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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. APHIS-2018-0007]

RIN 0579-AE73

Importation of Fresh Beef from Paraguay

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations governing the importation of certain animals, meat, and other animal products by allowing, under certain conditions, the importation of fresh (chilled or frozen) beef from Paraguay. Based on the evidence from a risk analysis, we have determined that fresh beef can safely be imported from Paraguay, provided certain conditions are met. This action would provide for the importation of fresh beef from Paraguay into the United States while continuing to protect the United States against the introduction of foot-and-mouth disease.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

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

- Federal eRulemaking Portal: Go to www.regulations.gov. Enter APHIS-2018-0007 in the Search Field. Select the Documents tab, then select the Comment button in the list of documents.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2018-0007, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at www.regulations.gov or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Ingrid Kotowski, Import Risk Analyst, Regionalization Evaluation Services, VS, APHIS, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; (919) 855-7732; email: AskRegionalization@usda.gov.

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 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. Under most circumstances, § 94.1 of the regulations prohibits the importation of live ruminants and swine and fresh (chilled or frozen) meat derived from ruminants and swine originating in, or transiting through, a region where FMD exists. Section 94.11 restricts the importation of ruminants and swine and their meat and certain other products from regions that are declared free of FMD but that nonetheless present a disease risk because of the regions' proximity to or trading relationships with regions affected with FMD. Regions that the Animal and Plant Health Inspection Service (APHIS) has declared free of FMD and regions declared free of FMD that are subject to the restrictions in § 94.11 are listed on the APHIS website at http://www.aphis.usda.gov/import_export/animals/animal_disease_status.shtml.

The regulations do allow for certain exceptions to the prohibitions contained in § 94.1. These exceptions include allowing the importation of fresh (chilled or frozen) beef and ovine

meat from Uruguay and fresh beef from certain regions of Argentina and a region of Brazil, subject to certain conditions. While there have been FMD outbreaks in the past in those regions, the disease is not currently known to exist in any of them. We do not recognize those exporting regions as FMD-free, however, because the Argentine, Brazilian, and Uruguayan governments all require that cattle be vaccinated for FMD.¹ The conditions for the importation of beef and ovine meat from Uruguay and beef from the exporting regions of Argentina and Brazil are set out in § 94.29 of the regulations and include the following:

- The meat is derived from animals born, raised, and slaughtered in the exporting region.
- FMD has not been diagnosed in the exporting region within the previous 12 months.
- The meat comes from bovines or sheep that originated from premises where FMD has not been present during the lifetime of any bovines and sheep slaughtered for the export of meat to the United States.
- 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.
- 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.
- The meat consists only of bovine parts or ovine parts that are, by standard practice, part of the animal's carcass that is placed in a chiller for maturation after slaughter and before removal of any bone, blood clots, or lymphoid tissue. The bovine and ovine parts that

¹ The position of the United States is that a country that vaccinates for FMD is not 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 individual animals in the herd may have a limited response, resulting in partial or no immunity. Therefore, so-called herd immunity may not always reflect individual animal immunity, and the disease may still be present in certain animals in a vaccinated population. As a result, importation of beef from areas in which cattle are vaccinated for FMD could result in importation of beef derived from infected animals.

may not be imported include all parts of the head, feet, hump, hooves, and internal organs.

- All bone and visually identifiable blood clots and lymphoid tissue have been removed from the meat to be exported (bone-in ovine meat from Uruguay may be imported under certain conditions listed in the regulations, however).
- The meat has not been in contact with meat from regions other than those listed in accordance with § 94.1(a).
- The meat came from carcasses that were allowed to mature 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 mature an additional 24 hours and be retested, and, if the carcass still has not reached a pH of less than 6.0 after 48 hours, the meat from the carcass may not be exported to the United States.
- An authorized veterinary official of the government of the exporting region certifies on the foreign meat inspection certificate that the above conditions have been met.
- 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.

Historically, trade in fresh (chilled or frozen) beef from Paraguay has not been allowed because APHIS has considered Paraguay to be a country affected with FMD. In response to a request from the Government of Paraguay that we allow fresh (chilled or frozen) beef to be imported into the United States from that country, we conducted a risk analysis, which can be viewed on the internet on the Regulations.gov website or in our reading room.² APHIS gathered

² Instructions on accessing Regulations.gov and information on the location and hours of the reading room may be found at the beginning of this document under ADDRESSES. You may

data to support this analysis from records of the Servicio Nacional de Calidad y Salud Animal (SENACSA), from publicly available information, and from published scientific literature. In addition, APHIS conducted site visits to Paraguay in December 2008 and July 2014 to verify the information submitted by SENACSA and to collect additional data.

We concluded that the overall risk associated with importing fresh beef from Paraguay is low and that Paraguay has the infrastructure and emergency response capabilities needed to effectively report, contain, and eradicate FMD in the event of an outbreak and to do so in a timely manner. We further concluded that Paraguay is able to comply with U.S. import restrictions on the specific products from affected areas. Based on the evidence documented in our risk analysis, we believe that fresh (chilled or frozen) beef can be safely imported from Paraguay, provided certain conditions are met. Accordingly, we are proposing to amend the regulations in § 94.29 to provide for the importation of fresh beef from Paraguay. Under this proposed rule, fresh beef from Paraguay would be subject to the same import conditions applicable to fresh beef and ovine meat from Uruguay (other than bone-in ovine meat imported under § 94.29(g)(1) through (3)) and fresh beef from the exporting regions of Argentina and Brazil.

Risk Analysis

Our risk analysis was conducted according to the eight factors identified in 9 CFR 92.2, “Application for recognition of the animal health status of a region or a compartment”: The 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. A summary evaluation of each factor is discussed below. Based on

also request paper copies of the risk analysis by calling or writing the person listed under FOR FURTHER INFORMATION CONTACT.

our analysis of these factors, we have determined that fresh (chilled or frozen) beef can be safely imported into the United States from Paraguay, under the conditions specified in § 94.29.

Scope of the Evaluation Being Requested

In addition to reviewing records submitted by SENACSA, publicly available information, and published scientific literature, APHIS conducted site visits in December 2008 and July 2014 to verify the information we reviewed and to collect additional data. The site visits focused on the veterinary and legal infrastructure of SENACSA, its FMD control program, border control procedures, disease control measures, laboratory and diagnostic capabilities, biosecurity procedures on cattle farms and in slaughter facilities, animal health recordkeeping systems, movement controls, and disease surveillance systems. The 2014 visit included an evaluation of FMD outbreaks that occurred in 2011 and 2012 and the effectiveness of SENACSA's response to the outbreaks.

Veterinary Control and Oversight

Based on our analysis of the data submitted by SENACSA and observations made during our site visits to Paraguay, we concluded that the competent veterinary authority of Paraguay is well-organized and has the legal authority and technical infrastructure in place to carry out official control, eradication, and quarantine activities at the central, regional, and local levels. SENACSA is also an active collaborator with neighboring countries in disease-eradication efforts.

SENACSA has a system of official veterinarians and support staff in place for carrying out FMD field programs and for import controls and animal quarantines. It also has a training program for animal health professionals, frequently in collaboration with the veterinary medical faculty of the National University. The overall structure and resources of SENACSA have significantly increased and been strengthened in reaction to the FMD outbreak in 2012.

Following feedback from the World Organization for Animal Health (WOAH) and the European Union (EU), SENACSA is also hiring new personnel to expand its workforce.

A very strong partnership exists between the competent authority and the livestock industry. A large proportion of SENACSA's funding comes from the private sector in the form of user fees paid by stakeholders associated with sales of animals or movement permits. While this funding method allows SENACSA to operate autonomously and with little political interference, it also makes SENACSA's budget dependent on user fees. SENACSA is addressing the issue and has increased its operational budget to U.S. \$36 million. Although the contribution of the treasury department compared to that of the private sector is small, APHIS found no evidence suggesting that resources from the private sector could change in the future or that available resources for FMD control programs would be reduced.

Disease History and Vaccination Practices

APHIS observed that SENACSA has an established program for the control and prevention of FMD which includes a well-organized vaccination strategy. The vaccine used in Paraguay has been assessed by international FMD reference laboratories to be appropriate for the strains that have been found in the region in the last 15 years. Serosurveillance has demonstrated adequate levels of immunity in cattle previously immunized.

Following the 2011/2012 FMD outbreak, SENACSA instituted changes to its vaccination program. Audits of vaccinators and the vaccine cold chain were conducted. Vaccination cycles were increased from two to three annually. The training provided by SENACSA and industry-based Animal Health Commissions (AHC) prior to each vaccination cycle also appears to have increased the level of awareness of good vaccination practices among AHC vaccinators.

Livestock Demographics and Traceability

Paraguay's animal identification system is similar to, and meets the requirements of, the EU and Chilean markets, both of which have stringent traceability requirements. Paraguay has two traceability systems: A mandatory system under SENACSA and an industry-based, voluntary program called the System for the Identification and Traceability of Rural Holdings in

Paraguay (SITRAP). Under SITRAP, there have been initiatives undertaken to facilitate and enhance traceability at slaughter.

Movement controls were well organized and coordinated. Internal control posts visited were well-equipped with access to telecommunications and information technology systems. Staff at these control posts were well aware of movement requirements and followed established procedures related to movement control. The staff had an organized and consistent way of assessing each animal transport and movement. Records at the control posts were well organized, and manuals of procedures were readily available.

We concluded that Paraguay has a sound system for animal identification and traceability, premises registration, and animal movement controls. The system is adequate to provide assurance that the U.S. import requirements for animals to be born, raised, and slaughtered in Paraguay can be met.

Epidemiological Separation from Potential Sources of Infection

Many natural barriers, such as large rivers and forest areas, exist along Paraguay's international and internal borders. These barriers restrict both animal movement and human traffic and prevent the spread of disease.

Movement of FMD-susceptible species or products into Paraguay could occur through international borders where sufficient physical barriers do not exist, e.g., along some areas bordering Brazil and Argentina. However, the international borders are actively monitored, and Paraguay collaborates effectively with neighboring countries to minimize the risk of introduction of FMD. Border control agreements between Paraguay and its neighbors have been in place since the 1970s, and efforts continue to strengthen and harmonize border activities. Sufficient controls exist at the airports for interdiction of prohibited material and for prevention of the recycling of confiscated products and international waste.

With the exception of Chile, APHIS does not consider the countries of South America to be free of FMD. Coordinated regional FMD control efforts have been effective in decreasing the

incidence of FMD and limiting it to certain regions, however. Based on the history of the disease on the continent, Paraguay's veterinary infrastructure, and SENASCA'S prompt response to the outbreaks in Argentina (2006), Brazil (2005-2006), and Bolivia (2007), APHIS concluded that it is unlikely that disease would be introduced from adjacent areas. However, at the time the risk analysis was prepared, Colombia had just eradicated an FMD outbreak. As long as FMD is endemic in certain areas in South America, there is a potential risk of reintroduction of the disease into the export area.

Surveillance Practices

Our evaluation led us to conclude that Paraguay has a good epidemiological surveillance system. The surveillance activities conducted and the use of sound statistical methodologies increase the likelihood of detection of FMD if it exists in the population.

Paraguay's surveillance system combines both active surveillance and passive surveillance. Active surveillance consists of annual seroepidemiological sampling at the national level to verify the absence of circulating FMD virus. The active surveillance strategy is updated based on the surveillance objectives for the year. Extensive serological surveys were also conducted following FMD outbreaks 2003 and 2011/2012 to ensure the absence of circulating FMD virus. Passive surveillance is based on the notification of vesicular disease by producers who are required by law to report any suspect cases to their Local Veterinary Unit, which must then respond within 12 hours of notification. Indemnification is predicated on this notification by the producer. Paraguay's passive surveillance efforts are enhanced by the extensive awareness of the clinical signs of FMD among the animal health field staff and within the industry, as well as the mandatory reporting requirement for suspect cases of vesicular diseases. SENACSA, producers, and the AHCs in particular all have a role in passive surveillance efforts.

Additional surveillance comes from herd immunity studies, which are conducted frequently. Enhanced epidemiological surveillance occurs in High Surveillance Zones, which were established by Paraguay in coordination with neighboring countries.

SENACSA has a manual of procedures that provides the field veterinarians with guidelines for sample collection, animal identification, aging by dentition, communications, and measures to be taken in case of reactors or suspect cases. The manual ensures consistency in surveillance activities and responses to suspects among field offices.

Diagnostic Laboratory Capabilities

The Directorate General for Laboratories (DIGELAB) is the official laboratory in Paraguay and is located in the SENACSA headquarters. Responsibilities include the diagnosis of SENACSA's program diseases such as FMD, bovine spongiform encephalopathy, tuberculosis, brucellosis, classical swine fever, and Newcastle disease. DIGELAB's FMD laboratory is the only laboratory in Paraguay authorized to conduct diagnostic testing for vesicular diseases, including FMD. Relative to the FMD program, DIGELAB's Vesicular Diseases Department is responsible for conducting FMD diagnostic testing of animals as required under SENACSA's active and passive surveillance strategy, including surveillance sampling at fairs and shows, as well as testing of animals for import or export.

APHIS concluded that Paraguay has the diagnostic capabilities to adequately test samples for the presence of FMD virus. DIGELAB's FMD laboratory has the necessary infrastructure, equipment, and personnel. The laboratory staff are well-trained in the diagnosis of vesicular diseases. Diagnostic test methodologies used in the identification of vesicular diseases are consistent with WOAHP guidelines. All laboratory standard operating procedures are thorough and systematic, and documentation is good. The laboratory conducts quality control on all FMD vaccines, both nationally produced and imported. SENACSA has an organized recordkeeping system for laboratory data and the ability to complete and report test results in a timely manner.

Emergency Preparedness and Response

SENACSA has established procedures for rapidly detecting and responding to FMD emergencies. SENACSA has surveillance and laboratory programs for early detection of FMD and the necessary infrastructure for carrying out emergency eradication programs, including an

FMD contingency plan supported by a legal framework and a sufficient budget. If FMD is confirmed in Paraguay through diagnostic testing, the National Animal Health Emergency System (SINAESA) is immediately activated, and a Director of Emergency is appointed to head up the emergency response effort. SINAESA is responsible for establishing a chain of command and for identifying and obtaining the necessary resources to carry out the activities needed to eradicate the disease. In responding to outbreaks in neighboring countries, as well as during the 2011/2012 outbreak in Paraguay, SENACSA demonstrated its capacity for rapid and effective emergency response.

The above findings are detailed in the risk analysis document. The risk analysis explains the factors that have led us to conclude that fresh (chilled or frozen) beef may be safely imported from Paraguay under the conditions enumerated above. It also establishes that Paraguay has adequate veterinary infrastructure in place to prevent, control, report, and manage FMD outbreaks. Therefore, we are proposing to amend § 94.29 to allow the importation of fresh beef from Paraguay under the conditions described above.

Executive Orders 12866, 13563, and Regulatory Flexibility Act

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

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 an initial regulatory flexibility

analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act.

Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect on a substantial number of small entities. However, we do not currently have all of the data necessary for a comprehensive analysis of the effects of this proposed rule on small entities. Therefore, we are inviting comments on potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

Introduction

This analysis examines potential economic impacts of a proposed rule that would allow fresh (chilled or frozen) beef from Paraguay to be imported into the United States provided certain conditions are met. APHIS currently considers the whole territory of Paraguay to be a region where FMD exists. With few exceptions, APHIS' regulations in part 94 prohibit the importation of fresh (chilled or frozen) meat of ruminants or swine that originates in or transits a region where FMD is considered to exist. APHIS does not consider Paraguay as free of FMD because Paraguay vaccinates against FMD. As explained in detail earlier in this document, the vaccination requirement could result in infected animals being imported into the United States.

This document provides a benefit-cost 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. This document also examines the potential economic effects of the rule on small entities, as required by the Regulatory Flexibility Act.

Overview of the Action and Affected Entities

U.S. beef production and trade

The United States is the largest beef producer in the world and produces primarily grain-fed beef for the domestic and export markets. Over the period 2016 to 2020, U.S. beef production averaged 12 million metric tons (MT); exports 1.4 million MT; and imports 1.3 million MT (Table 1).

Table 1: U.S. beef production, exports, and imports, 2016 to 2020

Year	Production	Imports	Exports
Metric Tons			
2016	11,468,481	1,365,986	1,159,637
2017	11,904,762	1,357,370	1,296,599
2018	12,216,780	1,359,637	1,433,107
2019	12,346,485	1,386,848	1,372,336
2020	12,355,556	1,515,646	1,338,322
5-year average	12,058,413	1,397,098	1,320,000

Source: U.S. Department of Agriculture (USDA), World Agricultural Outlook Board, “World Agricultural Supply and Demand Estimates” and supporting materials; U.S. Department of Commerce, Bureau of Economic Analysis (population); and USDA, Economic Research Service.

Most U.S. beef imports are grass-fed beef that is processed together with higher-fat trimmings from U.S. grain-fed beef to produce ground beef. Canada, Australia, New Zealand, and Mexico historically have been the largest sources of U.S. beef imports (Table 2). Entry of beef from Paraguay into the U.S. beef market would result in a change in market shares.

In terms of exports, between 2016 and 2020 the top destinations for U.S. beef were Japan (362,071 MT); South Korea (264,780 MT); Mexico (181,982 MT); Hong Kong (156,025 MT); and Canada (133,316 MT).

Table 2: U.S. beef imports from principal supply countries, 2016 to 2020 (1,000 MT)

Country	2016	2017	2018	2019	2020	Average
	1,000 Metric Tons, Carcass Weight Equivalent					
Canada	325.37	336.01	358.91	384.31	374.15	355.75
Australia	347.74	315.02	305.08	324.85	300.50	318.64
Mexico	223.67	259.99	230.36	262.90	295.25	254.44
New Zealand	277.67	252.48	259.54	181.77	233.73	241.04
Brazil	69.22	62.39	63.92	74.01	100.20	73.95
Nicaragua	50.43	60.44	71.07	82.83	85.83	70.12
Uruguay	54.72	54.61	51.91	53.89	66.73	56.37
Other Countries	16.42	15.81	18.20	21.57	58.39	26.07
Total	1,365.24	1,356.75	1,358.99	1,386.13	1,514.78	1,396.38

Source: USDA ERS carcass weight equivalent calculations using data from U.S. Department of Commerce, Bureau of the Census.

Note: Quantities include some processed beef and veal.

Paraguay's beef production and trade

Historically, beef cattle production has been one of the major agricultural activities in Paraguay with beef and soybeans being the leading exports. Paraguay recently surpassed Argentina for eighth place among the world's largest beef exporters. The Paraguayan beef industry is focused on exports with about 40 percent of the production consumed domestically. Paraguay ships roughly 90 percent of its beef to just five markets: Chile, Russia, Israel, Taiwan and Brazil. Today, cattle are being displaced from traditional production areas in Paraguay because of a steady increase in soybean acreage. Since the 1990s, there has also been increased grain supplementation of beef cattle feeding regimes in Paraguay.

For the period 2016 to 2020, Paraguay's average annual production was 582,000 MT, with domestic consumption averaging 224,000 MT, or about 40 percent of production (Table 3). Exports averaged 372,000 MT per year. Paraguay's average exports of 372,000 MT for the 2016 to 2020 period is equivalent to approximately 26 percent of U.S. fresh beef imports for the same period.

The quantity of fresh beef expected to be imported into the United States from Paraguay, ranging from 3,250 to 6,500 MT, is equivalent to about 0.05 percent of U.S. average annual fresh

beef production, about 0.05 percent of U.S. average annual imports of fresh beef, and about 0.50 percent of average annual exports of fresh beef, 2016 to 2020.

Table 3: Paraguay’s beef production, exports, and imports, 2016 to 2020

Year	Production	Consumption	Imports	Exports
1,000 Metric Tons				
2013	510	186	2	326
2014	570	183	2	389
2015	590	210	1	381
2016	610	222	2	390
2017	610	223	1	380
Average	578	231	2	373

Source: Compiled from various GAIN Reports of the USDA Foreign Agricultural Service using carcass weight equivalent data.

Expected Benefits and Costs of the Rule

For this analysis, we use a non-spatial, net trade, partial equilibrium approach to welfare analysis to compute expected impacts of the rule on U.S. producers and consumers of fresh beef. In this section, we describe assumptions and parameters of the welfare analysis, including the baseline price and quantities, projected imports from Paraguay, and domestic price elasticities of demand and supply. We then discuss the modeling results. The model evaluates how domestic market prices and quantities may adjust to the policy change, and how producers and consumers may potentially be impacted.

We assume that demand and supply functions are approximately linear near the initial equilibrium point. For small parallel shifts in supply and demand, this assumption results in reasonably accurate measures of consumer and producer surplus changes. Beef imports from Paraguay will affect prices and quantities of fresh beef on the U.S. market, and therefore result in welfare impacts as reflected in changes in consumer and producer surplus. Consumer surplus is the difference between what the consumer pays for a unit of a good or service and the maximum

price that the consumer would be willing to pay for that unit. Producer surplus is the difference between the price a producer is paid for supplying a unit of a good or service and the minimum price that the producer would be willing to accept to supply that unit.

Our analysis is non-spatial in that the price and quantity effects obtained from the model are assumed to be average effects across geographically separate markets. Partial equilibrium means that the model results are based on maintaining a commodity-price equilibrium in a limited portion of the overall economy. All other economic sectors not explicitly included in the model are assumed to have a negligible influence on the model results. A partial equilibrium analysis is appropriate because the rule is specific to imports of fresh beef from Paraguay and is therefore expected to have only limited effects on other sectors of the economy.

Baseline data for fresh beef are shown in Table 4. Baseline quantities are based on 5-year averages, 2016 through 2020. Domestic supply is equated to fresh beef production minus exports, where fresh beef exports are set equal to zero. In a net trade model, such as the one applied in this analysis, a country is identified as either a net exporter or a net importer of a particular commodity. In this instance, U.S. fresh beef exports are not included as part of domestic supply in the baseline in order to quantify the effects of permitting fresh beef imports from Paraguay. Domestic demand for fresh beef is equated to fresh production less exports plus imports. The baseline price is the 5-year average U.S. custom import value for fresh beef, 2016 through 2020.³

Table 4: U.S. fresh beef baseline data: production, imports, exports, domestic consumption, and price in 2016 dollars, 2016 to 2020

Year	Production	Imports	Exports	Domestic Supply	Price Per MT
Metric Tons					
2016	11,468,481	1,365,986	1,159,637	11,674,830	6,988
2017	11,904,762	1,357,370	1,296,599	11,965,533	7,092
2018	12,216,780	1,359,637	1,433,107	12,143,311	7,248

³ The custom import value is defined as the price actually paid or payable for merchandise when sold for exportation, excluding import duties, freight, insurance, and other charges incurred in bringing the merchandise to the importing country.

2019	12,346,485	1,386,848	1,372,336	12,360,998	7,533
2020	12,355,556	1,515,646	1,338,322	12,532,880	8,063
5 year average	12,058,413	1,397,098	1,320,000	12,135,510	7,385

Source: USDA, World Agricultural Outlook Board, “World Agricultural Supply and Demand Estimates” and supporting materials; U.S. Department of Commerce, Bureau of Economic Analysis (population); and USDA, Economic Research Service.

For this analysis, we use price elasticities of demand and supply for fresh beef of -1.52 and 0.34, respectively.⁴ In the short run, beef producers’ responsiveness is inelastic due to limitations in adjusting supply to market changes. In the long run, producers are better able to respond to changes in price associated with increased market supply. Likewise, a more price-elastic long-run demand would be indicative of increased price responsiveness of consumers over time.

As a measure of possible impacts of fresh beef imports from Paraguay, we consider import volumes of 3,250 to 6,500 MT (5 to 10 percent of the other countries tariff rate quota of 65,005⁵). For each of the three annual import levels, we modeled changes in U.S. consumption, production, price, consumer welfare, producer welfare, and net social welfare gain (Table 5). In each case, consumer welfare gains outweigh producer welfare losses with positive net welfare impacts. Producer welfare losses under the three import levels range between \$12 and \$23 million. Consumer welfare gains range between \$13 and \$26 million with net welfare gains of between \$1.3 and \$3.0 million. Beef imports from Paraguay may displace imports from other countries.

⁴ 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.

⁵ Harmonized Tariff Schedule of the United States (2018) Revision 4, Chapter 2, Meat and Edible Meat Offal. The tariff rate quota provides preferential-duty access for certain named countries and a category of countries grouped as Other Countries or Areas. The combined annual quantity of beef allowed to be imported from Other Countries or Areas is limited to 65,005 MT.

Table 5. Modeled impacts for U.S. fresh beef production, consumption, price, and consumer and producer welfare, assuming fresh beef imports from Paraguay of 3,250 MT, 4,875 MT, and 6,500 MT

Assumed annual fresh beef imports from Paraguay	3,250	4,875	6,500
Change in U.S. consumption, MT	2,715	4,072	5,430
Change in U.S. production, MT	-535	-803	-1,070
Change in domestic price of fresh beef, dollars per MT	(\$1.09)	(\$1.63)	(\$2.17)
% Change in domestic price	-0.0147	-0.0221	-0.0294
Change in consumer welfare	\$13,179,777	\$19,770,771	\$26,362,502
Change in producer welfare	(\$11,660,864)	(\$17,491,078)	(\$23,321,146)
Annual net benefit	\$1,518,913	\$2,279,694	\$3,041,356

Alternatives to the Rule

We considered alternatives to the chosen course of action, including maintaining the current prohibition on imports of fresh beef from Paraguay and using the WOAHP recommendations to determine import requirements. Continuing to prohibit fresh beef imports from Paraguay is not defensible, given that a complete restriction on imports is unnecessary for safeguarding the U.S. cattle industry provided certain conditions are met. We therefore reject the status quo alternative.

A second alternative considered by APHIS would be to allow fresh beef to enter from Paraguay under trade recommendations established by the WOAHP. The WOAHP recommendations, however, do not meet the acceptable level of protection of the United States. FMD is a highly contagious disease caused by a resilient virus readily transmitted to all cloven-hoofed animals. There are few effective mitigation measures to guard against the risk of exposure of susceptible U.S. livestock if FMD-infected animals or products contaminated with the FMD virus were imported into the United States. APHIS has determined therefore that a

cautious approach to allowing fresh beef imports from regions that vaccinate for FMD is warranted.

As noted earlier, the position of the United States is that a country that vaccinates for FMD is not 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 individual animals in the herd may have a limited response, resulting in partial or no immunity. Therefore, so-called herd immunity may not always reflect individual animal immunity, and the disease may still be present in certain animals in a vaccinated population. As a result, importation of beef from areas in which cattle are vaccinated for FMD could result in importation of beef derived from infected animals.

Under the World Trade Organization Sanitary and Phytosanitary Agreement, Member Countries are encouraged to base their import requirements on international recommendations but maintain the right to adopt additional measures provided that they are based on science, are transparent in the way they are developed and implemented, and do not arbitrarily or unjustifiably discriminate among members. APHIS does not recognize a country that vaccinates for FMD as free of the disease because vaccination may mask clinical signs. The virus can remain present but undetected in vaccinated populations. APHIS regulations allow for the importation of meat and meat products from regions that vaccinate for FMD provided that these products are processed in such a way as to ensure the inactivation of the FMD virus.

If APHIS were to follow the WOAHA recommendations, we expect that fresh beef imports from Paraguay would tend toward the upper end of the 3,250 to 6,500 MT range; more cattle and larger quantities of beef would likely qualify for export to the United States because the import sanitary requirements would be less stringent. Fresh beef imports from Paraguay exceeding 6,500 MT would enter under a higher tariff rate. Under the modeled 6,500 MT scenario,

wholesale beef price would decrease by 0.03 percent. U.S. beef production would decline by approximately 1,000 MT or less than a percent of total U.S. beef production.

We reject this alternative to the rule for reasons other than disproportionate economic impact and because it does not meet APHIS' determination of necessary sanitary requirements for the importation of fresh beef from Paraguay. The preferred alternative has been analyzed using the limited information available. We cannot certify that this rule would have no disproportionate impact on small entities, but at this time have found no evidence that it would have such impacts.

Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to evaluate the potential effects of their proposed and final rules on small businesses, small organizations and small governmental jurisdictions. This initial regulatory flexibility analysis describes expected impacts of this proposed rule on small entities, as required by section 603 of the Act.

Reasons action is being considered

In response to a request from the Government of Paraguay that fresh (chilled or frozen) beef be allowed to be imported into the United States from Paraguay, APHIS conducted a risk analysis to enable APHIS to develop appropriate regulatory conditions with mitigations to address potential risks of FMD disease introduction following any initiation of trade in fresh beef from Paraguay. In the analysis APHIS considered the epidemiological characteristics of FMD that are relevant to the risk of importing fresh and frozen beef under certain conditions into the United States and described appropriate mitigations to reduce that risk. The mitigations to be applied include restrictions on the origin of animals, requirements for maturation and pH testing of carcasses, ante-mortem and post-mortem inspections, and verification by Paraguayan officials that the various mitigations were applied appropriately. APHIS concluded from the assessments that the surveillance, prevention, and control measures implemented by the Government of Paraguay are sufficient and that fresh beef imported from Paraguay under the additional

mitigation measures imposed by the proposed action will be safe. It is highly unlikely that such imports from Paraguay will introduce or disseminate FMD within the United States. As of 2020, there are more than 70 markets opened to Paraguayan beef. Cattlemen in Paraguay and the Government of Paraguay aim at opening in the future important markets such as China, NAFTA countries, and South Korea⁶.

Objectives of and legal basis for the rule

With a few exceptions, APHIS regulations in 9 CFR part 94 prohibit the importation of fresh (chilled or frozen) meat of ruminants or swine that originates in or transits a region where FMD is considered to exist. APHIS does not consider Paraguay free of FMD because Paraguay vaccinates against FMD. The proposed rule would allow the importation of fresh (chilled or frozen) beef from Paraguay under certain conditions designed to ensure beef exported to the United States will not harbor FMD virus. In accordance with the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture has the authority to promulgate regulations and take measures to prevent the introduction of contagious animal diseases into the United States by means of import restrictions.

Potentially affected small entities

Entities that could be primarily affected by the proposed rule are beef and cattle producers, as well as feedlots and slaughter facilities. Of the 882,692 farms⁷ in the United States with cattle and calves, 711,827 sold cattle and calves, 729,0466 were classified as beef cow farms, and 54,599 had milk cows.⁸ Based on data from the 2017 Census of Agriculture and

⁶Paraguay Beef & Cattle Outlook 2020: <https://beef2live.com/story-paraguay-beef-cattle-annual-0-206336>.

⁷ Represents all farms that held cattle inventory whether or not they sold cattle.

⁸ U.S. 2017 Agriculture Census, tables 12, 13, 14, 16,

https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_US/st99_1_0011_0012.pdf.

https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_US/st99_1_0013_0014.pdf.

https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_US/st99_1_0015_0016.pdf.

Small Business Administration (SBA) standards⁹, we expect a majority of these entities to be small. Entities in the categories beef cattle ranching and farming (NAICS 112111) and dairy cattle and milk production (NAICS 112120) are considered small if their total annual sales do not exceed \$1 million. The 2017 Census of Agriculture indicates that 99 percent of beef cattle operations are classified as small; of the 582,380 (farms with sales) farms classified under the beef cattle ranching and farming category, 99 percent had annual sales of less than \$1 million. Of the 47,237 dairy operations, 95 percent are classified as small. Entities in the category cattle feedlots (NAICS 112112) are considered small if they have total annual sales of not more than \$8 million. Sales were not available for farms operating as feedlots. Entities classified as animal (except poultry) slaughtering (NAICS 311611) with not more than 1,000 employees are considered small by SBA standards. The 2012 Economic Census reports 1,494 establishments in this category. Of this number, 1,357 establishments (96 percent) had fewer than 1,000 employees.¹⁰ Thus, the majority of slaughter establishments are considered small by SBA standards.

Projected reporting, recordkeeping, and other compliance requirements

Reporting and recordkeeping requirements associated with the proposed rule are discussed in the proposed rule under the heading "Paperwork Reduction Act."

Duplication, overlap, or conflict with existing rules and regulations

APHIS has not identified any duplication, overlap, or conflict of the proposed rule with other Federal rules.

Alternatives to minimize significant economic impacts of the rule

⁹ Small Business Administration size standards: <https://www.sba.gov/document/support-table-size-standards>.

¹⁰ U.S. Bureau of Census, 2018 County Business Pattern Survey: <https://data.census.gov/cedsci/table?n=311611&tid=CBP2018.CB1800CBP>.

For the purposes of this Initial Regulatory Flexibility Analysis, we have used the best data available to examine feasible ways to achieve the desired policy goals. We cannot certify that this rule would have no disproportionate impact on small entities, but at this time have found no evidence that it would have such impacts.

We recognize we may not have all relevant information concerning economic impacts at this time. Therefore, we invite public comment on any additional relevant information. We also invite public comments on alternatives that may achieve the objective of this proposed rule.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this rule will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

In 2020, APHIS informed Tribal leaders of the proposed action and solicited comments and questions. APHIS did not receive any comments or questions from Tribal leaders in response. APHIS worked with the APHIS Office of the National Tribal Liaison to conduct the outreach in 2020 and also hosted a Tribal listening session on October 17, 2022, about the proposed rule. If a tribe requests consultation in the future, APHIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided.

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

The environmental assessment may be viewed on the Regulations.gov website or in our reading room. (A link to Regulations.gov and information on the location and hours of the reading room are provided under the heading ADDRESSES at the beginning of this proposed rule.) In addition, copies may be obtained by calling or writing to the individual listed under FOR FURTHER INFORMATION CONTACT.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), reporting and recordkeeping requirements included in this proposed rule have been submitted for approval to OMB. Written comments and recommendations for the proposed information collection should be sent within 60 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 60-day Review—Open for Public Comments" or by using the search function. Please send a copy of your comments to: (1) Docket No. APHIS-2018-0007, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OCIO, USDA, Room 404-W, 14th Street and Independence Avenue SW, Washington, DC 20250.

APHIS is proposing to amend the regulations in § 94.29 to provide for the importation of fresh (chilled or frozen) beef from Paraguay. Under this proposed rule, fresh beef from Paraguay

would be subject to the same import conditions applicable to fresh beef and ovine meat from Uruguay (other than bone-in ovine meat imported under § 94.29(g)(1) through (3)) and fresh beef from the exporting regions of Argentina and Brazil. The importation of fresh beef from Paraguay will require information collection activities such as the completion and signature of Foreign Meat Inspection Certificates by an authorized veterinary official of the Government of Paraguay and onsite evaluations and inspections of operations, records, and processing facilities to ensure they are following the procedures necessary to lead to the results listed in the Foreign Meat Inspection Certificate. The certificate, evaluation, and inspection ensure that exported fresh beef from Paraguay poses negligible risk of introducing disease into the United States. If this action is finalized and OMB approves of this information collection package, APHIS plans to merge this information collection into OMB control number 0579-0372, Importation of Beef and Ovine Meat from Uruguay and Beef from Argentina and Brazil.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public burden for this collection of information is estimated to average 1.3 hours per response.

Respondents: Authorized veterinary officials employed by the Government of Paraguay and beef producers in Paraguay.

Estimated annual number of respondents: 2.

Estimated annual number of responses per respondent: 1.

Estimated annual number of responses: 3.

Estimated total annual burden on respondents: 4 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the estimate of burden.)

A copy of the information collection may be viewed on the Regulations.gov website or in our reading room. (A link to Regulations.gov and information on the location and hours of the reading room are provided under the heading ADDRESSES at the beginning of this proposed rule.) Copies can also be obtained from Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851-2483. APHIS will respond to any information collection review-related comments in the final rule. All comments will also become a matter of public record.

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 trade partners who have fully automated systems, APHIS will accept computer extracts of electronic health certification data. These certificates are included in the government-wide use of the International Trade Data System via the Automated Commercial Environment to improve business operations and further Agency missions. Respondents are free to maintain required records as best suited for their organization. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851-2483.

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 propose to amend 9 CFR part 94 as follows:

PART 94--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. 1633, 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.

§ 94.29 [Amended]

2. Section 94.29 is amended as follows:

a. In the introductory text, by adding the words “fresh (chilled or frozen) beef from Paraguay;” after the word “Tocantins;”;

b. In paragraph (a)(1), by adding the words “or in Paraguay;” after the word “Brazil”; and

c. In paragraph (b), by adding the words “in Paraguay (for beef from Paraguay),” after the words “(for beef from Brazil).”

Done in Washington, DC, this 17th day of March 2023.

Jennifer Moffitt,

Under Secretary for Marketing and Regulatory Programs.

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