to protect the United States against the introduction of foot-and-mouth disease.

DATES: Effective August 31, 2015.

FOR FURTHER INFORMATION CONTACT: Dr. Silvia Kreindel, Senior Staff Veterinarian, Regional Evaluation Services Staff, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 851–3313.

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*.

On December 23, 2013, we published in the **Federal Register** (78 FR 77370–77376, Docket No. APHIS–2009–0017) a proposal [1] to allow, under certain conditions, the importation of fresh (chilled or frozen) beef from a region in Brazil (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).

We solicited comments concerning our proposal for 60 days ending February 21, 2014. We reopened and extended the deadline for comments until April 22, 2014, in a document published in the **Federal Register** on February 27, 2014 (79 FR 10999, Docket No. APHIS–2009–0017). We received 870 comments by that date. They were from producers, trade associations, veterinarians, representatives of State and foreign governments, and individuals. They are discussed below by topic.

Note: In our December 2013 proposed rule, we proposed to amend § 94.22 to allow the importation of fresh beef from Brazil subject to the conditions already laid out in that section for the importation of beef and ovine meat from Uruguay. Because that and other sections in part 94 have been redesignated since the publication of the proposed rule, in this final rule, we are amending § 94.29 instead.

General 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. Commenters noted that the FMD virus can travel up to 60 miles on the wind. Commenters also cited bird fecal matter and people traveling between affected and non-affected areas as additional vectors for transmission of the virus.

As noted in the risk assessment accompanying the December 2013 proposed rule, we considered the epidemiological characteristics of FMD. Based on our assessment, we concluded that beef from the exporting region of Brazil could safely be imported into the United States, provided that FMD has not been diagnosed in that region within the past 12 months, that there is no commingling of bovines or beef from that region with animals or beef from other regions prior to export, and that certain additional FMD-mitigation requirements, which include removal of bones and certain tissue and chilling of the carcasses until they reach a pH level of under 6.0, are met. We evaluated information submitted by Brazil's Ministry of Agriculture, Livestock and Food Supply (MAPA) and verified the accuracy of that information by conducting site visits. We concluded that Brazil 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 Brazilian export region and, in the unlikely event that one should occur, to detect, control, and eradicate the disease. Brazil's active and passive surveillance system would allow for rapid detection. In the event of an

[1] To view the proposed rule, the supporting risk assessment, economic analysis, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0017*.

outbreak, in the exporting region, Brazil would promptly report findings to the World Organization for Animal Health (OIE), and the United States would stop importing beef from Brazil. Our findings regarding Brazil's disease-control capabilities give us confidence that the mitigation methods required under this rulemaking will safely permit the importation of fresh beef from Brazil.

Some commenters cited FMD's 14-day incubation period as an additional risk factor. It was suggested that infected cattle may not exhibit clinical signs of FMD during the incubation period. According to those commenters, such cattle could be slaughtered and enter the food chain, with the FMD-infected beef derived from them potentially being exported to the United States. Commenters advised us to adopt what they stated was the recommendation of the OIE for a 3-week quarantine of animals from which beef for export is to be derived and for the complete segregation of animals in the export zone from animals in adjacent infected zones.

APHIS disagrees with the commenters. The OIE guidelines do not require the quarantine of cattle whose beef is destined for exportation from FMD-free regions with vaccination. Article 8.7.24 of the OIE Terrestrial Animal Health Code states that veterinary authorities of countries importing fresh meat from countries or regions recognized by the OIE as FMD-free with vaccination should require the presentation of an international veterinary certificate attesting that the entire consignment of meat comes from animals which (1) have either been kept in the free-with-vaccination region or country or otherwise meet OIE requirements for live animal imports under Chapter 8.7 and (2) have been slaughtered in an approved abattoir and have been subjected to ante- and post-mortem inspections for FMD with favorable results. Similarly, under this rulemaking we require that the animals from which the meat is derived must have been born and raised in the exporting region. Because the animals would have lived only in the exporting region, they would be unlikely to have been exposed to the FMD virus, and, if exposed, would have been immunized against the particular FMD strains that are prevalent in the region. APHIS does recognize the possibility, however remote, that because cattle that are in the early stages of the FMD incubation period may not show clinical signs of FMD, an ante-mortem inspection could fail to detect the disease, and FMD-infected cattle could be presented for slaughter, processing, and export of meat. In our view, however, the additional mitigation measures contained in this rulemaking, which include requiring the maturation of the beef in a chiller until the pH level in the longissimus dorsi is less than 6.0 and the removal of bovine parts, such as the head, feet, and internal organs, that are associated with a higher FMD risk than muscle tissue will ensure that beef may be safely imported into the United States from Brazil.

Some of the comments expressed reservations about the efficacy of the maturation requirements contained in the proposed rule, which included chilling of 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 stated that chilling beef may be inadequate for eliminating the FMD virus, since that virus can remain active in blood clots. Another commenter stated that the reduction of pH is not included as one of the recognized procedures for the inactivation of FMD virus in meat in the OIE Terrestrial Animal Health Code. It was suggested that, in order to effectively reduce the risk of FMD virus presence in meat, freezing should occur after maturation. According to one commenter, however, if freezing occurs too early after slaughter, any FMD virus that is present in the meat may survive for months.

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.

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 and organs must be removed from the carcasses prior to export to the United States.

Some commenters, though, also questioned the efficacy of those mitigation measures. It was stated that their effectiveness had not been demonstrated conclusively by the scientific literature. It was claimed that there is no agreed safe threshold level in the literature for FMD virus contamination for deboned beef. It was also claimed that scientific information is lacking on the amount of residual blood clot, lymph node, and bone tissue remaining after deboning, which is a concern because, as noted above, FMD virus can survive maturation in the lymph nodes and bone marrow. Information was also said to be lacking on the survivability of the FMD virus in deboned beef from carcasses where the normal acidification of skeletal muscle had not occurred and on FMD survival in fat tissues.

APHIS recognizes that blood clots and lymph nodes do not undergo acidification. As explained above, however, under this rulemaking, these tissues and organs must be removed from the carcasses prior to export to the United States. Carcasses in which normal acidification has not occurred would not be eligible for export to the United States. The rule allows the importation of muscle tissue, but not fat, into the United States. The demonstrated efficacy of maturation in inactivating the FMD virus in carcasses has already been noted. Even where marbling occurs, the maturation process is sufficient to inactivate the FMD virus.

A number of commenters expressed reservations about the effectiveness of vaccinating animals as a means of mitigating the risk of exposing U.S. livestock to FMD via imported beef. It was stated that vaccinated animals may become FMD carriers; that vaccinations are not foolproof due to variations in disease strain (FMD has seven distinct serotypes), mutations, and differences in susceptibility of organisms; and that wildlife cannot be vaccinated. The Government of Nicaragua, in comments submitted, claimed that the efficacy of immunization via vaccination with strains of attenuated virus remains a subject of scientific debate. Commenters further stated that FMD may spread by means of contaminated vaccines or the escape of the virus from vaccine production facilities. It was suggested that APHIS should stick to its previous policy of allowing imports only from regions free of a disease without vaccination.

APHIS acknowledges that vaccination of livestock has certain limitations as a risk-mitigation measure and for that reason, does not recognize a country that vaccinates for FMD as free of the disease. Vaccination of cattle against FMD introduces risks related to the immunological response within the vaccinated herd. While a large

percentage of individual animals in the herd may fully respond to FMD vaccination, some animals may have a limited response, resulting in partial or no immunity. Still, the scientific literature and decades of epidemiological, surveillance, and trade data indicate that the combination of vaccination and the mitigation measures we require under this rulemaking, (*e.g.,* inspection, removal of certain tissue from the carcasses, and maturation), are adequate to appropriately minimize the risk of introduction of FMD into the United States via the importation of fresh beef from countries that vaccinate for FMD. In 2003, APHIS authorized the importation of fresh beef under the same conditions that are found in this rule from Uruguay, a region that, like the exporting region of Brazil covered under this rule, is free of FMD with vaccination. The importation of such Uruguayan beef has not been associated with an increased risk of FMD. Further, as we described in the risk assessment and will discuss in greater detail later in this document, Brazil has an effective vaccination program. Quality control measures are in place to ensure that the FMD virus will not be spread by contaminated vaccines or insufficient biosecurity measures at vaccine production facilities. FMD vaccine production in Brazil complies with international guidelines.

Some commenters expressed reservations about APHIS' ability to prevent the introduction of FMD into the United States via beef imports from Brazil and to respond to an outbreak should one occur. It was stated that APHIS has neither the physical and financial resources to adequately inspect Brazilian beef production and processing sites or to control an outbreak in the United States. Additionally, some commenters stated that production and distribution of appropriate vaccines could prove challenging in the event of an outbreak in the United States.

We disagree with some of these comments. 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. We recognize that, depending on the size and scope of an 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, 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.

As discussed later in this document and in the risk assessment, we consider the feeding of FMD-contaminated waste to susceptible animals, particularly swine, to be the most likely pathway for the transmission of the disease. A commenter representing the pork industry questioned whether budget cuts to APHIS and State animal health staffs have had a negative effect on the ability to carry out the regulatory activities outlined in the Swine Health Protection Act (SHPA), and if so, whether the resulting reduction in regulatory activities had decreased the number of inspections and searches for unlicensed garbage-feeding operations to a level lower than that we found in a pathway analysis we conducted in 1995 to estimate the likelihood of exposing swine to infected waste.

Budget cuts to APHIS have necessitated a reordering of priorities in relation to SHPA-related activities. We have deemphasized or passed on to State partners or other cooperators lower-yield activities, such as visiting restaurants to inquire about garbage-disposal methods, in favor of allowing inspectors to spend more time interacting with and educating swine producers and conducting inspections. The regular presence of APHIS inspectors in U.S. garbage feeding facilities provides opportunities to educate operators on disease signs and reporting requirements and to conduct direct observation of animals for signs of illness. APHIS believes, therefore, that the presence of animal products infected with FMD or other reportable conditions entering the United States would be detected more quickly in these types of premises than in other, unregulated premises.

Brazilian Disease Control Measures

Many commenters opposed the December 2013 proposed rule on the grounds that, contrary to the conclusions of our risk assessment, Brazil's existing disease-control measures are inadequate to prevent producers in that country from exporting FMD-contaminated beef to the United States. Commenters expressed concerns about, among other things, Brazil's vaccination program, testing and disease reporting protocols, slaughter plant procedures, veterinary infrastructure, international border and internal movement controls, and the possibility of wildlife infecting the Brazilian cattle herd with FMD.

We have already noted that some commenters questioned the efficacy of vaccination as a means of combatting the spread of FMD. A number of commenters also expressed reservations specific to Brazil's vaccination procedures. It was stated that Brazil's reported 77 to 99 percent vaccination rate is inadequate for preventing the spread of FMD, that not all Brazilian States vaccinate, and that the lowest vaccination rate in the exporting region is in Mato Grosso, which has the country's highest cattle population. It was suggested, as noted above, that FMD could spread in Brazil through contaminated vaccines or escapes of the virus from vaccine production facilities. In addition, one commenter expressed concern about the qualifications of some individuals administering vaccinations in Brazil, noting that farmers may vaccinate their own animals or hire professionals who do not have to be registered with or accredited by the Brazilian Government to do the job for them.

In Brazil, vaccination is used to prevent the transmission of the FMD virus in the event that the disease were to be introduced in the region. Vaccination of cattle and buffalo is required in the exporting region. The aim of the vaccination program is to immunize at least 80 percent of bovines in a region in order to provide the protection and herd immunity needed to stop the spread of disease. While our risk assessment indicated that there was 76 percent coverage of bovines under 12 months of age in Mato Grosso, the much higher vaccination rates for bovines over that age, which represent most of the bovine population in the State, means that the overall vaccination rate there well exceeds 80 percent. More recent data described in a peer reviewed Journal, indicates that the vaccination coverage in Brazil as a whole exceeded 95 percent during the 2007–2011 (*http://dx.doi.org/10.1098/rstb.2012.0381*). All FMD vaccines produced or used in Brazil must follow OIE guidelines, including being tested for quality and safety by government officials. APHIS did not detect any evidence to suggest that unacceptable biologics or vaccines are being used in Brazil. Vaccination records are verified by local veterinary unit (LVU) personnel and may also be verified by field inspectors visiting individual premises. Despite the fact that Brazilian State or

Federal personnel do not physically observe all vaccinations, records in LVU offices that were reviewed by APHIS indicated that vaccination coverage was quite complete, reaching almost 100 percent.

Many commenters expressed concern about Brazil's disease-testing and reporting standards, citing delays in reporting a 2010 case of bovine spongiform encephalopathy (BSE) and in conducting the required testing in the wake of the detection and sending the OIE lab samples. It was also noted that during the time between the discovery of the case and the reporting of it, Brazil continued shipping processed meat to the United States.

APHIS agrees that the delays in the testing and reporting of the atypical BSE case detected in Brazil were problematic. Representatives of APHIS and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) visited Brazil in February 2013 to evaluate the BSE laboratory infrastructure, emergency response capabilities, and BSE-related mitigations at the slaughter level. In addition, as a result of the delays in testing and reporting of this case, MAPA conducted audits of the laboratories to identify areas for change and improvement and subsequently implemented several new procedures to assure the timely testing of samples and reporting of results. These included the addition of a second laboratory to conduct immunohistochemistry tests, the expansion of testing capabilities, and the development of an inter-laboratory data management system to issue reports, record improper samples, and flag delays in sample receipt, completion, and notification of test results.

To evaluate Brazil's FMD-related laboratory capabilities, APHIS' risk assessment included site visits to various diagnostic laboratories in Rio Grande do Sul, Pará, Recife, and Pernambuco in 2002, 2008, and 2013. Based on those visits, APHIS concluded that Brazil has the diagnostic capability to adequately test samples for the presence of the FMD virus. Staffing was sufficient at the facilities, and staff members were well-trained and motivated. Laboratory equipment was adequate for diagnosing FMD, and quality control activities included routine monitoring and calibrating of the equipment. The tests used to investigate evidence of viral activity were consistent with OIE guidelines. The laboratories also had effective and efficient recordkeeping systems for storage and retrieval of data, and were able to turn samples around quickly.

Some commenters claimed that Brazil has failed to report detections of FMD within its cattle population and, therefore, could not be relied upon to report such detections in the future.

We disagree with the commenters. During the FMD outbreaks in 2005 and 2006, MAPA demonstrated that it has the capability to detect disease quickly, limit its spread, and report promptly. FMD cases were quickly identified, the disease was contained, and international authorities were notified in a timely manner. Further, as stated in our risk assessment, we did not detect any evidence to suggest that active outbreaks of FMD exist in the export region. Despite occasional outbreaks of FMD in Brazil and in neighboring countries of South America, APHIS considers the disease to be under control in the export region.

It was also noted that the protocols in place for reporting disease within Brazil depend on self-reporting by producers, which some commenters view as an unreliable method.

While passive disease surveillance in Brazil relies on self-reporting, producers, veterinarians, and others are required by law to report clinical signs of FMD to veterinary authorities. Failure to comply with FMD reporting requirements may result in penalties or fines.

Many commenters, noted that the exporting zone in Brazil borders FMD-affected regions, including the affected zone in Brazil, as well as Paraguay, Bolivia, and Argentina, and is not separated from all those regions by physical or geographic barriers. Commenters pointed out that there has been a history of FMD incursions in Brazil from neighboring countries and that as long as FMD remains endemic in South America, the possibility of reintroduction from those neighboring countries exists. Concerns were expressed about the adequacy of Brazil's border control measures. Commenters stated, among other things, that Brazil's border with Peru is not fixed and secure, that Brazil does not effectively control cattle coming in from Paraguay, and that there have been eyewitness accounts of unmanned Brazilian border inspection posts. A commenter stated that there was a discrepancy between our risk assessment and our environmental assessment in the way we characterized the physical barriers between the exporting region and affected regions and the possibility of virus transmission across those barriers. It was stated in the environmental assessment that some areas that APHIS regards as barriers could actually be wildlife disease reservoirs, but that the risk assessment contained no such statement.

In the risk assessment, 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 that document and the environmental assessment, the exporting region 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, Brazil 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 Brazil's borders with Argentina and Paraguay. Additionally, as discussed in greater detail below, research has determined that wildlife has not played a significant role in the maintenance and transmission of FMD in South America. We have added a statement to that effect to the environmental assessment, under the heading ''Regulatory Control of FMD.''

One commenter suggested that we add to the final rule a requirement for a geographic buffer zone, *i.e.,* a disease-free area, surrounding the export region. The commenter did not specify whether such a zone should apply to adjacent areas in Brazil or neighboring countries, or both.

Some of the same natural barriers, described above, that separate Brazil from neighboring countries also are present along the boundaries between the export region and other Brazilian States. Brazil's national FMD program provides for surveillance and reporting in the exporting area as well as in the adjacent Brazilian States. Buffer zones are already employed under Brazil's FMD program in areas where no natural barriers exist, along with enhanced border patrols. In addition, APHIS's site-visit team did not find any laboratory evidence that FMD currently exists anywhere in Brazil.

Some commenters stated that uncontrolled or inadequately controlled movement of wildlife in South America generally, and countries bordering Brazil in particular, may pose a risk of spreading FMD into the exporting zone of Brazil.

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, the likelihood that they would become carriers under field conditions is rare. Therefore, it is unlikely that FMD would be introduced into the exporting region through movement of infected wildlife. Further, Brazil's biosecurity measures, surveillance activities, and response capabilities, which we evaluated in our risk assessment, would mitigate the already low risk of the FMD virus spreading from wildlife to livestock in the exporting region of Brazil.

One commenter stated that Brazil is OIE certified as FMD free in just 2 of 26 States and relaxed its vaccination regimen almost 2 years ago.

The OIE currently recognizes the Brazilian State of Santa Catarina as FMD-free without vaccination. In addition, however, the OIE recognizes States and zones within Brazil as FMD-free with vaccination. The area so recognized by the OIE, which largely coincides with part of the APHIS exporting region, may be viewed on the OIE Web site at *http://www.oie.int/animal-health-in-the-world/official-disease-status/fmd/list-of-fmd-free-members/.*

A commenter stated that beef from Brazil may not meet Canada's import requirements and therefore could not be commingled with U.S. beef being shipped to Canada. The commenter expressed concern that U.S. beef exporters wishing to export beef to Canada could be negatively affected as a result of this rule.

The commenter's statement is correct but is not germane to the current rulemaking. Brazil does not export beef to Canada. U.S. exporters wishing to export beef to Canada have a legal obligation to meet that country's requirements by not commingling beef that is eligible for export to Canada, with beef that is not.

Some commenters questioned the efficacy of Brazil's internal animal movement controls. Noting that greater market opportunities and the resulting higher prices offered in the export region might foster illegal animal movements into that region from affected regions in Brazil, commenters questioned whether there were sufficiently stringent procedures in place in Brazil to restrict such movements. It was further stated that a European Commission (EC) audit found deficiencies in those controls. Some commenters also stated that Brazil does not require animal identification and that its voluntary traceability program and applies only to cattle whose meat is intended for countries that require traceability from birth, which the United States does not. That group of commenters included the Government of Nicaragua, which suggested that Brazil's ''unreliable'' traceability system could hinder its response to an outbreak of FMD, potentially allowing the disease to spread to other countries. One commenter expressed some doubt as to whether Brazil's traceability system, even if relatively effective, could aid in combatting an FMD outbreak, since traceability was not documented as effective in combatting FMD outbreaks in the United Kingdom.

We do not agree with these comments. Based on our review of the veterinary infrastructure in Brazil, we determined that MAPA, which oversees animal movement within the country, has the legal authority, technical capabilities, and personnel to implement the FMD program within Brazil. Movement controls in Brazil are stringent. As described in the risk assessment, MAPA requires that all cattle owners identify their animals with a unique brand. Sheep and swine are identified by a brand in the ear. Each LVU keeps a registry of brands and a complete registry of the cattle holdings in the region, with animal populations listed by age group and sex. The registry of holdings is updated at least twice per year, during the vaccination period, or when the animals are moved to another place. The LVU must issue an animal movement permit (GTA), which is required whenever animals are moved. The staff of the LVU is responsible for verifying that the vehicle transporting the animals has been cleaned and disinfected as required by law. A copy of the GTA is sent to the destination. Any inspection associated with animal movement involves checking the documents and verifying the animal information, as well as clinical observation of animal health. The EC Food and Veterinary Office (FVO) audits conducted in 2012 and 2013 found that post-mortem inspection were carried out in line with the EU requirements, that FMD related mitigation were conducted appropriately, and that Hazard Analysis Critical Control Points plans including traceability and maturation were implemented and verified by the veterinary authority were found to be satisfactory. In its most recent audit, conducted in October 2014, the EC FVO reported that that FMD-related requirements were met, and that Brazilian officials were able to demonstrate full traceability to farms of origin.

Other commenters expressed broader concerns about Brazil's disease-control activities, highlighting occasions when, the commenters suggested, Brazil may have failed to comply with safety standards. It was stated that, in the past, Brazil has failed to maintain equivalent safety standards for cooked products exported to the United States, causing FSIS to suspend imports of such products, that FSIS has not allowed imports from Santa Catarina, which we recognize as FMD-free, on the grounds that Brazil's microbiological and residue testing programs are deficient, and that repeated audits by FSIS and the EC have shown a failure on Brazil's part to promptly institute and maintain corrective action for deficiencies noted in previous audits. Commenters suggested that the results of those audits indicate that Brazil lacks either the willingness or the infrastructure to execute the consistent management controls needed to sufficiently mitigate the risk of the introduction of FMD into the United States through the importation of fresh beef. One commenter suggested that there was a dearth of veterinarians in Brazil who had the necessary training and expertise to manage a national FMD program.

As discussed in the risk assessment, APHIS evaluated the veterinary infrastructure of Brazil and concluded that MAPA has a system of official veterinarians and support staff in place for carrying out field programs and implementing import controls and animal quarantine. Additionally, MAPA has sufficient legal authority to carry out official control, eradication, and quarantine activities. We also determined that Brazil's technical infrastructure was adequate for rapid detection of FMD and for carrying out surveillance and eradication programs and that advanced technologies are utilized in conducting several animal health programs. Import controls are sufficient to protect international borders at principal crossing points.

A number of commenters expressed misgivings about Brazil's slaughter-plant procedures. It was suggested that Brazilian slaughter plants may be deficient on both sanitary and humane grounds. One commenter expressed doubt that, given Brazil's previous compliance issues, APHIS can be certain that beef imported from Brazil would have the lymph nodes removed in all cases, as required under this rulemaking. One commenter stated that if a pH meter at a Brazilian slaughter

plant is faulty, infected beef may be exported to United States.

The commenters did not present specific evidence regarding deficiencies on sanitary or humane grounds at Brazilian slaughter plants. APHIS evaluated Brazil's ability to carry out slaughter-related mitigation measures, including ante-mortem and postmortem inspections and deboning and removal of lymph nodes from beef carcasses. We concluded that MAPA will be able to enforce compliance with our inspection and slaughter-plant processing procedures. Our assessment of Brazil's veterinary system included an evaluation of the likelihood of compliance with the pH requirement. Brazilian authorities monitoring slaughter plants calibrate the pH meters frequently. Beef that does not reach the required pH is not allowed to be exported to the United States and is diverted to the Brazilian domestic market.

A few commenters expressed BSE-related concerns about importing fresh beef from Brazil. One commenter stated that some countries have banned or restricted beef imports from Brazil due to concerns about safety, particularly regarding BSE. Another commenter questioned whether Brazil tests for E. coli and BSE.

These comments are beyond the scope of the present rulemaking, which contains FMD-related import restrictions. The risk assessment supporting the rulemaking specifically examined the potential risk of introducing FMD into the U.S. cattle population by allowing imports of fresh beef from Brazil under certain conditions. We would note, however, that the OIE currently recognizes Brazil as a negligible-risk country for BSE, a designation APHIS concurred with in a notice [2] published in the **Federal Register** on October 1, 2014 (79 FR 59207–59208, Docket No. APHIS–2013–0064). Should circumstances arise that would dictate a change in Brazil's BSE classification to a less favorable one, APHIS would require BSE mitigations for imports of beef as appropriate to the adjusted risk classification.

Some commenters, citing what they characterized as Brazil'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 Brazil's compliance with our required risk mitigation measures. It was stated that APHIS has not adequately described how it will continue to provide oversight and/or monitor Brazil's animal health infrastructure indefinitely, to ensure that the country will maintain adequate controls to prevent the spread of FMD from other regions of Brazil or from neighboring countries to the exporting area.

The regulations in § 92.2 provide for such monitoring of regions after we recognize them for animal health status. We may require such a region to submit additional information pertaining to its animal health status and may also conduct additional site visits or other information collection activities in order to monitor the region's continued compliance with our requirements.

As discussed in greater detail below in the section pertaining to issues raised regarding our risk assessment, the findings from that assessment led us to conclude that the most likely pathway of exposure of domestic livestock to the FMD virus in beef was through feeding of contaminated food waste to swine. A commenter representing the pork industry questioned whether APHIS has current data regarding the level of biosecurity, security, veterinary care, routine health observations, and knowledge of disease reporting pathways in garbage-fed populations in Brazil. According to the commenter, such data are necessary to meet the goal of a foreign animal disease preparation and response plan. The commenter further enquired about the level of confidence APHIS has regarding the education provided to licensed garbage feeders and whether biosecurity and veterinary care protocols and disease reporting procedures are being followed in Brazil.

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

One commenter cited the refusal of countries other than the United States whose producers are represented under the Five Nations Beef Alliance to accept Brazilian beef as a reason for not allowing it to be imported into the United States. The Five Nations Beef Alliance consists of the national beef cattle producers' organizations of Australia, Canada, Mexico, and New Zealand—our top livestock trading partners—as well as the United States. The commenter recommended that no Brazilian beef be imported into the United States until all the members of the Five Nations Beef Alliance decide that such imports are safe.

We do not agree with this comment. The Five Nations Beef Alliance is an industry association that lobbies on behalf of the beef industry in support of its economic interests. Our international trade agreements permit us to impose only those sanitary and phytosanitary measures necessary to protect human, animal, or plant life or health on the basis of scientific principles and evidence. We cannot take such actions for economic reasons alone or on the basis of the actions of industry associations.

Some commenters stated that any beef we import from Brazil should be labeled as such, thus enabling U.S. consumers to make informed decisions regarding their beef purchases.

Country of origin labeling is already required under the Agricultural Marketing Service regulations in 7 CFR part 65.

A commenter stated that there was a lack of information on disease serotypes and strains outside the export zone.

APHIS disagrees with the commenter. In our risk assessment, under Factor 3, ''Disease Status of Adjacent Regions'' (pp. 23 to 29), we describe FMD outbreaks that occurred in the countries and Brazilian States adjacent to the export area, including the serotypes involved in the outbreaks over the last 10 years.

Risk Assessment

A large number of commenters voiced reservations about both the methodology we used to conduct our risk assessment of the proposed exporting region of Brazil and the conclusions we reached in that document.

Some 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

[2] To view the notice and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0064.*

recognition of the animal health status of a region,'' we concluded that the specified region of Brazil 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, Brazil 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 Brazil, APHIS would implement critical prevention measures to respond to the outbreak, including alerting U.S. Customs and Border Protection inspectors at all ports of entry. Because § 94.29(b) 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 importation.

Some commenters questioned the methodology we employed for the site visits to Brazil. 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 assessment 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 Brazil. 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.

APHIS' site visits consist of an in-depth evaluation of the eight factors identified in § 92.2 (scope of the evaluation being requested, veterinary control and oversight, disease history and vaccination practices, livestock demographics and traceability, epidemiological separation from potential sources of infection, surveillance, diagnostic laboratory capabilities, and emergency preparedness and response) as factors to consider in assessing the risk of transmission of an animal disease to U.S. livestock via the importation of animals or animal products from a foreign region. Risk factors are identified from the information gathered on these topics, and applicable mitigations are discussed. The regulations in § 92.2 are publically available at: *http://www.gpo.gov/fdsys/pkg/FR-2012-07-27/html/2012-18324.htm.* Further information on site visits is available in a guidance document regarding APHIS' approach to implementing its regionalization process and the way in which APHIS applies risk analysis to the decisionmaking process for regionalization. This document is available to the public at: *http://www.aphis.usda.gov/import_export/animals/downloads/regionalization_process.pdf.*

Our five site visits to Brazil, conducted in 2002, 2003, 2006, 2008, and 2013, included visits to Federal, State, and local veterinary offices, farms, border control stations, and diagnostic laboratories. The findings from these visits are discussed thoroughly in the risk assessment document. As noted in that document, the scope of the 2002 site visit included verification of FMD outbreak controls, an overview of the surveillance program and laboratory capabilities, vaccination practices and eradication activities, and movement and border controls. The focus of the 2003 site visit was to collect data that APHIS used in its risk assessment. The focus of the 2006 site visit was to evaluate the FMD situation following the 2005–2006 outbreak in Paraná and Mato Grosso do Sul. The focus of the 2008 visit was to evaluate the Brazilian State of Santa Catarina for freedom from classical swine fever, FMD, African swine fever, and swine vesicular disease. Finally, the scope of the 2013 visit included the evaluation of the FMD diagnostic capabilities, FMD laboratories, and vesicular disease emergency response.

Another issue raised in regard to our site visits was that not all of the factors for animal health status were reviewed during each of the site visits by APHIS. It was stated that because each site visit had a different focus, some of the information our site-visit teams obtained may now be out of date. For example, one commenter claimed that some risk factors associated with the importation of beef from Brazil, such as movement and border controls, appeared not to have been verified through site visits since the 2002 visit.

Even though a site visit may have a particular focus, all factors are evaluated during each visit, with emphasis on changes implemented since the previous one. Any observed changes in risk are noted in the risk assessment. If no changes are noted, then no changes are made to that factor in the risk assessment, and the original date for which risk was described is maintained. In the example noted below, movement and border controls were verified in site visits subsequent to 2002. However, since no significant changes were noted in risk, the 2002 date was retained to indicate when the initial observation was made.

Some commenters viewed the documentation supporting our risk assessment as insufficient. It was further noted that some of those supporting documents were in Portuguese. 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.

All of the documents that were provided by the Government of Brazil have been shared with stakeholders who requested them. APHIS acknowledges that some of the documents used as references in the risk analysis were submitted to APHIS in Portuguese; however, APHIS personnel involved in the evaluation had sufficient language skills to read those documents without requiring that they be translated into English. In addition, in most instances, the same or related data were provided in other documents or verbally presented to APHIS during site visits. The information provided by Brazil and the conclusions reached are thoroughly described in the risk analysis that was made available for public review and comment.

Some commenters stated that APHIS should prepare a quantitative risk assessment for beef from Brazil and make it available for public review. Commenters took the position that the qualitative risk assessment 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 assessment 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 assessment for Brazil.

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

Some commenters raised issues regarding the scope of our risk assessment. 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 assessment guided by Chapter 2.1 of the OIE Terrestrial Animal Health Code, ''Import Risk Analysis.'' The Code recommends that risk assessments 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 assessment of Brazil, we followed the steps listed in the OIE Terrestrial Animal Health Code. Where there are differences between APHIS' methodology and that described by the OIE, 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.

Some commenters did not view the eight factors listed § 92.2 as sufficiently comprehensive for conducting a risk assessment, suggesting that we should have relied on the OIE guidelines instead.

We did evaluate Brazil using the factors listed in § 92.2. These factors, however, are essentially the same as the factors listed in Chapter 1.6 of the OIE Terrestrial Animal Health Code. Both § 92.2 and the OIE Code provide for the evaluation of a region seeking recognition for a disease status on the basis of, among other things, the region's veterinary infrastructure, disease history, geographical separation from affected regions, diagnostic and surveillance capabilities, and emergency response planning. Both the OIE Code and § 92.2 require the requesting region to provide the same documentation.

In contrast to the comments discussed above, one commenter criticized our risk assessment methodology on the grounds that we granted too much deference to the OIE guidelines, thus violating our statutory mandate to protect U.S. livestock.

We do not agree with this comment. As noted above, the OIE evaluation criteria and those in § 92.2 essentially cover the same topics. In addition, the site visits we conduct as part of our risk assessment process enable us to verify the requesting country's disease status and its ability to maintain that status and to control outbreaks if they occur.

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.

The epidemiology of the disease in South America over time and the information provided in the surveillance section of the risk assessment 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.

Some commenters also claimed that the biological pathways for the release of pathogens were not described clearly in the release assessment.

We address biological pathways for the release of the FMD virus in the exposure assessment, which we discuss in greater detail below.

Commenters stated that our exposure assessment identified only a single exposure pathway: The feeding of FMD-contaminated beef to susceptible animals. It was stated that the exposure assessment included no discussion of any alternative exposure pathways for FMD, such as illegal imports and backyard pig feeding. It was further stated that the exposure assessment should have focused on the effects of plate waste or manufacturing waste processing for swine feeding on the survival of FMD virus.

There is a general scientific understanding on the main pathway of FMD exposure via the importation of fresh beef. This pathway is through the feeding of food waste to swine. The likelihood of exposure of FMD-susceptible species to FMD-infected beef was evaluated by reviewing previous studies we conducted. In 1995, we conducted a pathway analysis to estimate the likelihood of exposing swine to infected waste. With 95 percent confidence, we estimated that 0.023 percent or less of plate and manufacturing waste would be inadequately processed prior to feeding to swine. Based on this percentage, less than 1 part in 4,300 of imported beef fed to swine as plate or manufacturing waste is likely to be inadequately cooked. The findings of a 2001 APHIS survey, which showed a substantial reduction in waste-feeding operations, further indicated that the risk of FMD exposure via feeding of contaminated waste to swine was continuing to decline.

Some commenters stated that that the pork industry has undergone significant changes since we conducted the 1995 risk analysis and 2001 survey cited above. A commenter representing a national pork producers' association questioned the validity of our 1995 pathway analysis in particular, stating that the findings are outdated and incomplete. Other commenters also expressed skepticism that the 1995 analysis and the 2001 survey adequately reflect the current risk to the U.S. pork industry of the introduction of FMD into the United States through garbage feeding. It was suggested that APHIS needs to consider obtaining updated scientific data, independent of the 2001 APHIS waste-feeder survey, in order to better verify the exposure assessment for FMD presented in the risk analysis.

APHIS acknowledges that the pork industry in general has undergone significant changes since 1995; however, the garbage-feeding industry in particular, which we discuss in greater detail immediately below, has not. In that discussion, we elaborate on our reasons for our confidence that the 1995 risk analysis and 2001 survey adequately reflect the current risk to the U.S. pork industry from the feeding of contaminated food waste to swine.

One commenter stated that, according to APHIS reports to the U.S. Animal Health Association's Transmissible Diseases of Swine Committee, from

2009 to 2013, a number of unlicensed garbage feeders were found each year by State and Federal animal health authorities. The commenter asked if APHIS has any supporting information that estimates the number of unlicensed garbage-feeding facilities.

Procedures for the handling, processing, and feeding of food waste to swine in the United States are subject to our swine health protection regulations in 9 CFR part 166. Compliance with the regulations has improved in recent years, thereby reducing the probability of survival of FMD virus in the food waste. Searches for non-licensed garbage feeding facilities are regularly conducted using several different techniques as part of the duties of APHIS animal health staff, as well as State animal health and other State agency staff. When unlicensed garbage feeding facilities are identified, the unauthorized activity is documented, and the facility is brought into compliance. Depending on the State, all swine on such premises may be quarantined and tested for foreign animal diseases. Information on the number of inspections conducted to detect unlicensed garbage feeding facilities, the number of unlicensed facilities identified, and resolution of cases resulting from such identification are captured at the State level and evaluated by APHIS on a regular basis. Given the regular monitoring of these facilities and their relatively small number, we stand by the conclusions we reached in our 1995 risk analysis.

A commenter stated that our consequence assessment should have focused on the specific commodity to be imported, as outlined in the scope of the risk assessment.

The consequence assessment did examine at some length the possible economic consequences for the cattle industry, as well as other livestock industries, that could result from an outbreak of FMD in the United States.

Commenters took issue with the methodology we used for evaluating the efficacy of Brazil's movement and border controls. As noted in the risk assessment, APHIS assumes that, if the riskiest pathways are sufficiently mitigated, then the overall spectrum of risk issues should be acceptable. The commenters viewed that assumption as unwarranted.

We do not agree with this comment. APHIS tries to target the riskiest border crossings (and other areas) during site visits as examples of a type of ''maximized risk scenario'' in order to address similar, but theoretically lower, risks in the remainder of the export region. Using this assumption and visiting the areas of highest risk in the export region, APHIS concluded that movement control measures for live animals are effective at both domestic and international checkpoints. The commenters did not present any evidence to support their claim that this methodology is flawed.

A commenter objected to the terminology we used in characterizing the FMD risk associated with imports of beef from Brazil. It was stated that the characterization of the risk of FMD introduction as ''low'' was arbitrary and misleading. The commenter stated that the term ''low'' actually falls in the middle of the risk spectrum, meaning, in the view of the commenter, that the actual risk of FMD introduction from Brazil was unacceptably high. The same commenter also stated that there was a discrepancy between the risk assessment, which characterized the risk as ''low'' and the environmental assessment, which characterized the risk as ''extremely unlikely.''

APHIS disagrees with the commenter. We employ the term ''low'' to characterize the risk associated with importing a particular commodity when we have determined, based on a risk assessment, that the commodity can be safely imported into the United States under certain conditions. We base such determinations on our assessment of the exporting region's disease-control capabilities, as evaluated in relation to the eight factors in § 92.2, and the known efficacy of the risk mitigation measures available to us. The statements in the risk assessment and the environmental assessment are not contradictory. The environmental assessment refers to the risk of introduction of FMD into the United States as extremely unlikely. The risk assessment characterizes the combined risks of introduction and dissemination of the disease as low.

Economic Analysis

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 December 2013 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 December 2013 proposed rule, we analyzed expected benefits and costs of annual imports of fresh (chilled or frozen) beef from Brazil averaging 40,000 metric tons (MT), and found that the expected changes in U.S. beef production, consumption, and exports would not be significant. We did not report on potential impacts of an FMD outbreak for the U.S. economy in the economic analysis accompanying the December 2013 proposed rule because, in our view, the risk-mitigation measures required of Brazil, which include deboning, maturation for at least 24 hours, and pH measurements below 6.0 in the loin muscle, will provide for the safe importation of beef from Brazil. The revised economic analysis accompanying this final rule, however, does analyze those potential impacts. We would further note that in the consequence assessment section of our risk assessment, we examined the potential economic and other consequences of an FMD outbreak in the United States at some length.

Some commenters also pointed out that an FMD outbreak in the United States could result in the loss of export markets for U.S. beef. It was further claimed that our economic analysis understated the value of those export markets.

An FMD outbreak would likely result in the loss of U.S. beef export markets. However, APHIS is confident that the required sanitary safeguards will ensure the safe importation of beef from Brazil as a result of this rule. Regarding the value of U.S. beef export markets, it can be measured differently depending on the combination of bovine products and composite prices used. The value can also vary based on how shipping and other transactional expenses may be included in reported prices. Commenters may consider the reported value of U.S. beef exports to be understated because of differences in product and price definitions. Nevertheless, attributing a higher value to U.S. beef export markets would not change our conclusion that the rule's impact on beef exports, as well as other segments of the beef industry, will be minor.

A commenter stated that allowing imports of beef from Brazil may cause a loss of consumer confidence in beef, resulting in a loss of profits for U.S. producers.

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

A commenter expressed the view that the rulemaking would depress markets for U.S. producers and affect export markets because allowing imports from Brazil would facilitate Brazil's access to other international markets.

The question of whether or not allowing Brazilian beef to be imported into the United States would facilitate Brazilian producers' access to other international markets is beyond the scope of our economic analysis. The commenter did not present data that would support the proposition that Brazil's beef exports are likely to increase so precipitously as a result of this rulemaking that U.S. exporters would experience negative effects.

A commenter expressed the concern that the rulemaking would have adverse effects not only on U.S. beef producers but on associated industries as well.

Based on how small the volume of beef we project will be exported from Brazil to the United States relative to U.S. beef production, we anticipate that both U.S. beef producers and associated industries will be affected little, if at all, by this rulemaking.

Commenters questioned our projections regarding the amount of beef likely to be imported from Brazil and also expressed doubts about our assumption that Brazilian beef imports will mainly displace other imports rather than increasing the total volume of beef imports. It was stated that because exporting beef to the United States may be profitable for Brazilian producers, they are likely to ship more than the 40,000 MT of beef to the United States that we estimated they would in an average year.

Our import projections are based on the data we obtain from industry and other sources and the use of published models. In the preamble to the December 2013 proposed rule, we noted that we did not have all of the data necessary for a comprehensive analysis of the effects of the proposed rule on small entities, and we solicited comments on the potential effects. Because the commenters did not supply information that contradicted the data upon which we relied, that called into question the model we used, or that supported in any way the suggestion that our projections were inaccurate, we did not have cause to revise our projections.

Another commenter, while agreeing with our projection that Brazilian beef imports would most likely displace imports from elsewhere, 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.

The United States and many other member countries are a part of the rules-based international trading system, which has benefitted Members through the maintenance of open international markets. Under our international trade agreements, we consider requests from countries and regions to import their animals and/or animal products. Before such requests are granted, we must first assess the risks to U.S. herds posed by imports by evaluating the requesting country or region's disease status and the efficacy of its risk-mitigation measures. The United States' and other WTO Members' international trade obligations ensure that decisions regarding market access are based on scientific principles and risk assessments. U.S. demand for these products is not a part of the consideration of such requests.

One commenter characterized the proposed rule as a misguided attempt 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.

The commenter's statement is a hypothetical one 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.

A commenter claimed that the rulemaking would result in a larger drop in steer prices than the 0.14 percent we projected in the economic analysis supporting the December 2013 proposed rule.

We arrived at that estimate using results from a published economic model.[3] Had the commenter supplied a different set of substantiated data, we could have reevaluated our estimate.

Some commenters suggested that in the event of an FMD outbreak in the United States, APHIS should indemnify or otherwise support U.S. cattle producers.

APHIS' ability to pay indemnities is dependent upon the availability of funds. In the past, APHIS has indemnified producers whose livestock had to be depopulated as part of disease-eradication efforts.

Some commenters objected to the proposed rule because of what they perceived as economic favoritism. Commenters claimed that the rulemaking favored meat packers and processors at the expense of farmers. It was also asserted that the proposed rule favored Brazilian producers at the expense of U.S. producers because U.S. producers would not be able to compete on price with their Brazilian counterparts, and that, therefore, the rule would have the unintended effect of shrinking the U.S. cattle herd and expanding Brazil's.

We undertook this rulemaking at the request of Brazil and in accordance with our international trade agreements. We based this rulemaking on the findings of our risk assessment that fresh beef could safely be imported into the United States from Brazil under certain conditions. We do not believe this rule favors one sector or country over another, and the commenters did not provide evidence to support their claims.

Miscellaneous Comments

In addition to the issues already discussed in this document, commenters raised a few others that did not fit neatly into any of the above categories.

One commenter recommended that we allow the importation of fetal bovine serum from Brazil.

That comment is beyond the scope of the present rulemaking, which concerns the FMD status of Brazil and the importation of Brazilian beef.

Other commenters suggested that the rulemaking may lead to deforestation and/or environmental degradation.

The commenters did not explain how the rulemaking would have those effects. USDA prepared an environmental assessment, but the focus of the environmental assessment is to evaluate the potential impacts of allowing for the importation of fresh, maturated, and deboned beef from a region in Brazil into the United States, and not on increased deforestation in Brazil.

One commenter stated that the rulemaking does not comply with our statutory obligation to develop rural America.

The commenter did not cite any particular statute to support the claim that we were not meeting our statutory obligations.

Commenters writing on behalf of an association representing Hispanic and Native American livestock producers claimed that the rulemaking violates the civil rights and fair trade rights of minority livestock producers.

As we noted in the economic analysis accompanying the December 2013 proposed rule, we do not anticipate that

[3] 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.

the rulemaking will have a significant economic effect on any livestock producers. In the absence of economic or competitive harm, we do not see this rule as violating the rights of any group.

Miscellaneous

We are making an editorial change to § 94.29(a) for the sake of clarity. In the December 2013 proposed rule, the paragraph read as follows: ''The meat is beef or ovine meat from animals that have been born, raised, and slaughtered in the exporting region of Brazil or in Uruguay.'' As written, that paragraph could be interpreted to indicate that not only beef but also ovine meat could be imported from the exporting region of Brazil. Since ovine meat may not be imported from Brazil under § 94.29, we have edited the paragraph in this final rule to read as follows: ''The meat is: (1) Beef from Brazil derived from animals that have been born, raised, and slaughtered in the exporting region of Brazil; or (2) Beef or ovine meat from Uruguay derived from animals that have been born, raised, and slaughtered in Uruguay.''

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 designated region in Brazil 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. Welfare gains for consumers will outweigh producer losses, 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 Brazil is sufficiently low so that such 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, equivalent to 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 Brazil are expected to range between 20,000 and 65,000 MT, with volumes averaging 40,000 MT. Quantity, price, and welfare changes are estimated for 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 Brazil 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 15,894 MT (79 percent of 20,000 MT) under the 20,000 MT scenario; 32,000 MT (80 percent of 40,000 MT) under the 40,000 MT scenario; and 52,654 (81 percent of 65,000 MT) under the 65,000 MT scenario.

If the United States imports 40,000 MT of beef from Brazil, total U.S. beef imports will increase by 2.8 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 0.65, 0.26, and 0.70 percent, respectively. U.S beef production will decline by 0.03 percent while U.S. beef consumption and exports will increase by 0.2 and 0.7 percent, respectively. The 20,000 MT and 65,000 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 40,000 MT import scenario, beef processors will experience a decline in surplus of $28.85 million or 0.85 percent, while consumers will benefit from the decrease in price by an increase in their surplus by $387.50 million or 1.14 percent. Cattle producers will experience decline in welfare of $216.01 million or 8 percent. The overall impact will be a net welfare gain of $358.36 million or 1 percent for producers and consumers in the beef processing sector. For the combined beef and cattle sectors, there will be a $142 million net welfare gain (0.36 percent net benefit).

The 20,000 MT and 65,000 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, but consumers of pork and poultry meat sectors 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 on small entities 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 a region in Brazil 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.[4] 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 0579–0414, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the **Federal Register** providing notice of what action we plan to take.

E-Government Act Compliance

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

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:

[4] Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2009-0017*. The environmental assessment and finding of no significant impact will appear in the resulting list of documents.

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.

§ 94.1 [Amended]

■ 2. In § 94.1, paragraphs (b)(4) and (d), introductory text, are amended by removing the words ''from Uruguay''.

■ 3. Section 94.29 is revised to read as follows:

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

Notwithstanding any other provisions of this part, 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 Brazil derived from animals that have been born, raised, and slaughtered in the exporting region of 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 Brazil or in 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. 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 under § 94.1(a).

(i) 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 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 and 0579–0414)

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

Gary Woodward,

Deputy Under Secretary for Marketing and Regulatory Programs.

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