

Rules and Regulations

Federal Register

Vol. 75, No. 220

Tuesday, November 16, 2010

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF HOMELAND SECURITY

8 CFR Part 103

[CIS No. 2490-09; DHS Docket No. USCIS-2009-0033]

RIN 1615-AB80

U.S. Citizenship and Immigration Services Fee Schedule; Correction

AGENCY: U.S. Citizenship and Immigration Services, DHS.

ACTION: Final rule; correction.

SUMMARY: The Department of Homeland Security corrects an inadvertent error in the amendatory language of the final rule *U.S. Citizenship and Immigration Services Fee Schedule* published in the **Federal Register** on September 24, 2010.

DATES: This correction is effective November 23, 2010.

FOR FURTHER INFORMATION CONTACT: Timothy Rosado, Acting Chief Financial Officer, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue, NW., Washington, DC 20529-2130, telephone (202) 272-1930.

SUPPLEMENTARY INFORMATION:

Need for Correction

On September 24, 2010, the Department of Homeland Security (DHS) published a final rule in the **Federal Register** adjusting the U.S. Citizenship and Immigration Services (USCIS) fee schedule. 75 FR 58962. As discussed in the preamble to the final rule, DHS determined that the fee for a refugee travel document for an adult age 16 or older should match the fee charged for the issuance of a passport to a United States citizen (\$110 plus a \$25 dollar execution fee). 75 FR at 58964, 58972. Accordingly, DHS intended to reduce the fee for filing Application for Travel Document, Form I-131, for a

refugee travel document to \$135 for an adult age 16 or older.

The final rule inadvertently listed a fee of \$165 for filing an Application for Travel Document, Form I-131, for a refugee travel document for an adult age 16 or older. 75 FR at 58987. DHS needs to correct that portion of the final rule to indicate that an adult age 16 or older must submit a fee of \$135 with an Application for Travel Document, Form I-131, to request a refugee travel document. No other changes are made in this correction.

Correction of Publication

■ Accordingly, the publication on September 24, 2010 (75 FR 58962) of the final rule that was the subject of FR Doc. 2010-23725 is corrected as follows:

§ 103.7 [Corrected]

■ 1. On page 58987, in the first column, § 103.7 is amended by revising the dollar figure “\$165” in paragraph (b)(1)(i)(M)(1) to read: “\$135”.

Dated: November 9, 2010.

Christina E. McDonald,

Acting Associate General Counsel for Regulatory Affairs, Department of Homeland Security.

[FR Doc. 2010-28719 Filed 11-15-10; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. APHIS-2009-0034]

RIN 0579-AD12

Changes in Disease Status of the Brazilian State of Santa Catarina With Regard to Certain Ruminant and Swine Diseases

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of certain animals and animal products by adding the Brazilian State of Santa Catarina to the list of regions we recognize as free of foot-and-mouth disease (FMD), rinderpest, swine vesicular disease, classical swine fever, and African swine fever. We are also

adding Santa Catarina to the list of regions that are subject to certain import restrictions on meat and meat products because of their proximity to or trading relationships with rinderpest- or FMD-affected countries. These actions will update the disease status of Santa Catarina with regard to FMD, rinderpest, swine vesicular disease, classical swine fever, and African swine fever while continuing to protect the United States from an introduction of those diseases by providing additional requirements for live swine, pork meat, pork products, live ruminants, ruminant meat, and ruminant products imported into the United States from Santa Catarina.

DATES: *Effective Date:* December 1, 2010.

FOR FURTHER INFORMATION CONTACT: Dr. Silvia Kreindel, Senior Staff Veterinarian, Regionalization Evaluation Services Staff, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737; (301) 734-4356 or (301) 734-8419.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation into the United States of specified animals and animal products in order to prevent the introduction of various animal diseases, including rinderpest, foot-and-mouth disease (FMD), African swine fever (ASF), classical swine fever (CSF), and swine vesicular disease (SVD). These are dangerous and destructive communicable diseases of swine and ruminants.

Section 94.1 of the regulations prohibits, with certain exceptions, the importation into the United States of live swine, live ruminants, and products from these species from regions where FMD or rinderpest is known to exist. Rinderpest or FMD exists in all regions of the world except for certain regions that are listed as free of rinderpest or free of both rinderpest and FMD in § 94.1. Section 94.11 of the regulations lists regions of the world that have been determined to be free of rinderpest and FMD, but that are subject to certain restrictions because of their proximity to or trading relationships with rinderpest- or FMD-affected regions. Section 94.8 of the regulations restricts the importation into the United States of pork and pork

products from regions where ASF is known to or reasonably believed to exist. ASF is known to or reasonably believed to exist in those regions of the world listed in § 94.8. Section 94.9 of the regulations restricts the importation into the United States of pork and pork products from regions where CSF is known to exist, and § 94.10 prohibits, with certain exceptions, the importation of live swine from regions where CSF is known to exist. Sections 94.9 and 94.10 provide that CSF exists in all regions of the world except the regions listed in those sections. Section 94.12 of the regulations restricts the importation into the United States of pork and pork products from regions where SVD is known to exist. SVD exists in all regions of the world except for certain regions that are listed as free of SVD in that section.

On April 16, 2010, we published in the **Federal Register** a proposal¹ (75 FR 19915–19920, Docket No. APHIS–2009–0034) to amend the regulations by adding Santa Catarina to the list in § 94.1 of regions that are free of rinderpest and FMD, the list in § 94.11 of regions that are declared to be free of rinderpest and FMD but that are subject to certain restrictions because of their proximity to or trading relationships with rinderpest or FMD-affected regions, the lists in §§ 94.9 and 94.10 of regions that are free of CSF, and the list in § 94.12 of regions that are free of SVD. We also proposed to exclude Santa Catarina from the list in § 94.8 of regions where ASF is known to or reasonably believed to exist.

We solicited comments concerning our proposal for 60 days ending June 15, 2010. We received 87 comments by that date. They were from U.S. ranchers and cattle producers, U.S. industry and trade organizations, a Tribal association, a consumer organization, State departments of agriculture, Brazilian trade and industry associations, a Brazilian Government agency, the Canadian embassy, and private citizens. They are discussed below by topic.

One commenter stated that Animal and Plant Health Inspection Service (APHIS) lacks the ability to design and implement effective risk mitigation techniques. Several commenters stated their belief that the proposed rule was not consistent with the APHIS' mission of protecting U.S. agriculture. Commenters voiced concern about the reliance on administrative barriers to protect against disease introduction and

stated that amending the regulations would put the United States at risk for an outbreak of FMD.

We disagree. APHIS considers all regions in the world to be affected by FMD (§ 94.1) until APHIS conducts an evaluation and concludes that the region or country is free of FMD and therefore able to export FMD-susceptible commodities to the United States. While there is always some degree of disease risk associated with the movement of animals and animal products, APHIS regulatory safeguards will provide effective protection against the risks associated with the importation of ruminants, swine, or their products from the Brazilian State of Santa Catarina. These safeguards include subjecting animals and animal products from Santa Catarina to certain restrictions because of the region's proximity to FMD affected countries (§ 94.11), certification that ruminants and swine have been kept in a region entirely free of FMD and rinderpest (for ruminants) and FMD, rinderpest, CSF, SVD, and ASF (for swine) for 60 days prior to export (§§ 93.405 and 93.505), and a minimum quarantine of 30 days from the date of arrival at the port of entry for most imported ruminants (§ 93.411) and 15 days for all imported swine (§ 93.510).

APHIS' evaluations are based on science and conducted according to the 11 factors identified in § 92.2, "Application for recognition of the animal health status of a region," which include veterinary and disease control infrastructures, disease status of the export region and adjacent regions, and animal movement controls. Based on these factors, as discussed in the proposed rule and its underlying risk evaluation, we have determined that ruminants, swine, and their products can be safely imported into the United States from Santa Catarina.

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. Many commenters rejected the concept of regionalization, stating that World Organization for Animal Health (OIE) recognition of FMD-free status was not sufficient reason for U.S. recognition of FMD-free status. Some commenters indicated that regionalization is not scientific. One commenter stated that APHIS lacks the ability to accurately assess the risk of FMD and the effectiveness of regionalization-based risk mitigations. One commenter

opposed following World Trade Organization (WTO) guidelines. One commenter opposed making decisions based on OIE's Terrestrial Animal Health Code.

As a signatory to the WTO's Sanitary and Phytosanitary Agreement, the United States is committed to following WTO 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 consistent with OIE guidelines. Evaluations are based on science and conducted according to the 11 factors identified in § 92.2. We have not automatically accepted OIE recognition of disease status as the basis for changes to our regulations; rather, we first conduct our own evaluation, such as that detailed in the proposed rule and its accompanying risk evaluation.

One commenter said that allowing regionalization in one region and not another would be a double standard, especially as regions neighboring Santa Catarina within Brazil have applied for recognition of disease-free status.

APHIS has established protocols for evaluating requests from other countries and regions for recognition of FMD or other disease freedom. Section 92.2 of the regulations provides for any country to request a change in the animal health status of a region. APHIS evaluates all requests based on sound science and internationally recognized guidelines established by the OIE and considers the unique characteristics of each region in its evaluation. APHIS has not received a request from Brazil for disease-free status for any regions that neighbor Santa Catarina; should APHIS receive such a request, APHIS would evaluate it in accordance with established procedures. APHIS is currently evaluating a request from Brazil for several Brazilian States, including States neighboring Santa Catarina, to export boneless beef under certain conditions designed to protect against the introduction of FMD into the United States. This request, however, does not involve declaring any Brazilian States free of disease.

Commenters also objected to linking this rule with a WTO negotiated settlement over a Brazilian cotton dispute. In this long-running dispute brought by the Government of Brazil against the United States, the WTO found that certain U.S. agricultural

¹ To view the proposed rule, supporting and related documents, and the comments received, go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2009-0034>.

subsidies, including cotton subsidies, are inconsistent with the United States' WTO commitments. As part of a negotiated settlement of this dispute with Brazil, the United States agreed to publish a proposed rule to recognize the State of Santa Catarina as free of FMD, rinderpest, CSF, ASF, and SVD.

While we acknowledge that publication of the proposed rule was part of a WTO negotiated settlement, the settlement did not affect the methodology or the conclusions in our risk evaluation. Our decision was based on our own evaluation of the disease status of Santa Catarina, which was conducted according to the 11 factors identified in § 92.2. We would not propose to recognize any region as free of a disease or diseases unless our evaluation of the region's disease status supported it, consistent with our statutory responsibility under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*)

Several commenters said that trade relations should be equitable. Commenters stated that trade restrictions the Government of Brazil has imposed against the United States were unfair, with one commenter noting that the Brazilian Government closed its borders to the importation of live cattle from the United States in 2003 due to an incidence of bovine spongiform encephalopathy. Another commenter expressed frustration at the Brazilian Government's trichinosis-related import restrictions on U.S. pork, which the commenter stated were not based on science.

APHIS agrees with the commenters that trade relations should be equitable. APHIS' regionalization decisions, however, are based on science and not on reciprocal trade agreements. We note that the United States has benefited from regionalization when certain animal diseases have been detected in specific areas of our own country. We will continue to work with the Brazilian Government to resolve animal health-related barriers to trade.

Many commenters expressed concern with the Brazilian Government's ability to maintain Santa Catarina's FMD-free status and asked whether the Brazilian authorities have the resources and infrastructure necessary for enforcement of laws and regulations. Many commenters noted that FMD outbreaks have occurred in regions that APHIS had recognized as free, and some commenters stated that the risk evaluation does not conclusively determine that the Brazilian authorities could maintain Santa Catarina's FMD-free status. One commenter expressed concern regarding the Brazilian

authorities' ability to respond to an FMD outbreak. One commenter stated APHIS lacked the ability to predict potential FMD outbreaks.

Because disease situations are fluid, no country, not even the United States, can guarantee perpetual freedom from a disease. Therefore, APHIS' risk evaluation considers whether a country's animal health authorities can quickly detect, respond to, and report changes in disease situations. For the reasons explained in the proposed rule and its underlying risk evaluation, we concluded that the local authorities in Santa Catarina have the legal framework, animal health infrastructure, movement and border controls, diagnostic capabilities, surveillance programs, and emergency response systems necessary to detect, report, and control an outbreak of FMD, CSF, SVD, or ASF should one occur in Santa Catarina. To amplify this conclusion, we have updated the risk evaluation to make it clear that authorities in Brazil have responded to past outbreaks of FMD in a timely manner by declaring sanitary emergency alerts and intensifying biosecurity, control, prevention, and surveillance within high-risk areas.

When a reportable animal disease outbreak does occur in a region previously recognized by APHIS as free of that disease, APHIS has the authority to take immediate action to prohibit or restrict imports of animals and animal products. APHIS has acted in accordance with that authority when regions have experienced FMD outbreaks.

Many commenters expressed concern that Brazil, in its entirety, is not free of FMD.

As discussed in the proposed rule, the importation of meat and other products from ruminants or swine into the United States from Santa Catarina would continue to be subject to certain restrictions because of Santa Catarina's proximity to or trading relationships with FMD-affected countries and regions. For example, we require that only inspected, authorized establishments be used to prepare products, and we prohibit using slaughterhouses that receive meat or animals from FMD- or rinderpest-affected areas. These restrictions mitigate the risk that products from FMD-free regions would be commingled with products from affected regions. Furthermore, border controls are proving effective at keeping FMD out of Santa Catarina from surrounding countries and regions.

Several commenters raised the issue of the possibility of animals from areas

that do not have disease-free status being moved into Santa Catarina. Some commenters also expressed concern that regionalization would increase the incentive to illegally import cattle into Santa Catarina. One commenter requested enforcement by Brazilian authorities and monitoring by APHIS of entry of animals from adjacent areas. One commenter requested information regarding Table 6 in the risk evaluation and why illegal trafficking of small herds was not being detected.

In our evaluation, conducted according to the 11 factors identified in § 92.2, we concluded that the local authorities in Santa Catarina have adequate controls at ports of entry for legal importation of species and products that could carry the diseases under evaluation (FMD, CSF, ASF, and SVD). The local authorities in Santa Catarina also have the legal framework and authority to deal with the entry of illegal animals or animal products into the State; we evaluated the controls of local authorities in Santa Catarina for the movement of animals into the State and concluded that risk from illegal importations from affected regions to be sufficiently mitigated. Accordingly, we have determined that APHIS monitoring of the movement of animals into Santa Catarina is unnecessary.

The table mentioned by the commenter, which appears on page 40 of the risk evaluation, depicts the results of border inspections conducted during 2005 and 2006 and does not contain any references to or inferences about illegal trafficking of smaller herds. The pathway of illegal cattle trafficking is hard to quantify by definition.

We consider exposure of susceptible U.S. animals to illegally imported infected live animals from Santa Catarina to be highly unlikely. In Santa Catarina, individual cattle identification is mandatory for the entire herd, making it extremely unlikely that any cattle that might be illegally imported into Santa Catarina could end up being exported to the United States. Furthermore, the local authorities in Santa Catarina require strict inventory control of animals at the farm and require producers to receive a permit prior to any animal movement, including movement to slaughter. This process includes a visit to the farm by the local veterinary unit to verify the identification of any animals going to slaughter and also check for signs of disease in the herd. So even if an animal were somehow smuggled into Santa Catarina, it could not move anywhere else, nor could any of its herd members, without a movement document that contains particulars about the animal

(including the individual animal identification).

Several commenters expressed concern with the reliance of the local authorities in Santa Catarina on administrative barriers rather than geographic barriers to prevent FMD.

We have determined that the administrative barriers in Santa Catarina are effective. As discussed in the proposed rule and its underlying risk evaluation, the local authorities in Santa Catarina enforce both geographic and administrative barriers. The use of these two types of barriers combined has prevented the introduction of the diseases under evaluation into Santa Catarina.

Many commenters expressed concern with delays in FMD vaccinations to regions surrounding Santa Catarina, referencing a May 2010 article in *MercoPress*² that outlined a growing concern in Uruguay with the Brazilian Government's delay in carrying out its FMD vaccination timetable for those States in Brazil that are considered to be FMD-free with vaccination.

Under § 94.11 of the regulations, animals and animal products are subject to certain restrictions because of a region's proximity to FMD-affected regions or countries; as APHIS restrictions do not distinguish between regions or countries that vaccinate for FMD and those that are affected with the disease, the vaccination status of regions surrounding Santa Catarina is not germane.

Two commenters wanted to know what APHIS' response would be should the disease status of countries or States contiguous to Santa Catarina change.

The regulations in § 92.2(a) provide that regions recognized as disease-free may be required to submit additional information pertaining to animal health status or allow APHIS to conduct additional information collection activities once regionalization is established. In the event that the disease status of a region bordering Santa Catarina changed, APHIS would require Brazilian authorities to submit additional information as necessary regarding Santa Catarina's animal health status and response to the situation. Because of Santa Catarina's proximity to or trading relationships with FMD-affected areas, the importation of meat and other animal products from ruminants or swine into the United States from Santa Catarina will already be subject to the restrictions in § 94.11.

It should be noted that recent changes in the disease status of surrounding areas have not affected Santa Catarina; there was no evidence of FMD viral activity in cattle or other species in Santa Catarina during or after the 2000–2001 and 2005–2006 outbreaks in other areas of Brazil.

One commenter indicated the need for precautions to ensure that the importation of animals or animal products does not result in the introduction of animal disease to the United States. One commenter expressed concern that animal products could be imported before a disease outbreak is diagnosed in the exporting country.

Animals and animal products from Santa Catarina will continue to be subject to certain restrictions because of the region's proximity to FMD-affected countries and regions (§ 94.11). Furthermore, current APHIS regulations require certification that ruminants and swine have been kept in a region entirely free of FMD, CSF, SVD, and ASF for 60 days prior to export (§§ 93.405 and 93.505). They also require a minimum quarantine of 30 days from the date of arrival at the port of entry for most imported ruminants (§ 93.411) and 15 days for all imported swine (§ 93.510). These requirements increase the likelihood of disease detection in exported animals. Considered with the protections afforded by the safeguards contained in § 94.11, the certification and quarantine requirements for imported animals will effectively mitigate the risk associated with the importation of ruminants, swine, and their products from Santa Catarina.

One commenter wanted to know what parameters APHIS used to define early detection of the diseases being evaluated, indicating that APHIS should better describe the estimated confidence, prevalence, and time to detection.

As we explained in the risk evaluation, the local authorities in Santa Catarina have surveillance programs in cattle and swine for the early detection of FMD, CSF, SVD, and ASF. Local veterinary units visit farms to conduct regular inspections, and they also check for signs of disease in the herd before the movement of any animals to slaughter. Ruminants and swine in Santa Catarina are not vaccinated for FMD or CSF, which means that clinical signs of disease would be more apparent in individual animals as well as herds.

The ability to rapidly confirm a disease outbreak via laboratory analysis is also necessary for early disease detection. We determined that Brazilian

animal health authorities have the diagnostic capability to adequately test for all the diseases under evaluation.

Furthermore, early disease detection is linked directly to OIE guidelines for notification of suspected notifiable diseases. As a member of the OIE, the Brazilian Government is obligated to follow OIE guidelines for suspected notifiable diseases, which include immediate notification of 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. We have updated the risk evaluation to reflect the fact that the 2005–2006 FMD outbreaks that occurred in the States of Mato Grosso do Sul and Parana were reported to the OIE and trading partners immediately after confirmation.

Several commenters requested scientific data showing the 11 requirements for regionalization have been met by the local authorities in Santa Catarina.

The 11 factors in § 92.2(b) also include information that is not scientific in nature, such as demographics and the authority of the veterinary services organization in the region. Section 92.2(d) says that we will share with the public all the information we receive in alignment with 92.2(b) and affirm that we did so. Thus, to the extent that any of the factors are addressed through scientific data, the data has been shared already.

One commenter said the risk evaluation was insufficient and requested a quantitative risk assessment as required under APHIS' regulations in 9 CFR part 92, which govern the importation of animals and animal products and provide procedures for requesting recognition of regions, and APHIS guidance documents. One commenter said we did not adequately address biosecurity measures or livestock demographics and marketing practices in our risk evaluation.

APHIS' evaluations are based on science and conducted according to the 11 factors identified in § 92.2, which include biosecurity measures, livestock demographics, and marketing practices. Neither the regulations in 9 CFR part 92 nor APHIS guidance documents require a quantitative risk assessment or indicate that one is needed here. The commenter did not specify how the results of the risk evaluation would be improved by a quantitative risk assessment.

² The article can be viewed at <http://en.mercoPress.com/2010/05/21/growing-concern-in-uruguay-with-brazilian-delay-in-fmd-vaccination-timetable>.

Some commenters requested additional information on animal identification and segregation methods in Santa Catarina. Other commenters indicated that animal identification could not prevent or control disease.

Additional information on Brazil's animal identification system can be found at http://www.agricultura.gov.br/portal/page?_pageid=33,5459468&_dad=portal&_schema=PORTAL. For the reasons explained in the proposed rule and its underlying risk evaluation, we concluded that the local authorities in Santa Catarina have an identification system that will allow it to comply with the certification requirements in § 94.11, which requires certification that meat and other products intended for export to the United States have not been commingled with meat or products not eligible for export to the United States. To be eligible for certification, meat or other animal products must originate from a region free from rinderpest and FMD. Animal identification is only one of the factors considered in determining whether the local authorities in Santa Catarina can detect, report, and control outbreaks of the diseases under evaluation. We agree that animal identification does not in and of itself prevent or control animal disease, but an effective animal identification system is a valuable tool for animal disease prevention and control efforts, which is why we evaluate it.

Some commenters indicated the local authorities in Santa Catarina should require tattoos rather than backtags for their animal identification system, as this is how swine in the United States are identified.

All animals imported into the United States must be identified with approved identification upon entering interstate commerce. In 9 CFR part 71 of our regulations governing the interstate movement of animals within the United States, § 71.19 includes backtags as an approved method of identification for swine moving to slaughter in the United States.

One commenter requested more explanation regarding mitigation efforts for risky herds of cattle and an explanation as to why they would remain free of FMD.

The local authorities in Santa Catarina take a proactive approach to addressing the risks posed by risky herds, defined as herds with one or more of the following risk factors: A high volume of movement of animals or products; proximity to animal or waste gathering facilities (including slaughterhouses, landfills, feedmills, and border areas); or containing over 100 animals. As we explained in the risk evaluation, local

veterinary personnel carry out supplemental inspections of herds classified as "risky" by the official service. Other mitigation measures include enhanced surveillance activities (both active and passive) which include serologic testing and are designed to demonstrate freedom from FMD.

One commenter requested a comparison of educational requirements for accredited veterinarians in Brazil and the United States.

Accredited veterinarians in Brazil undergo training similar to that required in the United States. During the site visit, APHIS was able to corroborate that official and accredited veterinarians in Brazil are able to detect, recognize, and report diseases and to follow protocols for disease prevention and eradication.

One commenter requested an explanation for the high percentage of vesicular lesion ruleouts that are toxic in nature, *i.e.*, why so many vesicular lesions, a possible indicator of FMD, were from toxic causes.

Because Santa Catarina does not contain any endemic vesicular diseases, vesicular lesions that occur must thereby be caused by some other means. The definitive diagnoses for suspicious lesions were generally due to traumatic injury or ingestion of caustic or toxic plants. We are providing this information in the risk evaluation to clarify this matter.

One commenter indicated that a discussion of serological monitoring for FMD and CSF at slaughter was missing from the proposed rule and risk evaluation.

While there is no serological monitoring for FMD or CSF at slaughter, the local authorities in Santa Catarina do not vaccinate for FMD or CSF. Therefore, any cattle or swine in the region exposed to the FMD or CSF virus can be considered sentinels for these diseases, precluding the need for serological monitoring.

One commenter requested more information regarding the plan to eradicate FMD in South America (the Plano Hemisferico de Eradicacai de Febre Aftosa).

Additional information on the plan can be found at http://www.fao.org/Ag/againfo/commissions/docs/research_group/erice/APPENDIX_06.pdf. It should be noted that, as we explained in the risk evaluation, the OIE recognized Santa Catarina as an FMD-free zone where vaccination is not practiced in 2007.

One commenter expressed concern that Santa Catarina does not have a diagnostic laboratory.

It is not unusual for countries to have only a few reference laboratories located

throughout the country to perform diagnostic testing, with standard laboratories located in specific States or regions to perform more routine testing. The United States, for example, uses such a system. As we explained in the risk evaluation, Brazilian animal health authorities have the diagnostic capability to adequately test for all the diseases under evaluation.

Several commenters noted that we indicated, in the preamble to the proposed rule, that the last case of FMD in Brazil was in 2005 when it actually occurred in 2006.

The risk evaluation correctly indicated that the last FMD outbreak in Brazil started in 2005 and ended in 2006. While we agree that the dates of that outbreak were incompletely reported in the proposed rule, this does not affect our risk evaluation or its conclusions.

Several commenters stated that we failed to discuss wildlife and feral swine and their possible role in transmitting FMD and CSF. Commenters also expressed concern regarding consumption of garbage by free-ranging swine.

The role of wild boar in the transmission of CSF is considered on page 73 of the risk evaluation. We agree that the risk evaluation did not address the FMD risk associated with wildlife and feral swine populations and have updated the risk evaluation to address this omission. 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 Santa Catarina through movement of infected wildlife.

Furthermore, the local authorities in Santa Catarina prohibit feeding garbage to animals. In the event that these laws were circumvented, other factors evaluated in the risk assessment, including biosecurity measures, surveillance activities, and response capabilities, would mitigate disease risks.

Several commenters addressed risks beyond the diseases evaluated in the proposed rule. Commenters expressed concern that residues of drugs, such as Ivermectin or pharmaceutical products would be present in the meat of animals from Santa Catarina. Other commenters questioned the adequacy of Brazil's food

safety standards and inspection practices.

These issues are beyond the scope of the Animal Health Protection Act. The U.S. Food and Drug Administration and the United States Department of Agriculture's Food Safety and Inspection Service have oversight of these issues, and we coordinate with these agencies as needed.

One commenter indicated that tuberculosis and brucellosis should be considered in the proposed rule.

The analysis of these issues is beyond the scope of the proposed rule, which focused on specific diseases addressed by our regulations in 9 CFR part 94. Measures to prevent the introduction by imported live animals of bovine tuberculosis and brucellosis, along with other livestock diseases, are addressed by our regulations in 9 CFR part 93.

Several commenters raised issues in response to the economic analysis. One commenter requested an analysis of possible changes to market prices in Santa Catarina due to the implementation of a final rule. One commenter requested an analysis of marketing pressures in Santa Catarina and movement and marketing practices. One commenter requested a peer-reviewed economic analysis on the impact of a foreign animal disease outbreak in the United States. One commenter requested a more thorough explanation of the number of years it would take for producers to recover to pre-event prices should FMD or CSF be introduced into the United States.

The analysis of market prices, marketing pressures, and impacts of foreign animal disease outbreaks is not required under the Regulatory Flexibility Act. The Regulatory Flexibility Act requires an economic analysis to examine the potential economic effects of an action on small entities in the United States, and we determined that the factors cited by the commenters do not need to be analyzed in order to determine those effects. A 2008 report on the economic impacts of a foreign animal disease outbreak, developed by USDA's Economic Research Service, is available at <http://www.ers.usda.gov/publications/err57/err57.pdf>. We have determined that the requirements in this final rule will effectively mitigate the risk of introducing FMD or CSF into the United States via imports from Santa Catarina.

One commenter requested a risk/benefit analysis in connection with the potential impact on the U.S. gross domestic product. Several commenters expressed concerns about negative economic impacts as a result of the proposed rule, including negative

impacts on U.S. cattle and beef producers, pork producers, and rural economies. One commenter requested an analysis of possible changes to market prices in the United States.

Under the Animal Health Protection Act, we have the authority to prohibit or restrict the importation of animals and animal products only when necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock. We do not have the authority to restrict imports on the grounds of potential economic effects on domestic entities that could result from increased imports. While the final rule is not expected to result in beef or other ruminant meat exports to the United States of any appreciable quantity, we have, however, considered the possible negative economic impacts with respect to pork in the final economic analysis and determined that the rule will not have a significant impact on a substantial number of small entities.

Several commenters expressed concern that the potential imports of beef were understated in the economic analysis, noting that Santa Catarina has more cattle operations than any single State in the United States. Commenters stated that Brazil is the largest beef exporter in the world, that the representation of the Brazilian cattle industry was not accurate, and that the potential for beef exports should be included in the analysis based on beef harvesting or processing facilities.

We disagree with the commenters. The analysis discusses and references information on the size of the cattle industry in Brazil. As discussed in the proposed rule and its underlying analysis, Santa Catarina contains less than 2 percent of Brazil's cattle, most of which are dairy animals, and the final rule is not expected to result in beef or other ruminant meat exports to the United States of any appreciable quantity.

Many commenters expressed concern with the economic and other impacts of an FMD outbreak in the United States. Commenters also indicated we did not analyze the impact of an FMD outbreak on U.S. wildlife.

As discussed in the environmental assessment, we evaluated the nature of each disease, its causal agent, and its potential impacts on the physical environment as well as the health of human, livestock, and wildlife populations in the United States.

One commenter said the environmental assessment was deficient because it lacked multiple scenarios and modeling needed to consider all

potential effects to the human environment.

In the environmental assessment, we considered the potential effects to the human environment in accordance with the National Environmental Policy Act, including the natural and physical environment and the relationship of people with that environment. The environmental assessment is a threshold analysis that does not require "multiple scenarios and modeling." The lack of modeling has no effect on the findings in the EA. If a proposed action has the potential to significantly impact the environment, then an environmental impact statement is prepared, which involves a more comprehensive environmental analysis of the proposal and reasonable alternatives and might require such detail.

One commenter said we lacked data needed to respond to an FMD outbreak, including data on how the disease would spread to wildlife.

These issues have been studied extensively and APHIS has detailed contingency and preparedness action plans developed for use should there be an outbreak of FMD or another animal disease. The environmental assessment discusses, cites, and references credible scientific information on the five viruses of concern (including FMD) and how they could be spread to wildlife.

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

Effective Date

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**. This rule relieves certain restrictions related to rinderpest, FMD, SVD, CSF, and ASF for the importation into the United States of live swine, swine semen, pork meat, pork products, live ruminants, ruminant semen, ruminant meat, and ruminant products from Santa Catarina. We have determined that approximately 2 weeks are needed to ensure that APHIS and Department of Homeland Security, Bureau of Customs and Border Protection, personnel at ports of entry receive official notice of this change in the regulations. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be effective 15 days after publication in the **Federal Register**.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available on the Regulations.gov Web site (*see* footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

The final rule is not expected to result in beef or other ruminant meat exports to the United States of any appreciable quantity. Santa Catarina contains less than 2 percent of Brazil's cattle, most of which are dairy animals. Brazil's sheep and goat populations are also concentrated in parts of the country other than Santa Catarina, and their products are nearly entirely destined for the domestic market.

Pork imports from the State of Santa Catarina will compete with imports from Canada and Denmark, currently the United States' largest suppliers of pork. Taking into consideration probable partial displacement of pork imported from these countries by projected imports from Santa Catarina, the net increase in U.S. imports attributable to this rule is expected to be well under 3 percent. Given the United States' position as one of the largest pork exporters in the world, the market impacts resulting from the small amount of imports expected to come from Santa Catarina are likely to be minimal.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 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 Santa Catarina is free of FMD, rinderpest, SVD, CSF, and ASF and that the importation of live swine, swine semen, pork meat, pork products, live ruminants, ruminant semen, ruminant meat, and ruminant products into the United States from Santa Catarina under the conditions specified in this rule will not have a significant impact on the quality of the human environment.

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) APHIS 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 (*see* footnote 1 in this document for a link to Regulations.gov). 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) 690–2817 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

This final rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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, EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, SWINE VESICULAR DISEASE, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, 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, paragraph (a)(2) is amended by adding the words “the Brazilian State of Santa Catarina,” after the word “Bermuda,”.

§ 94.8 [Amended]

■ 3. In § 94.8, the introductory text is amended by adding the words “(except the State of Santa Catarina)” after the word “Brazil”.

§ 94.9 [Amended]

■ 4. In § 94.9, paragraph (a) is amended by adding the words “the Brazilian State of Santa Catarina,” after the word “Australia,”.

§ 94.10 [Amended]

■ 5. In § 94.10, paragraph (a) is amended by adding the words “the Brazilian State of Santa Catarina,” after the word “Australia,”.

§ 94.11 [Amended]

■ 6. In § 94.11, paragraph (a) is amended by adding the words “the Brazilian State of Santa Catarina,” after the word “Belgium,”.

§ 94.12 [Amended]

■ 7. In § 94.12, paragraph (a) is amended by adding the words “the Brazilian State of Santa Catarina,” after the word “Belgium,”.

Done in Washington, DC this 12th day of November 2010.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2010-28976 Filed 11-15-10; 8:45 am]

BILLING CODE 3410-34-P