UNITED STATES — MEASURES AFFECTING THE IMPORTATION OF ANIMALS, MEAT AND OTHER ANIMAL PRODUCTS FROM ARGENTINA

(WT/DS447)

FIRST WRITTEN SUBMISSION OF THE UNITED STATES OF AMERICA

November 5, 2013

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US – 3	United States General Accounting Office (GAO), *Foot and Mouth Disease* (July, 2002)	GAO, Foot and Mouth Disease
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US – 6	Committee on Foreign and Emerging Diseases of the United States Animal Health Association, Foreign Animal Diseases (Seventh Edition) (2008)	Committee on Foreign and Emerging Diseases of the United States Animal Health Association, Foreign Animal Diseases
US – 7	Nick J. Knowles et al., *Pandemic Strain of Foot-and-Mouth Disease Virus Serotype O*, Emerging Infectious Diseases 11:12, 1887-1893 (December, 2005)	Knowles, et al., Pandemic Strain of Foot-and-Mouth Disease Virus Serotype O
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US – 9	R.P. Kitching, *Clinical Variation in Foot and Mouth Disease: Cattle*, Rev. sci. tech.	Kitching, Clinical Variation in

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USA – 120	United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (USDA, APHIS, VS), National Center for Import and Export, *Foot and Mouth Disease in Uruguay* (December 13, 2000)	USDA, APHIS, VS, Foot and Mouth Disease in Uruguay
USA – 121	United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (USDA, APHIS, VS), National Center for Import and Export, Regionalization Evaluation Services, *Site Visit Report: Uruguay* –	USDA, APHIS, VS, Site Visit Report: Uruguay – Foot and Mouth Disease (September, 2002)

	Foot and Mouth Disease (September, 2002)	
USA – 122	World Fact Book, "Argentina"	World Fact Book, "Argentina"
USA – 123	World Organization for Animal Health (OIE), *Foot and Mouth Disease, Paraguay* (2011)	OIE, Foot and Mouth Disease, Paraguay (2011)
USA – 124	World Organization for Animal Health (OIE), *Foot and Mouth Disease, Paraguay* (2011-2012)	OIE, Foot and Mouth Disease, Paraguay (2011-2012)
USA – 125	World Organization for Animal Health (OIE), *Foot and Mouth Disease, Bolivia* (2007)	OIE, Foot and Mouth Disease, Bolivia (2007)
USA – 126	Importation of Beef from Uruguay, 68 Fed. Reg. 6673 (February 10, 2003)	68 Fed. Reg. 6673
USA – 127	United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA, APHIS), *Evaluation of the Foot and Mouth Disease Status of Japan* (April 1, 2011)	USDA, APHIS Evaluation of the Foot and Mouth Disease Status of Japan
USA – 128	World Trade Organization (WTO), Committee on Sanitary and Phytosanitary Measures, *Guidelines to Further the Practical Implementation of Article 6 of the Agreement on the Application of Sanitary and Phytosanitary Measures*, G/SPS/48 (May 16, 2008)	Guidelines to Further the Practical Implementation of Article 6 of the Agreement on the Application of Sanitary and Phytosanitary Measures
USA – 129	Oxford English Dictionary (1993), "Criteria"	Oxford English Dictionary (1993), "Criteria"
USA – 130	Oxford English Dictionary (1993), "Guideline"	Oxford English Dictionary (1993), "Guideline"
USA – 131	United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA, APHIS), *Countries/Regions Free of Foot and Mouth Disease (FMD) and Rinderpest* (January 24, 2013)	USDA, APHIS, Countries/Regions Free of Foot and Mouth Disease (FMD) and Rinderpest

I. INTRODUCTION

1. Argentina's first written submission starts with the assertion that "This is a simple dispute."[1] But after reviewing Argentina's submission, the natural question is whether Argentina's assertion was made with a sense of irony. Argentina presents approximately 40 separate claims. Its written submission is well over 160 pages, accompanied by over 90 exhibits. And the dispute addresses issues involving the appropriate reaction to Argentina's failure to control outbreaks of the world's most infectious and economically devastating livestock disease – namely, foot and mouth disease (FMD). One wonders what, exactly, is "simple" in this dispute.

2. The United States suggests instead that an appropriate starting point for evaluating this dispute is to consider issues of time and timeliness. Indeed, such issues underlay the scientific, technical, and legal questions raised by the dispute.

3. First, Argentina does not dispute, and cannot dispute, that at the time the United States revoked Argentina's FMD status in 2001 in response to an Argentine FMD outbreak, the U.S. action was completely justified and fully consistent with U.S. obligations under the WTO Agreement. Indeed, Argentina itself stopped its exporters from shipping affected products. Instead, Argentina's complaint is based on the contention that the United States has not acted promptly enough to review and modify the U.S. 2001 action in light of what Argentina asserts are changed circumstances involving Argentina's FMD status and Argentina's control measures. Thus, the core legal and factual issues in this dispute revolve around the timeliness of a regulatory response to alleged changes in conditions in an exporting country.

4. Such issues present questions of first impression under the WTO dispute settlement system, and are in no way "simple." Rather, addressing these questions will involve a careful review of relevant provisions of the SPS Agreement, as well as the legal arguments and the factual records presented by both parties. And, as the United States will explain in detail below, a careful review will lead to the conclusion that U.S. regulators have acted prudently and have not responded with undue delay or in an unreasonable amount of time.

5. Second, the United States has not had an FMD outbreak in approximately 80 years. The long-term U.S. success in the prevention of FMD outbreaks is the result of the very types of prudent regulatory action that Argentina now challenges. In contrast, Argentina has had a long history of FMD outbreaks, including three separate FMD outbreaks since 2000. In light of these radically different experiences in controlling FMD over time, Argentina has no basis for arguing that U.S. regulators should cut corners and rush to conclusions about Argentina's current FMD status.

6. Third, the record will show that time is of the essence in preventing and controlling FMD outbreaks. Due to the fact that the United States has not had an FMD outbreak in 80 years, U.S. livestock are not vaccinated for FMD. As a result, even a single shipment of an FMD-infected product could cause massive economic damage. In these circumstances, it is not sufficient to

[1] Argentina's First Written Submission, para. 1.

learn after the fact that an exporting country has had an FMD outbreak. Rather, a prudent regulator has to consider whether the exporting country has adequate controls in place so as to prevent outbreaks, and -- should an outbreak nonetheless occur -- to report any outbreak immediately. Argentina's pending applications present particular challenges in these areas: Argentina has had three relatively recent FMD outbreaks, and Argentina has a history of intentional concealment and delayed reporting of outbreaks. Thus, for this reason also, the question of whether U.S. regulators are taking too much time to examine such issues is anything but simple.

7. Fourth, while Argentina argues that its FMD status is radically different than when it had an outbreak in 2000-2002, or when it had an outbreak in 2003, or when it had an outbreak in 2006, Argentina presents the U.S. regulatory situation as static. The record will show, however, that Argentina's depiction of the U.S. regulatory process is misleading. In fact, the United States is actively considering Argentina's two outstanding applications for changes to Argentina's FMD status. For example, just this month – in November 2013 – the United States sent a team of veterinary specialists to Argentina to review Argentina's FMD control measures. Due to this ongoing activity, it is quite possible that by the time this dispute is concluded, the United States will have made, or will be close to making, decisions on Argentina's outstanding applications. The fact that the U.S. regulatory process is proceeding belies any claim by Argentina that the United States has some sort of definitive, permanent ban on Argentine products, or that the United States is acting in a manner that results in undue or unreasonable delays.

8. Finally, given that U.S. regulatory procedures are continuing and may be completed in about the same amount of time as involved in the completion of a complex SPS dispute, the question arises as to why Argentina has initiated this dispute at this time. Of course, only Argentina knows the answer to this question. The United States would note, however, the following publicly available information: On May 25, 2012, the European Union (EU) requested consultations with Argentina regarding Argentina's wide-ranging non-automatic import licensing measures. Within several weeks – on August 17, 2012 – Argentina requested consultations with the EU regarding the importation of biodiesel products. On August 21, the United States joined the EU dispute by presenting its own request for consultations addressed to Argentina's non-automatic import licensing measures. Within 9 days – on August 30, 2012 – Argentina initiated this dispute by requesting consultations on the U.S. 2001 regulatory action. This sequence of events may shed light on why Argentina has decided to launch a dispute at this time concerning an ongoing regulatory process.

* * *

9. At core, Argentina's legal complaints are about the length of time taken by the United States to decide whether or not Argentina has sufficiently established any credibility over its claims to have controlled FMD. The United States will argue that this is the question that this Panel should tackle first under Annex C(1) and Article 5.7 of the SPS Agreement. In examining this issue, it will be clear that the United States took the appropriate science-based action in removing Argentina's authorization to import beef during Argentina's widespread FMD outbreak crisis between 2000-2002. It will also be clear that the deliberate re-evaluation of this

authorization is in accord with accepted international standards and science, particularly given Argentina's inability to be transparent and effective in dealing with FMD.

II. PROCEDURAL HISTORY

10. On August 30, 2012, Argentina requested consultations with the United States pursuant to Articles 1 and 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU"), Article XXIII of the General Agreement on Tariffs and Trade, 1994 ("GATT 1994"), and Article 11 of the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"), concerning United States measures affecting the importation of animals, meat and other animal products from Argentina.

11. The United States and Argentina held consultations on October 18 and 19, 2012, but were unable to resolve the dispute.

12. Argentina requested the establishment of a panel on December 6, 2012.[2] The WTO Dispute Settlement Body ("DSB") established the panel with standard terms of reference on January 28, 2013.[3] On July 29, 2013, Argentina requested that the Director General compose the panel pursuant to Article 8.7 of the DSU. The Director General composed the Panel on August 8, 2013.[4]

III. FACTS

13. The discussion of facts in this dispute is divided into four sections.

14. Section A discusses what is at stake in this dispute: the exposure of millions of cloven-hoofed animals to one of the most contagious and debilitating livestock diseases in the world: : namely, foot and mouth disease or 'FMD.' Because of FMD's survivability, transmissibility, and ability to incapacitate, it is internationally recognized as a critical threat to the economic livelihood of many countries, including the United States.

15. Section B describes how FMD has been a long-time scourge in Argentina, and has repeatedly laid waste to its animal herd and the agricultural community that relies on it. Argentina has struggled to control FMD. In response to outbreaks between 2000 and 2002 that ultimately exposed more than 2 million animals to FMD, Argentina's response was to conceal the outbreaks from the world and delay taking effective action to stop the disease. At the same time, Argentina continued to sell and export potentially affected meat in international markets. The disease continued to affect Argentina, evidenced by the fact that the country reported additional FMD outbreaks through 2006.

[2] WT/DS447/2 (Dec. 7, 2012).

[3] WT/DS447/3 (Aug. 9, 2013).

[4] WT/DS447/3 (Aug. 9, 2013).

16. Section C discusses, in stark contrast, the absence of FMD in the United States for over eighty years. The United States has established a thorough system of FMD surveillance, detection, and control inside and outside its borders. National and local authorities devote substantial resources to preparing for a potential FMD outbreak in the United States. As part of its FMD control strategy, the United States also provides technical assistance and actively cooperates with other countries to control and eradicate FMD worldwide.

17. Section D discusses the science-based regulatory process through which the United States authorizes importation of animal and animal products that are susceptible to FMD. It then details the history of Argentina's request for import authorization, which occurred in between periods of FMD outbreaks -- just after the 2000 – 2002 FMD outbreaks. This section also highlights the complications from a regulatory perspective that resulted from Argentina's concealment of its FMD outbreaks.

A. Foot and Mouth Disease is a Highly Contagious and Economically Devastating Animal Disease

18. Overwhelming scientific evidence, including over a hundred years of real-world experience, shows that foot and mouth disease is a highly contagious and economically devastating animal disease. As the World Organization for Animal Health (OIE) has stated, "foot and mouth disease (FMD) is the most contagious disease of mammals and has a great potential for causing severe economic loss[.]"[5]

19. FMD affects some of the world's most economically-important livestock, namely cloven-hoofed animals such as cattle, pigs, sheep, goats and water buffalo.[6] For mature animals, FMD is painful and causes long-term harm; for young animals, it can be fatal.[7] Once infected, the animal runs a fever, loses appetite, and miscarries if pregnant.[8] Even if an infected animal eventually recovers, it will remain emaciated for many months and is unlikely to return to its full economic value. Once an outbreak has occurred, control measures often require the mass culling of entire herds. And, until the problem has been resolved, trade in products from the infected animals may be restricted or prohibited altogether. For these reasons, FMD cripples communities that depend on cattle for meat and milk production. Experts view FMD as "the most economically devastating livestock disease in the world."[9]

20. FMD is widespread throughout the world. (The map immediately below depicts the types of FMD virus present worldwide.) At the end of 2011, the OIE identified more than 100

[5] OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals Chapter 2.1.5 at 145 (USA – 1).

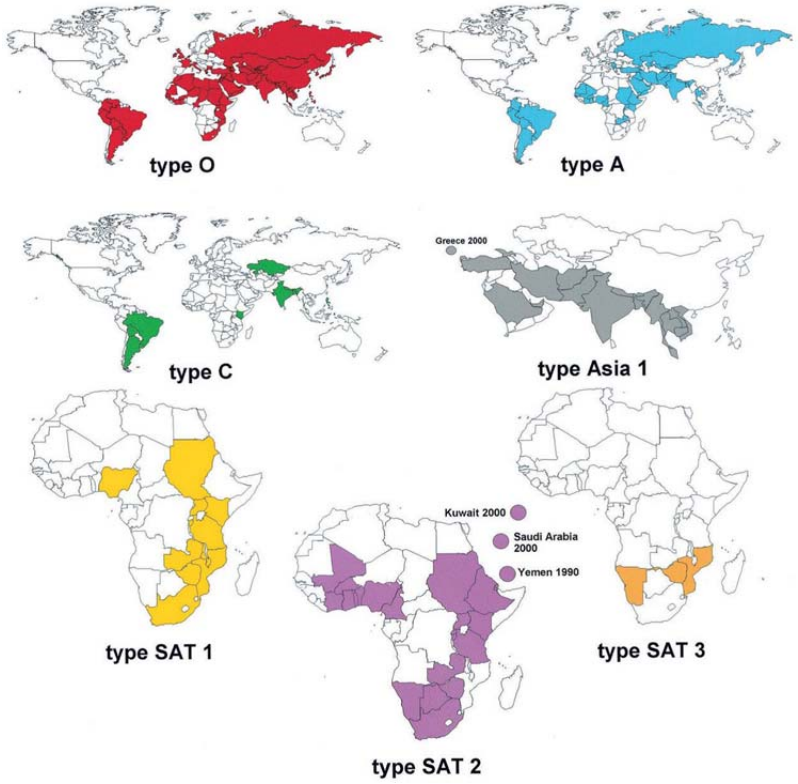
[6] OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals Chapter 2.1.5 at 146 (USA – 1).

[7] OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals Chapter 2.1.5 at 145 (USA – 1); Rushton, et al., OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 1 at 2 (USA – 2).

[8] GAO, Foot and Mouth Disease at 12 (USA – 3).

[9] Fukase, OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 4 at 2 (USA – 4).

countries as having the disease (*i.e.*, the OIE did not consider these countries FMD-free).[10] "Foot and mouth disease . . . is endemic in almost all developing countries."[11] The prevention of outbreaks requires constant vigilance and stringent control measures. Because FMD is widespread, the chance of infection is always present. In fact, in this era of global trade and rapid transport, FMD-free countries face a growing risk of contracting the disease.[12] As the OIE puts it, "Countries that are free of FMD today remain under constant threat of an incursion."[13]



Types of FMD present throughout the world (2004)

Marvin J. Grubman, et al., "Foot and Mouth Disease," Clin. Microbiol. Rev. 2004, 17(2):465 at 466

21. A major contributor to the threat posed by FMD is that the virus is extraordinarily easy to transmit. An infected animal can spread FMD to other animals within three to five days of infection.[14] Transmission can occur through exposure to an infected animal's milk, semen,

[10] Global Foot and Mouth Disease Control Strategy, World Organization for Animal Health (OIE) (2012) at 4 (USA – 5).

[11] Rushton, et al., OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 1 at 2 (USA – 2).

[12] Global Foot and Mouth Disease Control Strategy, World Organization for Animal Health (OIE) (2012) at 4 (USA – 4).

[13] Global Foot and Mouth Disease Control Strategy, World Organization for Animal Health (OIE) (2012) at 5 (USA – 4).

[14] Rushton, et al., OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 1 at 2 (USA – 2).

blood, saliva, and feces.[15] Moreover, unlike some other harmful viruses, the FMD virus can also travel through the air, and thus even the breath of an infected animal can spread the infection.[16] Animals, people, and common everyday materials that are exposed to the virus can spread FMD by coming into contact with susceptible animals.[17]

22. Control measures are also very difficult to implement. With respect to physical decontamination, the virus can survive for long periods of time in a variety of environments.[18] And with respect to vaccinations, many different types and subtypes of the FMD virus exist and that complicates treatment.[19] Accordingly, immunity to, or vaccination for, one type of the FMD virus does not necessarily protect an animal from infection with another type.

23. Stopping FMD requires both vigilant and stringent controls by individual countries, as well as international cooperation. The OIE plays a leading role in international cooperation and information sharing, and as a source of technical expertise. The OIE however, has limited resources and cannot itself adopt or enforce control measures. Accordingly, the main responsibility for controlling FMD must fall upon each Member's animal health authorities.

1. Biology of Foot and Mouth Disease

i. Clinical Signs and Effects of Foot and Mouth Disease

24. As noted, FMD is a highly contagious viral infection that affects all cloven-hoofed domestic livestock and wild animals.[20] Susceptible animals include cattle, sheep, goats, pigs, and water buffaloes.[21] The incubation period for FMD is relatively short (two to fourteen days).[22]

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[15] Committee on Foreign and Emerging Diseases of the United States Animal Health Association, Foreign Animal Diseases at 264 (USA – 6).

[16] Committee on Foreign and Emerging Diseases of the United States Animal Health Association, Foreign Animal Diseasesat 264 (USA – 6).

[17] Materials that can spread FMD include "animal products, such as meat, milk, hides, skins, and manure; transport vehicles and equipment; clothes or shoes worn by people; and hay, feedstuffs, and veterinary biologics." *See* GAO, Foot and Mouth Disease at 12-13 (USA – 3); Committee on Foreign and Emerging Diseases of the United States Animal Health Association, Foreign Animal Diseases at 264 (USA – 6).

[18] 36 hours in the human nasal passages; 1 to 24 weeks in manure; 1 moth in fodder; 9 to 14 weeks on shoes; etc. *See* GAO, Foot and Mouth Disease at 13 (USA – 3).

[19] FMD has 7 types and over 60 subtypes. *See* Committee on Foreign and Emerging Diseases of the United States Animal Health Association, Foreign Animal Diseases at 261 (USA – 6).

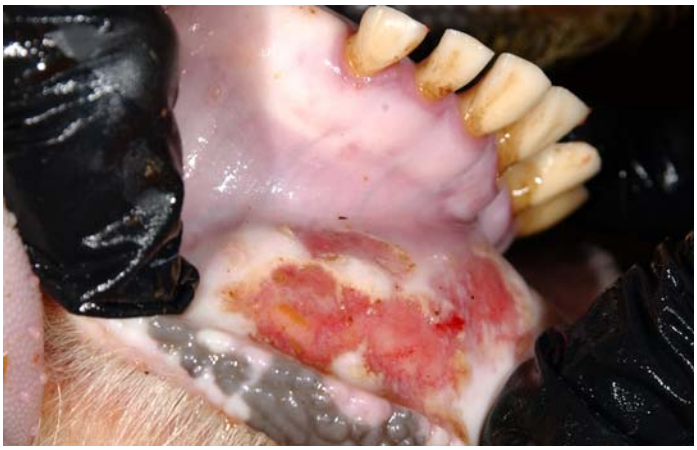
[20] Knowles, et al., Pandemic Strain of Foot-and-Mouth Disease Virus Serotype O 1887-1893 (USA – 7).

[21] OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals Chapter 2.1.5 at 145 (USA – 1).

[22] OIE, Foot and Mouth Disease (USA – 8).

25. Clinical signs of FMD vary among susceptible animals but are generally gruesome. (Some examples are shown below.) In cattle, initial clinical signs during acute infection include pyrexia, anorexia, shivering, profuse salivation, mucopurulent nasal discharge, and a reduction in milk production.[23] This is caused by the formation of vesicles on the tongue, buccal and nasal mucous membranes, interdigital spaces, on the coronary band, and on the mammary glands.[24] Smacking of the lips, grinding of the teeth, profuse drooling, lameness, and stamping or kicking of the feet are commonly associated with vesicle formation. After about 24 hours, the vesicles rupture, resulting in erosions of the affected membranes.[25] In sheep, vesicles are common on the dental pad and interdigital spaces, but lesions are generally less pronounced.[26] Pigs may develop vesicles on the snout and tongue.[27]

26. FMD has serious long-term effects on infected animals. Complications include tongue erosions, secondary infection of lesions, hoof deformation, mastitis and permanent reduction in milk production, myocarditis, abortion, permanent loss of weight, and loss of heat control.[28] By disabling, and not killing, adult animals, "the virus harnesses its hosts as long-suffering vectors of contagion."[29] Younger animals may simply die from infection.[30]



Ruptured vesicles on the lower lip of bovine. Note ulcerated areas.

[23] Kitching, Clinical Variation in Foot and Mouth Disease: Cattle 499-504 (USA – 9).

[24] OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals Chapter 2.1.5 at 146 (USA – 1).

[25] OIE, Foot and Mouth Disease (USA – 8).

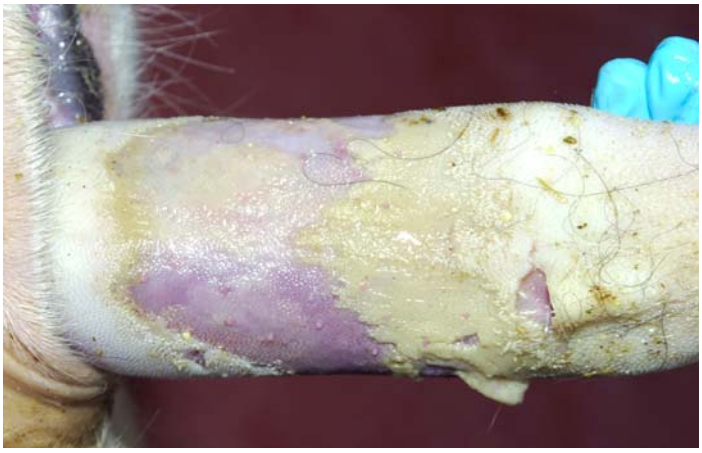
[26] Alexandersen, et al., The Pathogenesis and Diagnosis of Foot-and-Mouth Disease 13-17 (USA – 10).

[27] OIE, Foot and Mouth Disease (USA – 8).

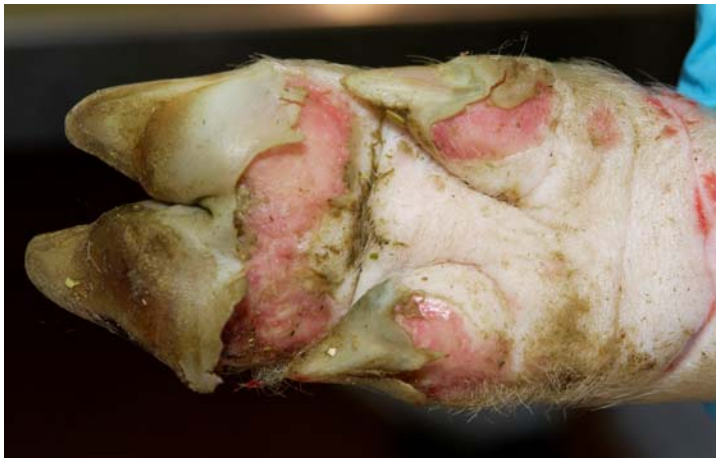
[28] OIE, Foot and Mouth Disease (USA – 8).

[29] Horwitz, Foot-and-Mouth Disease (FMD) as a Hazard for New England Dairies at 14 (USA – 11).

[30] Kitching, Clinical Variation in Foot and Mouth Disease: Cattle 499 (USA – 9).



Ruptured vesicles and ulcers on the tongue of bovine.



Ruptured vesicles on foot pad of swine

ii. Ease of Transmission of Foot and Mouth Disease

27. FMD is readily transmissible. It survives and can be spread directly or indirectly by living organisms and inanimate objects through air and liquid. The FMD virus' ease of transmission is a function of several key characteristics of the virus.

28. First, many domestic species of livestock are at risk of contracting the FMD virus. As discussed, nearly all cloven-hoofed animals are potential targets.[31] Humans are not significantly at-risk for FMD infection but can spread the disease.[32] It is estimated that FMD is present

[31] Committee on Foreign and Emerging Diseases of the United States Animal Health Association, Foreign Animal Diseases at 262 (USA – 6).

[32] GAO, Foot and Mouth Disease at 12-13 (USA – 3).; Horwitz, Foot-and-Mouth Disease (FMD) as a Hazard for New England Dairies at 13 (USA – 11).

among 77 percent of all livestock in the world.[33] In the United States, which is free of FMD, key agricultural stock, including 94 million cattle, 67 million swine, and 8 million sheep and goats remain at risk.[34]

29. Second, the FMD virus is hardy. Unlike many other pathogens, the virus that causes FMD can strike "anywhere, any time of year."[35] The virus also remains active in an unusually broad range of conditions. For example, the virus survives heat up to 50 degrees Celsius and is only effectively inactivated by heating up to 70 degrees Celsius for at least 30 minutes.[36] It thrives in moist and cool temperatures and can resist drying.[37] The FMD virus can be harbored in the respiratory tract of humans for over 1 day, meaning that persons can spread it by touch or even by simply breathing near a susceptible animal.[38]

30. Third, the FMD virus spreads very efficiently. A small concentration of the virus multiplies and spreads through direct or indirect exposure. As few as ten particles of the FMD virus may be sufficient to cause the disease. A single millimeter of raw cow's milk (less than a quarter teaspoon, before pasteurization or acidification) contains as many as five million infective doses. It can also be aerosolized and windborne as far as 60 km. (37 mi.) overland and 300 km. (186 miles) over water.[39]

31. Fourth, vaccination is not an ironclad method to prevent the disease. Immunity to one type of FMD virus does not necessarily protect an animal against other types.[40] The vaccination must protect against the specific type of FMD circulating.[41] Developing a vaccine can be time intensive, and enough supply of the vaccine must be manufactured. Even after an animal is administered the vaccine, immunity to FMD may not develop for several weeks. Additional booster shots will be required at four to six weeks after the initial administration and then again six months later. Even if vaccination programs are "successful," vaccinated as well as recovered

[33] Rushton, et al., OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 1 at 4-5 (USA – 2).

[34] Horwitz, Foot-and-Mouth Disease (FMD) as a Hazard for New England Dairies at 13 (USA – 11).

[35] Horwitz, Foot-and-Mouth Disease (FMD) as a Hazard for New England Dairies at 14 (USA – 11).

[36] OIE, Foot and Mouth Disease (USA – 8).

[37] OIE, Foot and Mouth Disease (USA – 8).

[38] Horwitz, Foot-and-Mouth Disease (FMD) as a Hazard for New England Dairies at 14 (USA – 11).

[39] Horwitz, Foot-and-Mouth Disease (FMD) as a Hazard for New England Dairies at 14 (USA – 11).

[40] Horwitz, Foot-and-Mouth Disease (FMD) as a Hazard for New England Dairies at 19-21 (USA – 11). In fact, the OIE notes "[b]ecause of the presence of multiple serotypes of the virus it is common practice to prepare vaccines from two or more different virus serotypes." Chapter 2.1.5, Foot and Mouth Disease, OIE Terrestrial Manual 2012, at 159 (USA – 1).

[41] OIE Global Foot and Mouth Disease Control Strategy Annex 6 at 3 (USA – 12).

animals can carry a strain of FMD virus not covered by the administered vaccine, potentially with no visible symptoms.[42] This may further devastate populations of susceptible animals.

2. Devastating Economic and Social Effects of Foot and Mouth Disease

32. Because FMD is so readily transmissible, it is considered to be one of the most important livestock diseases in terms of negative economic impact throughout the world.[43]

i. Economic Effects of Foot and Mouth Disease

33. Simply put, "Foot and Mouth Disease (FMD) is widely believed to be the most economically devastating livestock disease in the world."[44] Today, "the global impact of Foot and Mouth Disease…is colossal due to the huge numbers of animals affected."[45] It is estimated, for example, that the global annual economic impact of FMD in terms of production losses and vaccination alone exceed 5 billion USD.[46]

34. For countries that are FMD-free, the introduction of FMD is especially devastating. "It has been estimated that countries free from FMD that suffer an outbreak lose between 0.6% to 0.3% of their GDP."[47] FMD (1) destroys livestock because countries resort to culling or "stamping out" to control outbreaks, (2) reduces the productivity of remaining herd, (3) suppresses domestic and international demand for affected animal products, (4) generates costly emergency response operations, and (5) decreases affiliated activities such as tourism.[48]

35. The framework found in Supporting Document No. 1 of the OIE's Global Foot and Mouth Disease Control Strategy provides a structural breakdown of FMD's economic impacts.[49] Impacts are categorized into direct losses such as reduction in production and changes in herd structure, as well as indirect losses, such as FMD control and management costs and forgone revenue.[50]

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[42] Horwitz, Foot-and-Mouth Disease (FMD) as a Hazard for New England Dairies at 19-21 (USA – 11).

[43] Pendell, et al., The Economic Impacts of a Foot-and-Mouth Disease Outbreak: A Regional Analysis at 21 (USA – 13).

[44] Fukase, OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 4at 2 (USA – 4).

[45] Rushton, et al., OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 1 at 1 (USA – 2).

[46] Rushton, et al., OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 1 at 1 (USA – 2).

[47] Rushton, et al., OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 1 at 18 (emphasis added) (USA – 2).

[48] Horwitz, Foot-and-Mouth Disease (FMD) as a Hazard for New England Dairies at 23-24 (USA – 11).

[49] Rushton, et al., OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 1 at 3 (USA – 2).

[50] Rushton, et al., OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 1 at 1 (USA – 2).

36. Direct losses include reduced milk production (up to 80 percent yield reduction with chronic FMD), reduced livestock growth, and animal death.[51] FMD also causes fertility problems, including miscarriage and reduced probability of conception, increasing the cost of production.[52]

37. Indirect losses can be divided between control costs and forgone revenue. In the event of a FMD outbreak, control measures such as culling, movement restrictions, and vaccinations can be costly, with a wide range of ripple effects throughout the economy.[53] Foregone revenue is also a major impact shouldered by individuals in livestock, agriculture, and related sectors. This impact flows from restrictions on domestic livestock trade, international trade restrictions and prohibitions, reduced investment in the livestock sector, and stagnation in the development of commercial farming.[54]

a. Case Studies

38. As noted, FMD is endemic in much of the world, and it is currently present in parts of South America, Europe, Asia, and Africa.[55] These FMD-infected areas represent "a giant reservoir of FMD."[56] Recent FMD outbreaks in FMD-free countries have illustrated the economic devastation that results from the introduction of the disease.

39. For example, in 1997, a FMD outbreak occurred in Taiwan, after it had been free of FMD for nearly 70 years. As a result, animals on more than 6,000 farms became infected. Control measures resulted in the slaughter of approximately 4 million pigs (40 percent of the population at risk). The direct economic costs of the control measures were estimated at $379 million U.S. Dollars (USD). Moreover, this was just a fraction of the total economic loss. Due to resulting restrictions on international trade, Taiwan is estimated to have incurred additional economic losses of 1.6 billion. Further, Taiwan "never managed to regain the export markets it lost due to

[51] Rushton, et al., OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 1 at 4-5 (USA – 2).

[52] Rushton, et al., OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 1 at 5 (USA – 2).

[53] Rushton, et al., OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 1 at 5-6 (USA – 2).

[54] Rushton, et al., OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 1 at 7 (USA – 2).

[55] Pendell, et al., The Economic Impacts of a Foot-and-Mouth Disease Outbreak: A Regional Analysis at 20 (USA – 13).

[56] Horwitz, Foot-and-Mouth Disease (FMD) as a Hazard for New England Dairies at 16 (USA – 11).

the [1997] FMD outbreak."[57] Other economic losses included the elimination of more than 65,000 jobs.[58]

40. An outbreak in the Republic of Korea also illustrates the severe economic consequences of an FMD outbreak. Korea experienced FMD outbreaks in 2000 and 2010. Control measures resulted in the destruction of 3.37 million pigs, cows, goats, and deer. Economic losses associated with the outbreaks were estimated to have been $2 billion USD.[59]

b. Potential Economic Effects of Foot and Mouth Disease in the United States

41. Due to constant vigilance and the types of control measures that Argentina challenges in this dispute, the United States has successfully avoided FMD outbreaks for the last 80 years. An FMD outbreak in the United States would cause widespread and lasting economic and social damage reaching into the billions of dollars.[60]

42. Economic costs for controlling the outbreak would be substantial. Estimates of the cost of disease control and eradication, the destruction and disposal of infected animals, vaccines, and possible compensation to producers for the costs of disease containment are approximately 24 billion USD.[61]

43. Because of the importance of the livestock and agriculture sectors in the United States, the loss of export revenue accompanying an FMD outbreak would cause significant economic loss for the United States. According to the United States Department of Agriculture (USDA), the United States exported more than 10 billion USD of beef and pork in 2011, representing 10 percent of the beef and 22 percent of the pork produced within the country.[62] Trade restrictions following a FMD outbreak could therefore result in losses as high as 10 billion USD a year.[63] Moreover, indirect economic losses resulting from the disruption of agricultural commodity markets could result in additional losses of $14 billion USD (9.5 percent) in U.S. farm income.[64]

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[57] Hayes, et al., Economy Wide Impacts of a Foreign Animal Disease in the United States at 5-6 (emphasis added) (USA – 14).

[58] Carpenter, et al., Epidemic and Economic Impacts of Delayed Detection of Foot-and-Mouth Disease: A Case Study of Simulated Outbreak in California at 26 (USA – 15)

[59] Rushton, et al., OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 1 at 6 (USA – 2).

[60] Paarlberg, et al., Economic Impacts of Foreign Animal Disease (USA – 16).

[61] GAO, Foot and Mouth Disease at 19-20 (USA – 3).

[62] Hayes, et al., Economy Wide Impacts of a Foreign Animal Disease in the United States at 5 (USA-14).

[63] GAO, Foot and Mouth Disease at 19-20 (USA – 3).

[64] Losses in gross revenue for each sector were estimated to be the following: live swine: 34 percent; pork: 24 percent; live cattle: 17 percent; beef: 20 percent; milk: 16 percent; live lambs and sheep: 14 percent; lamb and sheep meat: 10 percent; forage: 15 percent ; and soybean meal: 7 percent, *see* Paarlberg, et al., Potential Revenue Impact of an Outbreak of Foot-and-Mouth Disease in the United States at 988 (USA-17).

44. Other costs include those burdening agricultural industries and other sectors of the economy, such as tourism. An FMD outbreak would also result in unemployment, loss of income, and decreased economic activity.[65] By some estimates, more than 33,000 full-time jobs, accounting for $1 billion USD in annual wages, could be lost if the United States' three largest markets for ruminant products alone (Japan, the Republic of Korea, and Mexico) imposed trade restrictions following a FMD outbreak.[66]

45. Several studies have estimated the economic impacts of FMD introduction in the United States at the local level.

46. One study examined the economic implications of a FMD outbreak in a specific region in the state of Kansas, an area with a large cattle industry which accounted for over 50 percent of the value of all regional economic activity (valued at $12.8 billion USD in 2004) and 25 percent of employment and total income.[67] The study looked at several scenarios for FMD introduction in the region. If the disease were introduced in a single cow herd, with rapid detection and ability to arrest the disease quickly and restore normal cattle and meat movement in the region in a relatively short time frame, local economic damages would amount to $35 million USD[68]— a best case scenario. However, if the disease were introduced in five large feedlots, the total economic impact in the area would approach $1 billion USD.[69] The study notes that if the disease hit several large feedlots at once, "the economic loss would be very substantial for the local community."[70]

47. Another study focused on the costs of an FMD outbreak in a dairy in the state of California. FMD-susceptible livestock in California are located in approximately 22,000 herds with a total population of 6.4 million animals, including 660,000 beef cows, 1.8 million dairy cows, 3 million calves and bulls, 150,000 pigs and hogs, 600,000 sheep and lambs, and 131,000 goats and kids.[71] Delayed diagnosis can exacerbate the economic effects of FMD introduction and was observed both in the 1997 FMD outbreak in Taiwan and 2001 FMD outbreak in the

[65] GAO, Foot and Mouth Disease at 19-20 (USA – 3).

[66] Horwitz, Foot-and-Mouth Disease (FMD) as a Hazard for New England Dairies at 24 (USA-11).

[67] Pendell, et al., The Economic Impacts of a Foot-and-Mouth Disease Outbreak: A Regional Analysis at 22-23 (USA-13).

[68] Pendell, et al., The Economic Impacts of a Foot-and-Mouth Disease Outbreak: A Regional Analysis at 29-30 (USA-13).

[69] Pendell, et al., The Economic Impacts of a Foot-and-Mouth Disease Outbreak: A Regional Analysis at 29-30 (USA-13).

[70] Pendell, et al., The Economic Impacts of a Foot-and-Mouth Disease Outbreak: A Regional Analysis at 29-30 (USA-13).

[71] Carpenter, et al., Epidemic and Economic Impacts of Delayed Detection of Foot-and-Mouth Disease: A Case Study of Simulated Outbreak in California at 27 (USA-15).

United Kingdom.[72] The study concluded that as diagnostic delay increased from 7 to 22 days, significant economic devastation ensued. The median number of animals slaughtered ranged from 8,700 to 260,400 (0.1 to 4.1 percent of California's livestock) with the maximum number of animals slaughtered at 419,300. The median number of herds under quarantine ranged from 680 to 6,200 (2.6 to 23.7 percent of California's livestock herds) with the maximum number at 11,100 herds.[73] If FMD diagnosis were delayed 21 days, $55.4 billion USD in economic losses could be expected.[74] The following photographs depict animal destruction to control an FMD outbreak.

Disposal of FMD-infected animals by burial

Disposal of FMD-infected animals through incineration

[72] Carpenter, et al., Epidemic and Economic Impacts of Delayed Detection of Foot-and-Mouth Disease: A Case Study of Simulated Outbreak in California at 26-27 (USA-15).

[73] Carpenter, et al., Epidemic and Economic Impacts of Delayed Detection of Foot-and-Mouth Disease: A Case Study of Simulated Outbreak in California at 29 (USA-15).

[74] Carpenter, et al., Epidemic and Economic Impacts of Delayed Detection of Foot-and-Mouth Disease: A Case Study of Simulated Outbreak in California at 30 (USA-15).

ii. Social Effects of Foot and Mouth Disease

48. A FMD outbreak can have significant social impacts. Such impacts include enormous psychological damage, especially on localities and families directly affected by an outbreak.

49. The 2001 FMD outbreak in the United Kingdom illustrates this reality. According to the Welsh Institute of Rural Health, individuals affected by the FMD outbreak experienced a range of symptoms, including tearfulness, lack of sleep, loss of appetite, increased anger, irritability, and general depression.[75] During the outbreak, some farming families elected to send their children away rather than have them witness the slaughter and disposal of the family's livestock. On farms where culling occurred, suicide increased amongst farmers.[76] Lost income was a source of stress for farming families, forcing many to cut back on household expenditures and renegotiate loans. Enforced isolation caused by quarantines added to tensions and stress already in place. According to one study of the effects of FMD on farm life in the Cumbria area of the United Kingdom, most farming households had to curb their usual daily activities and only the most essential movements on and off farms were permitted. [77]

3. National and International Control of FMD

50. FMD is a global disease that is a threat to each country. Ultimately, control and eradication of FMD depends upon the regulatory and veterinary infrastructure in each country. This infrastructure must provide stringent and vigilant control measures to prevent outbreaks, timely surveillance of country conditions, and effective response to infection and outbreak.

51. International cooperation is also important to facilitate efforts of each country to control FMD, because the disease can spread rapidly across borders. Because of the development in global transportation networks and international commerce, states recognized the importance of working together to organize their collective efforts.

i. Role and Structure of the World Organization for Animal Health (OIE)

52. The World Organization for Animal Health (OIE) reflects this effort to work together. States formed the OIE by international agreement in 1924, in recognition of the need to fight animal diseases at the global level. Currently, 178 countries are members of the OIE.

53. The OIE has six core objectives: (1) ensure transparency in the global animal disease situation ("transparency"); (2) collect, analyze, and disseminate veterinary scientific information ("scientific information"); (3) encourage international solidarity in the control of animal diseases ("international solidarity"); (4) safeguard world trade by publishing health standards for

[75] GAO, Foot and Mouth Disease at 21 (USA-3).

[76] Rushton, et al., OIE Global Foot and Mouth Disease Control Strategy Supporting Document No. 1 at 5-6 (USA-2).

[77] GAO, Foot and Mouth Disease at 21 (USA-3).

international trade in animals and animal products ("sanitary safety"); (5) improve the legal framework and resources of national Veterinary Services ("promotion of veterinary services"); and (6) provide a better guarantee of food of animal origin and promote animal welfare through a science-based approach ("food safety and animal welfare").[78]

54. The OIE is governed by the World Assembly of Delegates, which is comprised of delegates of all member countries. The World Assembly meets at least once a year, typically at a General Session held each May in Paris. The major functions of the World Assembly of Delegates include adopting international standards in the field of animal health and resolutions on the control of major animal diseases.

55. The technical work of the OIE is handled in part through several regional and specialist commissions. For purposes of this dispute, the OIE's specialist commissions are the most relevant, particularly the Scientific Commission for Animal Diseases ("Scientific Commission"—formerly the Foot and Mouth Disease and Other Epizootics Commission). The Scientific Commission and its subcommittee evaluate dossiers from country applicants that seek inclusion on OIE's FMD status list. This process is discussed further below.

ii. OIE Recognizes That the Primary Responsibility of Controlling FMD Falls Upon States' Veterinary Authorities

56. The OIE recommends in its Terrestrial Code that "before trade in animals or their products may occur, an importing country must be satisfied that its animal health status will be appropriately protected."[79] The OIE also recognizes, consistent with the Agreement on Sanitary and Phytosanitary Measures, "the legitimacy of different approaches to achieving [an] importing country's appropriate level of protection."[80] The OIE, consistent with the SPS Agreement, recognizes that "an importing country has the right to set the level of protection it deems appropriate . . . in relation to human and animal life and health in its territory" and therefore has the prerogative to select approaches consistent with realizing that level of protection.[81]

57. OIE international activities reflect the premise that each country is responsible for protecting its animal health status of FMD freedom. The OIE itself has neither the human or financial resources, nor the legal authority to take independent actions on the ground in countries around the world to eradicate or control the disease. Accordingly, OIE's global strategy is based on elements such as the strengthening veterinary services through capacity building and training in countries around the world.[82] The burden, the cost, the responsibility, and the decision

[78] "Objectives," World Organization for Animal Health (OIE), *available at* http://www.oie.int/about-us/our-missions/ (USA-18).

[79] Terrestrial Animal Health Code, Article 5.3.3 (2013) (USA-19).

[80] Terrestrial Animal Health Code, Article 5.3.3 (2013) (USA-19).

[81] Terrestrial Animal Health Code, Article 5.3.5 (2013) (USA-19).

[82] "The Global FMD Control Strategy," Global Foot and Mouth Disease Control Strategy, World Organization for Animal Health (OIE) (2012) at 5-6 (USA-5).

making, ultimately fall upon national veterinary authorities and regulators to keep a country safe from FMD.

iii. Responsibility of OIE Countries to Notify

58. One of the key elements for FMD control is notification. Because FMD travels so quickly across borders, timely notification is an important principle. As the OIE has said, "The successful control of epidemics—whether they are diseases of humans or animals—depends on rapid access to complete information on the national disease situation."[83] The OIE Code provides: "Member Countries shall make available to other Member Countries, through the OIE, whatever information is necessary to minimise the spread of important animal diseases, and their aetiological agents, and to assist in achieving better worldwide control of these diseases."[84] The OIE recognized that science is always developing, and so noted that Member Countries "shall ensure through their reports that they comply with the spirit and intention" of notification.[85] This is despite the temptation that "notification of diseases may have a negative impact on the economic performance of a country (e.g. by causing loss of export markets or discouraging tourism) . . . . A country's credibility must be based on timely and accurate notification of diseases, and this also gives the respective government a much better position to contain a disease[.]"[86] Trust between veterinary authorities in countries and with the OIE is critical for FMD control, and that trust is based on the credibility of each country's reporting.

iv. OIE Approach in Assessing Country FMD Status

59. To assist countries in understanding the FMD situation in other countries around the world, the OIE established a program in the mid-to-late 1990s under which it would provide a mechanism for countries to receive some formal OIE assessment as to their FMD status. Each year, the OIE would release a list in which it would designate certain countries as "FMD free."

60. The program works in the following way.

61. An applicant country voluntarily applies to the OIE for FMD status designation by submitting completed questionnaires provided in Article 1.6.5 of the Terrestrial Animal Health Code. An applicant country must provide paper responses that address topics such as the geography of the country, the livestock industry, the veterinary system (including legislation), history and situation related to FMD surveillance, prevention, and control measures.

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[83] OIE, Notification of animal and human diseases: Global legal basis, at http://www.oie.int/fileadmin/vademecum/eng/PDF_WORD_Vademecum/WAHIS-WAHID_FINAL/Slide%2022/EN/Legal_basis_EN.pdf (USA-20).

[84] OIE Code Article 1.1.2.1 (2013) (USA-21).

[85] OIE Code Article 1.1.2.4 (2013) (USA-21).

[86] OIE, Notification of animal and human diseases: Global legal basis, at http://www.oie.int/fileadmin/vademecum/eng/PDF_WORD_Vademecum/WAHIS-WAHID_FINAL/Slide%2022/EN/Legal_basis_EN.pdf (USA-20).

62. OIE FMD status designation can only be granted after (1) a country submits a paper application for it to be recognized; (2) the ad hoc sub-committee under the Scientific Commission of the OIE completes its review of the papers (the application is not circulated to all Member countries); (3) the ad hoc sub-committee recommends a decision to the Scientific Commission; 94) the Scientific Commission recommends the list of all countries for designation to the OIE World Assembly of Delegates; and (5) the OIE World Assembly of Delegates adopts the resolution (by consensus) containing the list of all countries with a recognized status. Due to resource constraints, very rarely are site visits conducted by the OIE, and the costs of any site visits are borne by the applicant country.[87]

63. With respect to the OIE, a country that does not obtain an FMD-free status is viewed as an FMD infected country.[88] Accordingly, the OIE's import conditions for this status would apply.[89] This is consistent with the fact that FMD is endemic worldwide and that an area cannot simply be assumed to be free of FMD.

64. In sum, FMD is considered one of the most dangerous animal diseases by international and national authorities. It is not only in the interests of each country but also in the interest of international commerce that FMD is contained. To achieve this objective, individual countries must act truthfully, effectively and transparently.

B. Argentina's Record of FMD Exposure and Infection

65. Argentina has had an ongoing, tumultuous battle with FMD that dates back to the 1860s. After a storied record of unsuccessful attempts to eradicate FMD, Argentina made progress in controlling the disease during the late 1990s. The international community recognized Argentina as FMD-free; however, the success was short-lived, as the country experienced epidemic level outbreaks in the 2000s. In effort to preserve its designation, Argentina was not entirely forthcoming of the magnitude of the outbreaks. Throughout the past decade, Argentina made multiple unsuccessful attempts to eradicate and control the disease, which consequently prolonged the United States' efforts to evaluate the status of FMD in the country.

1. FMD Historically Endemic in Argentina

66. FMD has a long history in Argentina. It was first reportedly identified in the country between 1864 and 1866.[90] In subsequent years, Argentina had repeated outbreaks. FMD

[87] Standard Operating Procedures for official recognition of disease or risk status of bovine spongiform encephalopathy and for the endorsement of official control programmes of Member Countries, at http://www.oie.int/fileadmin/Home/eng/Animal_Health_in_the_World/docs/pdf/EN_SOP_June2013.pdf ((USA-22).

[88] Article 8.6.7, Terrestrial Code (2013) (USA-23).

[89] *See* Chapter 8, Terrestrial Code (2013) (USA-23).

[90] Cane, Foot and Mouth Disease in Argentina: The Experience of Eradication and the Crisis as an Opportunity to Produce Sustainable Change in the Cattle Industry (USA-24); *see also* Pecker, Fiebre Aftosa: Su Paso Por La Argentina 23 (SENASA, 2007) (USA-25).

infections were reported in 1870 and again in the early 1900s.[91] Argentina was unable to confine the disease within its territory and as a result, the country's FMD-infected meat spread beyond its borders.

67. Outbreaks originating in Argentina affected countries receiving Argentine meat products. In 1929, the last FMD outbreak in the United States was traceable to infected meat delivered by steamship from Buenos Aires.[92] It is estimated that between1954 and 1967, 43 outbreaks of FMD in the United Kingdom also originated from Argentine meat.[93] The well-documented FMD outbreak of 1967 in the United Kingdom was traceable to lamb imports from Argentina.[94]

68. Between 1967 and 1987, Argentina experienced a continuous period of FMD outbreaks. The disease remained prevalent in the country notwithstanding the vaccination program Argentina implemented in the areas north of Patagonia during the period.[95] In 1968, Argentina experienced 6,300 FMD outbreaks, and the in following year, a total of 7,350 outbreaks.[96] Over the next four years (1969-1973), more than 20,000 FMD outbreaks occurred.[97] Between 1971 and 1973 alone, Argentina saw FMD outbreaks rise from 6,500 to 6,900, per year.[98] From 1974-1979, Argentina experienced more than 16,000 additional disease outbreaks.[99] FMD outbreaks continued throughout the decade and from 1980 to 1987, nearly 8,000 more FMD outbreaks occurred.[100] In total, over 60,000 FMD outbreaks occurred during this uninterrupted period of 20 years.[101]

2. Argentina's Short Respite from FMD between 1995 and 1999

69. Due in part to an FMD vaccination program, Argentina experienced a short respite from FMD outbreaks from 1995-1999. Hopes were high that the country's FMD control strategy had

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[91] *See* Pecker, Fiebre Aftosa: Su Paso Por La Argentina 23 - 26 (SENASA, 2007) (USA-25)

[92] USDA, The 1929 Outbreak of Foot-And-Mouth Disease in Southern California. (The outbreak resulting from this event lasted over one month, leading to the destruction of a significant number of animals) (USA-26).

[93] Reynolds & Tansey, Foot and Mouth Disease: The 1967 Outbreak and its Aftermath (USA-27).

[94] United Kingdom Department for Environment, Food and Rural Affairs, Comparisons with the 1967 FMD Outbreak: How the 2001 Outbreak of Foot-and-Mouth differs from the 1967 Outbreak 2 (stating that the 1967 FMD epidemic resulted in more than 2,364 detected FMD outbreaks across the United Kingdom and led to the slaughter of 442,000 animals.) (USA-28).

[95] Cane, Foot and Mouth Disease in Argentina: The Experience of Eradication and the Crisis as an Opportunity to Produce Sustainable Change in the Cattle Industry (USA-24).

[96] Pecker, Fiebre Aftosa: Su Paso Por La Argentina, at 49 (USA-25).

[97] Pecker, Fiebre Aftosa: Su Paso Por La Argentina, at 49 (USA-25).

[98] Pecker, Fiebre Aftosa: Su Paso Por La Argentina, at 49 (USA-25).

[99] Pecker, Fiebre Aftosa: Su Paso Por La Argentina, at 59 (USA-25).

[100] Pecker, Fiebre Aftosa: Su Paso Por La Argentina, at 49 (USA-25).

[101] Pecker, Fiebre Aftosa: Su Paso Por La Argentina, at 49 (USA-25).

finally pacified the disease. The United States shared this aspiration, and in 1997, authorized the importation of fresh, chilled, and frozen beef from Argentina under certain conditions.[102]

70. By April 1999, Argentina was confident that FMD had been eradicated, and so it decided to discontinue the practice of vaccination.[103] As discussed in the next section, this decision would have calamitous results.

3. Argentina's Widespread FMD Outbreaks 2000-2002

71. On May 24, 2000, the OIE recognized Argentina as a country free of FMD where vaccination is not practiced.[104] The designation recognized that Argentina demonstrated the absence of the disease at that time; however, in determining a country's status, the OIE relies heavily on the completeness and accuracy of the country's dossier, which may not accurately predict the likelihood of an outbreak or the effectiveness of the country's response. With respect to Argentina, this classification did not appear to represent its ability to protect against the disease without vaccination.**{**

72. Argentina experienced one of its largest and most intense outbreaks of FMD beginning less than two months after receiving the OIE FMD-free designation. On June 5, 2000, an Argentinian veterinarian working in Paraguay alerted Argentinian animal health officials of an FMD diagnosis in Paraguay.[105] In July, FMD infected cattle were illegally imported into Argentina from a neighboring country.[106] Over the next 17 months – between July 2000 and January 2002 – FMD spread rapidly across Argentina's provinces. Argentina could not prevent the disease from dispersing throughout the country.

i. Thousands of FMD Outbreaks Afflict Multiple Provinces

73. FMD rapidly crisscrossed the Argentine pampas between the years 2000 and 2002. The outbreaks were voluminous and expansive—FMD hit 14 provinces, 228 districts, and 324 quadrants in this period.[107] During this timeframe, SENASA calculated a total of 2,563 FMD outbreaks, which affected a reported 152,619 animals.[108] Close to 3 million animals were exposed to FMD between July 2000 and January 2002, a figure that reflects the magnitude of and the danger posed by the disease in Argentina.[109]

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[102] 62 Fed. Reg. 34385 (USA-29).

[103] 65 Fed. Reg. 82894 (USA-30).

[104] Pecker, Fiebre Aftosa: Su Paso por La Argentina, at 122 (USA-25).

[105] USDA, APHIS Argentina Site Visit Report (December 4, 2000) (USA-31).

[106] 65 Fed. Reg. 82894 (USA-30).

[107] SENASA Application: Argentina (November, 2002) 14 (USA-32).

[108] SENASA Application: Argentina (November, 2002) 16 (USA-32).

[109] See SENASA Application: Argentina (November, 2002) 16 (USA-32).

74. SENASA reported that the first outbreaks occurred on a community farm in Clorinda, Province of Formosa on July 20, 2000, and spread to the provinces of Corrientes and Entre Rios within 9 days.[110] In July alone, SENASA reported 4 outbreaks, in which 1,560 animals were affected, and 7,180 animals were exposed, creating an attack rate of 21.72 percent.[111] The following month, another outbreak was reported in Formosa, and new cases of FMD were confirmed in the neighboring provinces of Chaco, Cordoba, Misiones, Buenos Aires, and La Pampas.[112]

75. Although SENASA took measures in an attempt to address the initial FMD outbreak, their actions were too late and failed to prevent the disease from spreading into August. Upon first suspecting infected cattle in July, Argentina authorities issued warnings to border provinces, increased surveillance of farms, intensified border controls and banned shipments from the border surveillance area.[113] On August 2, Argentina discovered 10 illegally-imported steers from Paraguay on a community farm in the Province of Corrientes.[114] This prompted SENASA to ban all animal shipments and place all imported and contact animals in quarantine.[115] SENASA then tested serum and oesophageo-pharyngeal fluid samples from 10 steers believed to be infected.[116] The VIAA and EITB tests revealed that 4 of the 10 steers were positive for the antibodies associated with FMD infection.[117]

76. Upon confirming the infections, SENASA then ordered the sanitary slaughter of the steers – a total of 3,617 contact animals and 1,308 bovines with indirect contact with the steers in the Formosa, Corrientes and Entre Rios provinces.[118] Nonetheless, the slaughter occurred too late, as other, non-detected animals were exposed, and the disease had already spread to many provinces. Consequently, on August 10, Argentina suspended the certification of fresh, chilled

[110] See SENASA Application: Argentina (November, 2002) 16 (USA-32); see also SENASA National FMD Eradication Plan, 3, February 2002 (USA-33).

[111] SENASA Application: Argentina (November, 2002) 16, (November 2002) (USA-32).

[112] SENASA National FMD Eradication Plan, 3, February 2002 (USA-33).

[113] USDA APHIS Argentina Site Visit Report, 4, Dec. 4, 2000 (USA-31).; Report of the Meeting of the OIE Foot and Mouth Disease and Other Epizootics Commission (September, 2000) (USA-34).

[114] Report of the Meeting of the OIE Foot and Mouth Disease and Other Epizootics Commission, at 12 (Sept. 2000) (USA-34).

[115] USDA, APHIS, Epidemiological Report (USA-35).

[116] USDA, APHIS, Epidemiological Report (USA-35).

[117] *See* Report of the Meeting of the OIE Foot and Mouth Disease and Other Epizootics Commission, at 12 (USA-34); *see also* Certification of Beef from Argentina, 65 Fed. Reg. 82894, Dec. 29, 2000 (codified at 9 C.F.R. 94) (USA-30).

[118] Risk Analysis: Evaluation of the Risk to the United States (US) of Importing Foot and Mouth Disease (FMD) Virus in Fresh or Frozen Beef from Argentina, Epidemiological Report, at 8, December 4, 2000 (USA-35); *see also* Report of the Meeting of the OIE Foot and Mouth Disease and Other Epizootics Commission, at 12 (Sept. 2000) (USA-34).

and frozen beef exports to the United States.[119] In all, during the month of August, Argentina reported 38 FMD outbreaks, which spread across 6 provinces, infected 3,609 animals, exposed 27,164 animals, and generated an attack rate of 13 percent.[120]

77. Between September and December 2000, a total of 82 outbreaks expanded into the Santa Fe and Misiones provinces.[121] 7,305 animals were affected by and 158,024 animals were exposed to FMD during this 4 month period.[122] SENASA could not control the spread of FMD, and the outbreaks intensified into the following year. The table below, provided by SENASA, details the number of outbreaks and the impact on animals during the 2000 – 2002 FMD epidemic.[123]

[119] Letter from Argentina Ambassador to the U.S. Guillermo Gonzalez to USDA Secretary Dan Glickman, August 10, 2000 (USA-36).

[120] SENASA Application: Argentina (November, 2002) 16, (November 2002) (USA-32); *see also* SENASA *National FMD Eradication Plan*: Report of 2000-2001 FMD outbreaks, actions adopted and contingency program in case of FMD risks, 3, February 2002 (USA-33).

[121] SENASA National FMD Eradication Plan, 3, February 2002 (USA-33).

[122] SENASA Application: Argentina (November, 2002) 16 (November 2002) (USA-32).

[123] SENASA Application: Argentina (November, 2002) 16 (November 2002) (USA-32).

	Month	Outbreaks	No. of Affected Animals	No. of Exposed Animals	Attack Rate
2000	JULY	4	1,560	7,180	21.72
	AUGUST	38	3,609	27,164	13.28
	SEPTEMBER	18	1,301	25,383	5.12
	OCTOBER	16	1,114	28,625	3.89
	NOVEMBER	11	1,655	20,473	8.08
	DECEMBER	37	3,235	83,543	3.87
2001	JANUARY	65	4,307	78,816	5.46
	FEBRUARY	203	12,619	166,278	7.58
	MARCH	247	13,134	223,558	5.87
	APRIL	359	18,276	310,642	5.88
	MAY	605	38,807	726,466	5.34
	JUNE	540	30,290	557,328	5.43
	JULY	324	17,598	394,062	4.46
	AUGUST	68	3,654	73,904	4.94
	SEPTEMBER	17	948	51,318	1.84
	OCTOBER	1	8	28	28.57
	NOVEMBER	7	439	8,240	5.32
	DECEMBER	2	45	406	11.08
2002	JANUARY	1	20	228	8.77
	Total No. of Outbreaks	2563			

FMD Outbreaks and Animals Affected Between 2000 and 2002

(Source: Information Provided by SENASA to Attain Recognition of Argentina as a Region, as defined in Section 92.2, Title 9, of the Code of Federal Regulations for Foot and Mouth Disease (FMD) (November 2002))

78. The disease continued to spread across the country in January 2001, where SENASA reported an increase of FMD outbreaks to 65, affecting 4,307 animals and exposing 78,816.[124] In February 2001, the number of FMD outbreaks would increase by more than 300 percent to 203.[125] The disease expanded into the San Luis province during this month, where a total of 12, 619 animals were affected by and 166, 278 were exposed to FMD.[126] Over the following three months from March to May 2001, Argentina reported 1,211 outbreaks, afflicting primarily the provinces of Entre Rios and Buenos Aires, a section of which is now a recognized region within Patagonia North A.[127] 70,217 animals were affected by and 1,260,666 animals were exposed to the disease during the short three month period.[128]

79. The OIE and Argentina acknowledged that the disease posed a problem for the entire continent of South America, and that the catastrophe was due to Argentina's ineffective controls.[129] On April 6, 2001, during the intensified outbreak period, SENASA intended to use mass vaccination combined with regional border controls.[130]

80. In June 2001, SENASA reported a total of 540 FMD outbreaks, affecting 30, 290 animals, and exposing another 557,328 animals.[131] Although total FMD outbreaks began to decrease during the second half of 2001, Argentina still experienced 449 FMD outbreaks between July and December 2001.[132] 22,692 animals were affected by the disease and another 527,958 animals were exposed to FMD throughout this period.[133] On January 23, 2002,

[124] SENASA Application: Argentina (November, 2002) 16, (November 2002) (USA-32)

[125] SENASA Application: Argentina (November, 2002) 16, (November 2002) (USA-32).

[126] SENASA Application: Argentina (November, 2002) 16, (November 2002) (USA-32).

[127] SENASA Application: Argentina (November, 2002) 16, (November 2002) (USA-32)

[128] SENASA Application: Argentina (November, 2002) 14-15, (November 2002) (USA-32).

[129] SENASA Resolution No. 5, April 6, 2001 (USA-37); *see also* 69th General Session, at 8 ("The year 2001 had seen an explosion in the number of outbreaks of foot and mouth disease in Europe and South America, reflecting the reduced efficacy of Veterinary Services in other countries where the disease is endemic. In this context, it is the responsibility of the international community to react to restore consumer confidence, to protect the livestock production industry, to stabilize [sic] the world animal health situation, and above all to contain epizootic diseases at their source.") (USA-38).

[130] SENASA Resolution No. 5, April 6, 2001 (USA-37).

[131] SENASA Application: Argentina (November, 2002) 16, (November 2002) (USA-32).

[132] SENASA Application: Argentina (November, 2002) 16, (November 2002) (USA-32).

[133] SENASA Application: Argentina (November, 2002) 16, (November 2002) (USA-32).

Argentina reported an outbreak in the province of Córdoba, marking the final reported FMD outbreak of the 19 month epidemic period.[134]

81. The economic impact of the FMD outbreaks on Argentina's beef industry was significant. Government statistics indicate that, during the 2001 FMD outbreak period, Argentina's beef exports were 26 percent less than the $322 million USD generated during the first seven months of 2003.[135]

ii. Argentina Fails to Report the FMD Outbreak

82. As the following will illustrate, it is clear that, as a matter of national policy, Argentina concealed FMD outbreaks from its trading partners and the international community from approximately August 2000 to March 2001.

83. Multiple Argentine government officials were aware of the outbreaks and admitted that the concealment activities occurred. SENASA admitted that it purposely concealed the presence of the disease in Argentina.[136] The active concealment was corroborated by an agency veterinarian,[137] a February 2002 report on the 2000-2001 FMD outbreaks, [138] and a private meeting of government officials.[139]

84. The concealment was based on an understanding between high-level officials in SENASA and the Ministry of Agriculture to keep the circumstances of the FMD in reserve.[140] The officials discussed an agreement to conceal the outbreaks in effort to preserve the internationally recognized health status[141] – the OIE designated status of FMD-free without vaccination. One former SENASA president acknowledged that Argentina knew of the outbreaks but intentionally neglected to reveal the cases because of the political and economic costs, and the desire to keep markets open to Argentine beef.[142] The then-Secretary of

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[134] See SENASA Application: Argentina (November, 2002) 14 (November 2002) (USA-32).

[135] EMPRES Transboundary Animal Diseases Bulletin, No. 24, 10-11 (2004) (Argentina did not report any FMD outbreaks during the initial seven months of 2003; the first outbreak was reported in August) (USA-39).

[136] "Disease Outbreak In Argentine Cows Spurs Beef Bans," Wall Street Journal, February 13, 2006: C.4 (USA-40).

[137] *See* Pecker, Fiebre Aftosa: Su Paso Por La Argentina , 123-124 (SENASA, 2007) (USA-25).

[138] SENASA National FMD Eradication Plan, 3, February 2002 (stating that "the government of Argentina failed in notifying FMD outbreaks registered before March 2001.") (USA-33).

[139] "Agreement", August 9, 2000 (USA-41); *see also* "General Auditing Office of Argentina: SENASA Program for the Fight Against Foot and Mouth Disease," General Auditing Office of Argentina, August 22, 2003, at 9 (42).

[140] "Agreement", August 9, 2000 (USA-41); *see also* "General Auditing Office of Argentina: SENASA Program for the Fight Against Foot and Mouth Disease," General Auditing Office of Argentina, August 22, 2003, at 9 (USA-42).

[141] "Agreement", August 9, 2000 (USA-41); *see also* "General Auditing Office of Argentina: SENASA Program for the Fight Against Foot and Mouth Disease," General Auditing Office of Argentina, August 22, 2003, at 9 (USA-42).

[142] *See* "Argentina Knows about the FMD cover-up," Es Mas, March 15, 2001, *available at,* http://www.esmas.com/noticierostelevisa/internacionales/86726.html (USA-.43)

Agriculture later confirmed that everyone knew of the outbreak, and that it was a state policy not to mention the disease.[143]

85. Argentina's animal health officials implemented a sophisticated concealment plan, characterized by SENASA veterinarian Dr. Alberto Pecker as a "denial complex."[144] Although Argentina notified the OIE of the illegal crossing of FMD infected animals from Paraguay into its borders, it did not reveal the extent of the outbreaks. In fact, Argentina did not report the 38 outbreaks in August, the 18 outbreaks in September, the 11 outbreaks in November, the 37 outbreaks in December, the 65 outbreaks in January or the 203 outbreaks in February to the OIE in a timely manner.[145] SENASA officials were aware of the presence of FMD, were complicit in vaccinating against FMD while simultaneously denying its existence, removed labels from bottles, and granted official transit documents to animals infected with the disease.[146] These agents engaged in carrying uncontrolled animals long distances, thereby exponentially increasing the risk of infecting more animals with FMD.[147] When the United States conducted a site visit to Argentina from September 27 to October 6, 2000, SENASA did not notify visiting U.S. officials of the ongoing outbreaks.[148] In fact, Argentina did not notify the United States and the international community until March 2001.

86. The World Bank likewise criticized SENASA's management of the 2001 FMD outbreak epidemic, stating that the "incident highlighted a number of institutional weaknesses."[149] Additionally, the World Bank acknowledged that "failure of SENASA to provide prompt and official notification of the disease outbreak created an issue of trust with foreign regulatory agencies."[150] As a result of the concealment policy and institutional weaknesses, the United States and the OIE were deprived an opportunity to evaluate all of the information, and to

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[143] *See* "Argentina Knows about the FMD cover-up," Es Mas, March 15, 2001, *available at*, http://www.esmas.com/noticierostelevisa/internacionales/86726.html (USA-43).

[144] See Pecker, Fiebre Aftosa: Su Paso Por La Argentina, 123, October 2007 (USA-25).

[145] *See* SENASA Application: Argentina (November, 2002) 16 November 2002 (USA-32)

[146] *See* Pecker, Fiebre Aftosa: Su Paso Por La Argentina, 123-124, October 2007 (USA-25).

[147] Pecker, Fiebre Aftosa: Su Paso Por La Argentina, 123, October 2007 (USA-25).

[148] Risk Analysis: Evaluation of the Risk to the United States (US) of Importing Foot and Mouth Disease (FMD) Virus in Fresh or Frozen Beef from Argentina, Epidemiological Report, December 4, 2000 (USA-35).

[149] McClean M. "The Impact of International Sanitary Requirements on the Beef Industry in Buenos Aires Case Study, undated, at p. 3 ("This incident highlighted a number of institutional weaknesses, including: a failure by SENASA to recognize that continuing high levels of prevention and surveillance were required to maintain the disease free status that had been achieved under previous eradication campaigns; a lack of adequate border controls to prohibit the entry of infected or suspect animals; and a failure by SENASA to notify its international partners of the disease outbreak in a timely fashion. This lack of transparency on the part of SENASA has damaged its reputation among foreign regulatory agencies and jeopardized market access not only for beef exports but for other agricultural products as well.") (USA-44).

[150] McClean M. "The Impact of International Sanitary Requirements on the Beef Industry in Buenos Aires Case Study, (2004), at p. 12 (USA-44).

respond quickly to danger posed by the FMD-infected beef in Argentina. Argentina adopted this policy to avoid economic losses, and consequently, the delays in reporting outbreaks played a pivotal role in the spread of FMD within Argentina and across its borders.[151]

iii. The Failure of Argentina's Animal Health Agency

87. Not only did Argentina conceal one of the largest FMD outbreaks in its recent history, Argentina's regulatory authorities also failed on a technical level to control the outbreak. The failures were at the systemic and leadership levels.

88. At the systemic level, SENASA failed multiple ways.[152] At a basic level, it was unable to control its border. The virus entered virtually at will across the borders to infect large populations of susceptible animals. SENASA could not detect FMD adequately and in time. It had little information on the regional FMD situation. Moreover, field veterinarians, including private-sector physicians, were unable to diagnose the disease accurately.

89. Control measures were also insufficient. SENASA subsequently acknowledged that it did not have enough vaccines on hand to combat the disease. Farmers were not adequately educated and sensitized to the potential FMD threat. There was also insufficient regulatory presence at local levels to respond.

90. At the level of leadership, high-level SENASA leaders were removed and replaced several times as the outbreak crisis continued to unfold. After taking "technical responsibility" for the FMD outbreak in August, the President of SENASA took a leave of absence in September 2000. [153] The SENASA President subsequently resigned in November 2000.

91. In March 2001, SENASA introduced a new president, who resigned after 10 days, which led to the reappointment of a former president to head the agency.[154] In April 2001, SENASA passed a decree, and changed its leadership.[155] The decree proclaimed the appointment of a new president, vice president, and provided for the appointment of a new board of directors.[156]

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[151] Aftosa: Cronica de Una Decepcion, *Unoentrerios*, March 28, 2010 (USA-45) ; Argentina's secrecy on foot-and-mouth proves costly, *Food Chemical News*, March 26, 2001 (USA-46).

[152] The following discussion on systemic failures is drawn from SENASA National FMD Eradication Plan, 10, February 2002 (USA-33).

[153] "SENASA Responsible for FMD," El Mercado, August 23, 2000, available at, http://www.mercado.com.ar/notas/economa-y-poltica/10763/se%3Cb%3Enasa%3Cb%3E; (USA-47) *see also* "Oscar Bruni Resigns; Victor Machinea Becomes New Head of SENASA," El Diario, November 17, 2000, available at: http://www.fyo.com/noticia/renuncio-oscar-bruni-victor-machinea-es-el-nuevo-titular-del-senasa (USA-48).

[154] Cane Returns to Lead SENASA, La Nacion, March 30, 2001, available at, http://www.lanacion.com.ar/57923-cane-regresa-para-conducir-el-senasa (USA-49).

[155] SENASA Decree No. 394, April 1, 2001 (USA-50).

[156] SENASA Decree No. 394, April 1, 2001(USA-50).

Argentina then announced a new plan to address the failures exposed by the outbreaks. That plan, however, did not immediately eliminate the disease.[157]

92. Despite renewed efforts to control the outbreaks and the replacement of SENASA leadership, the outbreaks continued until January 23, 2002, more than one and a half years after the first series of outbreaks.[158]

4. Argentina Experiences Another FMD Outbreak in 2003

93. Argentina experienced another outbreak of FMD on August 28, 2003, one month after attaining the OIE designation of FMD-free where vaccination is practiced.[159] SENASA reported the outbreak to an OIE on September 5, 2003. On the same date, SENASA forwarded a copy of an epidemiological report prepared on September 2, which revealed that 37 pigs were exposed to FMD, 16 were infected, and 2 died.[160] The outbreak exposed close to 60 animals to FMD.[161] As a result of the outbreak, the OIE removed Argentina of its status as a zone free of FMD where vaccination is practiced.

94. Argentina responded to the outbreak by stamping out susceptible and contact animals, and by adopting vaccination and control measures.[162] In December 2003, over 3 months after the presence of FMD was reported in the San Martin district of Salta, Argentina reported no further signs of the disease.[163] The OIE restored Argentina's FMD-free status on May 24, 2005.[164] And yet, Argentina would experience another FMD outbreak less than two years later.

5. Argentina Experiences Another FMD Outbreak in 2006

95. Less than one year after the OIE reassigned Argentina to the list of countries free of FMD where vaccination is practiced, Argentina experienced additional outbreaks in February 2006.[165]

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[157] Bernardo Gabriel CANE, SENASA Foot and Mouth Disease in Argentina Report, International Conference on Prevention and Control of Foot and Mouth Disease, 2 (Dec. 2001) (USA-24).

[158] SENASA Application: Argentina (November, 2002) 14, (November 2002) (USA-32).

[159] EMPRES Transboundary Animal Diseases Bulletin, No. 24, 11 (2004) (The outbreak occurred in Targatak, Province of Salta) (USA-39)

[160] Facsimile from Embassy of Argentina Minister Jose Molina to APHIS Peter Fernandez, September 5, 2003 (USA-51).

[161] EMPRES Transboundary Animal Diseases Bulletin, No. 24, 12 (2004) (USA-39).

[162] OIE – Request to Regain Status of Foot and Mouth Disease Free Area with Vaccination, 4 (October 2004) (USA-52).

[163] OIE – Request to Regain Status of Foot and Mouth Disease Free Area with Vaccination, 2 (October 2004) (USA-52).

[164] 73rd General Session, 150, May 24, 2005 (USA-53).

[165] Foot and Mouth Disease, Argentina, Impact Worksheet, 1 (February 15, 2006) (The outbreak occurred in San Luis del Palmar, Province of Corrientes) (USA-54).

In particular, the outbreaks occurred on a livestock operation, where 3,012 head of cattle were exposed to the disease.[166] A total of 46,904 bovines were reported susceptible to FMD in the surrounding areas.[167] Consequently, the OIE removed Argentina from the FMD-free list at its May 2006 General Session meeting, exactly one year after restoring Argentina's FMD-free recognition.[168]

96. From December 5-13, 2006, an OIE Scientific Commission visited the zones that experienced FMD outbreaks earlier in the year.[169] In its February 2007 report, the Commission observed during the investigations that not all animals were sampled on the farms affected by the outbreaks.[170] Additionally, the investigating mission reported that "more intensive and complete epidemiological investigations in the event of an outbreak should be carried out."[171]

97. During the 2000 – 2006 outbreak period, Argentina demonstrated an inability to maintain the OIE designation because of the failure to prevent the disease from spreading across the country. The following map illustrates the extent to which FMD devastated the majority of Argentina's provinces.

[166] Foot and Mouth Disease, Argentina, Impact Worksheet, 1 (February 15, 2006) (USA-54).

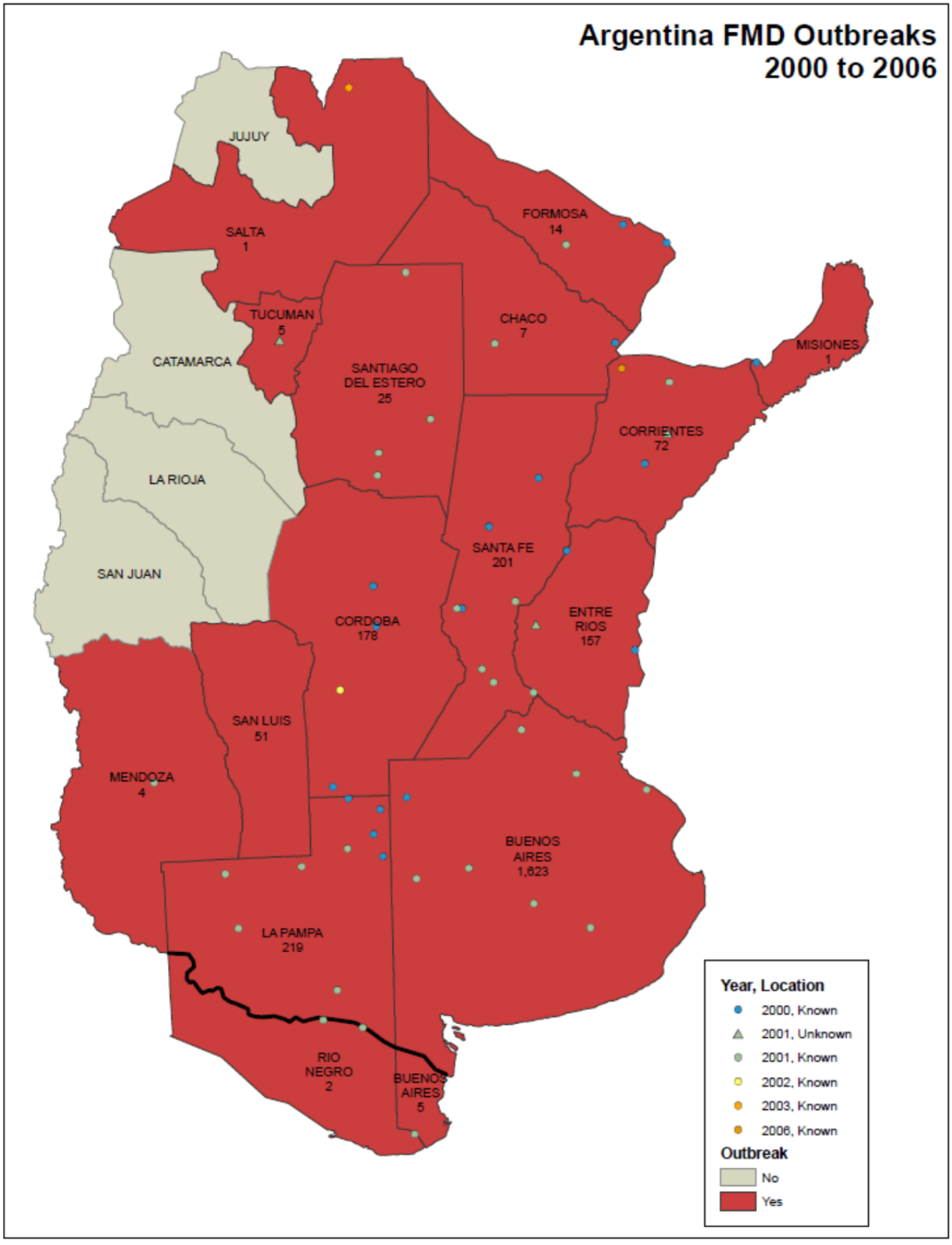
[167] 74th General Session, Final Report 2006, at 45 (USA-55).

[168] 74th General Session, 144, May 23, 2006 (USA-55).

[169] Letter from SENASA President Jorge Amaya to APHIS John Clifford, July 19, 2010 (USA-56).

[170] Report of the Meeting of the OIE Scientific Commission for Animal Diseases, Annex IX (d), February 2007 (USA-57).

[171] Report of the Meeting of the OIE Scientific Commission for Animal Diseases, Annex IX (d), February 2007 (USA-57).


Argentina FMD Outbreaks
2000 to 2006
JUJUY
SALTA
1
FORMOSA
14
TUCUMAN
5
CHACO
7
MISIONES
1
CATAMARCA
SANTIAGO
DEL ESTERO
25
CORRIENTES
72
LA RIOJA
SANTA FE
201
SAN JUAN
ENTRE
RIOS
157
CORDOBA
178
SAN LUIS
51
MENDOZA
4
BUENOS
AIRES
1,623
LA PAMPA
219
RIO
NEGRO
2
BUENOS
AIRES
5
Year, Location
2000, Known
2001, Unknown
2001, Known
2002, Known
2003, Known
2006, Known
Outbreak
No
Yes

Argentine Districts Affected by FMD Outbreaks between 2000 and 2006

6. Patagonia Reorganization

98. The repeated FMD outbreaks have caused SENASA to make continuing changes to its measures involving Patagonia. Since 2001, Argentina has introduced multiple resolutions that restructured Argentina's internal border measures, affecting the transport of beef, pork and live cattle into the Patagonia area. The repeated reorganizations have complicated the U.S. Animal and Plant Health Inspection Service's (APHIS) evaluation of the FMD status for the Patagonia area.

99. In 2001, Argentina began to introduce resolutions in effort to address the spread of FMD outbreaks between different regions. Resolution No. 9 implemented a sanitary barrier at 42° parallel to attempt to preserve the area south of the parallel as a region free of FMD where vaccination is not practiced.[172] On May 24, 2001, SENASA implemented Resolution No. 58 pursuant to the agency's April FMD eradication plan, again with the objective of preventing the spread of FMD to Patagonia.[173] Resolution No. 58 introduced traffic checkpoints, and general bans on the transport of live, FMD susceptible animals to Patagonia South and Patagonia North B.[174]

100. In December 2002, SENASA passed Resolution No. 1051, which removed the outright ban on the entry of FMD-susceptible animals to Patagonia South and Patagonia North B.[175] The resolution replaced the outright ban with seven less-stringent control measures[176] In addition, the resolution recognized that Patagonia South and Patagonia North B as having the same FMD sanitary status as free areas where vaccination is not practiced.[177]

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[172] USDA Risk Analysis: *Risk of Exporting Foot-and-Mouth Disease (FMD) in FMD-Susceptible Species from Argentina, South of the 42° Parallel (Patagonia South), to the United States*, 32, June 2005 (USA-58).

[173] SENASA Resolution No. 58 (May 24, 2001) (USA-59).

[174] SENASA Resolution No. 58 (May 24, 2001) (The resolution provided for the following limited exceptions to the transport of fresh bovine meat from the region north of Patagonia North B: animals must come from establishments where there were neither FMD outbreaks during the last 60 days nor in a radius of 25 kilometers for the last 30 days) (USA-59).

[175] SENASA Resolution No. 1051 (December 30, 2002) (USA-60).

[176] SENASA Resolution No. 1051 (December 30, 2002) (measures included requirements for the: submission of an inspection application, attaching the Register of Pedigree of breeding animals; disease-susceptible animals must be subjected to two (2) negative serological tests for FMD within an interval of 21 days, during a period of isolated quarantine; cattle and sheep must be subjected to 2 negative Probang tests within an interval of 21 days; disease-susceptible animals must have remained in the source facilities for a least 90 days before dispatch application; animals must move to destination with official dispatch and previous notice; at the destination, animals must be kept isolate during 21 days, after which premises must be cleared after clinical inspection of disease-susceptible animals; and animals must be transported in sealed trucks and they must not move through zones where FMD disease vaccination is practiced.) (USA-60).

[177] SENASA Resolution No. 1051 (December 30, 2002) (USA-60).

101. SENASA introduced Resolution No. 725 in November 2005, which qualified this equivalence between the two regions by imposing traceability requirements. Resolution No. 725 maintained the general ban on transport to Patagonia South and Patagonia North B of animals susceptible to FMD; in addition, the resolution specified traceability requirements for animals traveling through the two zones.[178]

102. On March 11, 2008, SENASA passed a resolution to authorize the conditional transport of animals and plants from Patagonia North B into Patagonia South.[179] The regulation modified Resolution No. 725 by requiring transporters of commercial goods to obtain certified permits to transport products into Patagonia South.[180] The change signaled Argentina's apparent commitment to liberating the transport restrictions between Patagonia South and Patagonia North B.

103. On December 16, 2008, Argentina passed Resolution No. 1282, further relaxing transport restrictions between Patagonia South and Patagonia North B. Although the overall result was to reduce restrictions, the regulations included a new set of eight different control measures[181].

104. In short, Argentina has continually changed the measures governing the internal transportation between Patagonia and other regions of Argentina. These continual changes have necessarily delayed U.S. evaluations of Argentina's request for regionalization regarding separate FMD statuses for separate, yet related Argentine regions

[178] SENASA Resolution No. 725 (November 15, 2005) (Introducing the following additional requirements: Two negative serological tests for FMD from FMD-susceptible species within an interval of 21 days, during which period the animals must be isolated under quarantine from other animals or other species; Two negative Probang tests from cattle and sheep with an interval of 21 days between samples; FMD-susceptible animals must have remained in the source facilities for at least 90 days prior to movement application; Movement of animals to destination with official dispatch and previous notice; Animals must be kept isolated for 21 days at the destination, after which period premises shall be cleared of potential disease contamination after a clinical inspection of FMD-susceptible animals on the premises; Animals must be transported in sealed trucks and shall not move through zones where FMD vaccination is practiced.) (USA-61).

[179] SENASA Resolution No. 148 (March 11, 2008) (USA-62).

[180] SENASA Resolution No. 148 (March 11, 2008) (USA-62).

[181] SENASA Resolution No. 148 (March 11, 2008) (including: admission of animals susceptible to FMD from Patagonia North B to Patagonia South, to any destination and for any purpose; animals must be transported in SENASA authorized trucks with a valid truck disinfection certificate; the owner of the farm must submit to SENASA the itinerary that the truck must follow; animals must be transported in sealed trucks and must not move through zones where FMD vaccination is practiced; if animals are destined to slaughter, the shipment will be authorized only to slaughterhouses inspected and authorized by SENASA; the owner of the farm receiving the animals must communicate to SENASA within 48 hours of arrival of the animals; upon arrival to the destination farm, the animals must remain separate from all other animals of FMD susceptible species for 21 days; during that time, animals may be sent to slaughter only if authorized by the local SENASA veterinarian; and transit of animals through areas where FMD vaccination is practiced, under specific requirements) (USA-62).

C. Foot and Mouth Disease Eradication and Prevention in the United States

105. Due to constant vigilance, and the type of stringent control measures that Argentina has challenged in this dispute, the United States has not had an FMD outbreak for over 80 years. And, as discussed below, the last outbreak resulted from the import of FMD-infected products from Argentina.

106. FMD was first discovered in the United States in 1870 when infected Canadian cattle crossed the border into New England.[182] Other outbreaks of mostly limited scope followed in 1880, 1884, 1902.[183] In the early 20th Century, the United States had some severe FMD outbreaks.[184] For example, a 1902 outbreak spread across state lines, infecting animals in several New England states. Later outbreaks also affected multiple regions of the country.[185] The United States suffered its last FMD outbreak in California in 1929. The outbreak resulted from meat imported from Argentina. According to USDA records, approximately 3,600 animals were slaughtered before the outbreak was controlled.[186]

107. The United States has been FMD free for over eighty years. As a result, animals are not vaccinated against the virus.

108. To maintain this status of disease freedom, the United States has established a highly developed system to prevent the introduction of FMD into the country. This system includes preventive measures at U.S. borders (such as those challenged here by Argentina), development of preparedness and rapid response capabilities, the creation of a comprehensive FMD outbreak response strategy, and international collaboration activities.

1. The United States Maintains a Sophisticated FMD Prevention and Response System

109. The first line of defense against FMD in the United States is at the border.[187] The United States has adopted different, complementary measures to address the key pathways through which FMD could enter the country. Key potential pathways, and the corresponding control measures, are summarized below.[188]

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[182] United States Department of Agriculture, Yearbook of the United States Department of Agriculture 1915, at 20. (USA-63)

[183] *Id.* (USA-63)

[184] *Id.* (USA-63)

[185] *Id.* (USA-63)

[186] United States Department of Agriculture, The 1929 Outbreak of Foot-And-Mouth Disease in Southern California, at 15 (USA-64).

[187] GAO, Foot and Mouth Disease at 37 (USA-3).

[188] GAO, Foot and Mouth Disease at 38 (USA-3).

- Live animal imports. The United States Department of Agriculture (USDA) typically only permits live ruminants and swine to enter the United States from countries determined to be FMD free and that do not vaccinate against FMD. These animals gain entry only through designated border ports or animal import centers. A health certificate attested to by a government official from the country of origin must accompany the animal. Quarantine and testing may be required.

- Animal products. Generally, fresh, chilled, or frozen meat from cattle, sheep, and pigs and fresh milk are prohibited from countries that are not recognized by USDA's Animal and Plant Health Inspection Service (APHIS) as free of FMD. Processed meat and dairy products are allowed from FMD infected countries if they meet certain requirements. For example, meat products must be fully cooked, dry cured, or canned and shelf-stable, with all bones removed. Dairy products must be in concentrated liquid form and shelf-stable without refrigeration. Similar to live animal imports, certificates attesting to the condition of the product are required. Other materials such as grass, hay, or straw for feeding, bedding, or other purposes are also generally prohibited, if they are sourced to FMD infected countries. Animal products are inspected at points of entry to identify violations and threats.

- International passengers. This is another critical pathway. At border control, United States customs officers ask all persons crossing into the United States to declare any animal or plant products and to state whether they have visited agricultural sites. Relevant persons are searched and processed. USDA inspectors use sniffer dogs and other methods to identify potential threats at ports of entry.

- Garbage from international carriers. Waste generated during travel is also another important vector. USDA works with international carriers on protocols to minimize the risk of transmission of FMD through waste. USDA supervises the removal, transport, and safe disposal of international waste from airplanes and ships.

- International mail. U.S. Customs and USDA officials inspect international mail by hand and through the use of technology.

110. APHIS's Veterinary Services department numbers 1,858 permanent employees including veterinarians, Master of Science and Ph.D.-level scientists, animal health technicians, information technology specialists, laboratory personnel, and management and professional development staff, as of January 2010. It has 564 permanent veterinarians and 309 animal health technicians on staff. Sixty percent of those veterinarians are in the field, while 13 percent are in the National Animal Health Policy Program (NAHPP) unit.

111. Federal, state, and local agencies in the United States regularly train so that they are prepared to respond quickly and effectively to an FMD outbreak. Experts develop protocols that

reflect the many possible scenarios that may develop in the event of an outbreak. Training exercises ensure that federal, state, and local authorities can communicate effectively and address key issues such as FMD eradication, movement control, and the social and economic implications of a FMD outbreak. National Veterinary Services (NVS) training aims to ensure that it can work together with local authorities to supply vaccine and deploy them in an outbreak situation.[189] Other preparedness and response activities include:[190]

> 1) Vesicular disease surveillance: As noted, a prominent FMD symptom is the appearance of vesicules on the affected animal. APHIS rapidly responds to reported or suspected cases of vesicular conditions in the United States by investigating whether the condition results from FMD. These investigations are intended to rapidly detect and diagnose any vesicular disease in the United States.[191]
>
> 2) Other preparedness and disease models: APHIS uses various models to develop computer-generated scenarios for FMD. This allows it to evaluate the potential consequences of FMD in the United States, as well as the counter-measures, materials, and supplies need for control and eradication.[192]
>
> 3) Emergency veterinary assistance: APHIS works to assist states in training and maintaining state incident management teams and veterinary reserve corps. State groups can serve as early response teams in the event of a FMD outbreak and can educate groups on the signs, symptoms, and reporting procedures.[193]

112. A comprehensive FMD outbreak response strategy is in place should an FMD outbreak occur in the United States. The strategy includes establishing a focal point responsible for coordination of response teams in the field, developing a specific response strategy, and communicating with the public. [194]

2. United States Supports FMD Control Efforts in Other Countries

113. International collaboration is a major feature of U.S. measures to prevent the spread of FMD. These collaboration efforts include substantial cooperative efforts with Argentine

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[189] "Foot and Mouth Disease Response Plan, The Red Book," USDA, APHIS, VS, June, 2012 at 3-1 (USA-65).

[190] The following points are paraphrased and drawn from the Red Book. "Foot and Mouth Disease Response Plan, The Red Book," USDA, APHIS, VS, June, 2012 at 3-2 (USA-65).

[191] "Foot and Mouth Disease Response Plan, The Red Book," USDA, APHIS, VS, June, 2012 at 3-2 (USA-65).

[192] "Foot and Mouth Disease Response Plan, The Red Book," USDA, APHIS, VS, June, 2012 at 3-2 (USA-65).

[193] "Foot and Mouth Disease Response Plan, The Red Book," USDA, APHIS, VS, June, 2012 at 3-2 (USA-65).

[194] "Foot and Mouth Disease Response Plan, The Red Book," USDA, APHIS, VS, June, 2012 at 2-3. Specific potential responses include: "quarantine and movement control, epidemiologic investigation, appraisal and compensation, depopulation (euthanasia) of effected livestock, carcass disposal, cleaning and disinfection, active surveillance for additional cases, diagnostics, and, potentially, emergency vaccination." (USA-65)

veterinary officials. The United States worked with Argentina over many years to build its technical capacity in combatting FMD. Some examples include the following: From 1999-2009, eight Argentine scientists trained at the U.S. Foreign Animal Disease Diagnostic Laboratory.[195] The United States worked with Argentina in the 1960s to combat FMD, loaning the country $14 million in an attempt to support the country's industry.[196] In addition, from 1963 to 1967, the United States provided technical assistance in Argentina, training scientists and fostering development of laboratories to combat FMD.[197]

114. Given that transportation across land borders is a major mode of transmission, the United States cooperates closely with Mexico and Canada to eradicate and control FMD. For example, the Mexico-United States Commission for the Prevention of Foot and Mouth Disease and Other Exotic Animal Diseases was formed in 1947 as a combined U.S.-Mexican effort to eradicate FMD from Mexico. It helped to build Mexico's animal health infrastructure, and successfully helped to eradicate FMD from Mexico in 1954.[198] USDA also supports joint efforts with Mexico to track and identify FMD movements.[199]

115. The United States, Mexico, and Canada meet regularly to share information on FMD control to improve coordination in the fight against FMD. In 2000, the United States, Mexico, and Canada held joint FMD response exercises.[200] They also agreed to work closely to harmonize FMD import requirements.[201]

116. USDA also established cooperative programs with nations in South and Central America. In Panama, the USDA supports the U.S.-Panama Cooperative Program for the Prevention of Foot and Mouth Disease, which "conducts field surveillance at high-risk border points and annual training, analyzes technical data, and improves infrastructure."[202] Through a partnership with Colombia, the USDA helps to maintain a FMD-free barrier along the Colombia-Panama border.[203]

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[195] *See* Table of Veterinarians from Argentina Trained at the U.S. Foreign Animal Disease Diagnostic Laboratory (USA-66).

[196] Manuel A. Machado, Aftosa, A Historical Survey of Foot-and-Mouth Disease and Inter-American Relations 72 (1972) (USA-67).

[197] Project Data for Technical Cooperation on Foot and Mouth Disease, US AID FY 1965 Report (USA-68).

[198] GAO, Foot and Mouth Disease at 35 (USA-3).

[199] GAO, Foot and Mouth Disease at 35 (USA-3).

[200] GAO, Foot and Mouth Disease at 36 (USA-3).

[201] GAO, Foot and Mouth Disease at 36 (USA-3).

[202] GAO, Foot and Mouth Disease at 36 (USA-3).

[203] GAO, Foot and Mouth Disease at 36 (USA-3).

117. The United States also assists other nations when FMD outbreaks occur. For example, in 2001, in response to the FMD outbreak in the United Kingdom, the United States sent 327 animal health professionals, including over 300 veterinarians, to assist in control efforts.[204]

118. In sum, the United States invests considerable energy and resources in ensuring that the country remains free of FMD. It also works together with partners around the world to provide technical assistance and resources to combat this global problem

D. United States System for Protection from Foot and Mouth Disease

1. The U.S. Regulatory Approach to FMD Control

119. As described in the prior sections, the United States views FMD as a critical threat to cloven-hoofed animals and the social and economic communities that depend on them. The rigorous approach of the United States to protecting and preventing an outbreak of FMD in the country has a long-established legal and regulatory history. After the last outbreak of foot and mouth disease in the state of California in 1929, the United States prohibited the importation of animals susceptible to FMD and their products from countries where FMD existed. The United States has always taken such a strong position against any presence of FMD that live FMD virus is authorized to be used for scientific research in one, tightly controlled federal laboratory.

120. In the United States, cloven-hoofed animals are not vaccinated against FMD, but instead are raised in an absolutely FMD-free environment. In order to protect the substantial population of unvaccinated cattle and other cloven-hoofed animals that lack any FMD immunity in the United States from the introduction of the FMD virus from outside its borders, the United States implements a science-based application and authorization system, grounded on the framework articulated by the OIE and consistent with its obligations under the WTO. The purpose of this science-based application and authorization system is to prevent the introduction into or dissemination within the United States of FMD.

121. The Animal and Plant Health Inspection Service (APHIS) is responsible for preventing the introduction of the FMD virus into the United States. APHIS is a science-based regulatory agency with a broad mission to protect and promote U.S. agricultural health. These efforts support the overall mission of USDA, which is to protect and promote food, agriculture, natural resources and related issues. APHIS is responsible for conducting the technical work and issuing regulatory decisions to protect the United States from an occurrence of FMD.

2. APHIS Legal and Regulatory Framework for Authorizing Import of FMD-Susceptible Animal and Animal Products

122. APHIS follows an administrative process designed to reach a science-based determination that sets out the terms under which importation of animal and animal products can

[204] GAO, Foot and Mouth Disease at 37 (USA-3).

occur. For animal and animal products susceptible to FMD, this process begins when a country submits an application to APHIS for authorization to import. It is followed by a risk assessment process, in which APHIS scientifically evaluates the likelihood of entry, establishment, or spread of the disease. APHIS communicates the results of the risk assessment to the applicant country and other potentially affected and interested parties by publishing a proposed regulatory document in the Federal Register, the official journal of the U.S. federal government.

i. APHIS Application System

123. Because FMD is internationally recognized as one of the most contagious and easily transmitted animal diseases, the movement of FMD-carrying animals and animal products between countries that have the disease and those that do not is only permitted when the country not infected with FMD is assured that its appropriate level of protection (ALOP) will not be compromised. The internationally recognized term for the determination of the extent of an animal disease in a country or region is that country or region's "animal health status." In the words of the OIE, "[t]he animal health situation in the *exporting country*, in the *transit country* or *countries* and in the *importing country* should be considered before determining the requirements for trade."[205]

124. Since the applicant country's authorities have the most information regarding the prevalence of FMD in their own country, the United States reasonably requires that the applicant country "submit [ ] sufficient data to APHIS to allow [it] to conduct an assessment of the risk presented by potential imports from the region."[206] A region is "[a]ny defined geographic land area identifiable by geological, political, or surveyed boundaries" including ". . . [p]art of a national entity (zone, county, department, municipality, parish, province, State, etc."[207]

125. The goal of this APHIS process is to determine on the basis of a country's application whether, and under what import conditions, if any, specified products[208] from a particular region may be safely exported to the United States without introducing into or disseminating within the

[205] Article 5.1.1, OIE Terrestrial Code (2013) (emphasis added) (USA-69).

[206] Importation of Animals and Animal Products, 62 Fed. Reg. 56,002 (Oct. 28, 1997) (emphasis added) (USA-70).

[207] 9 C.F.R. § 94.0 (2013). (USA-71)*See also* 9 C.F.R. § 92.1 (2013) (USA-72).

[208] Argentina seems to assert, at para. 83 of its first written submission, that as of August 27, 2012, that APHIS no longer permits product-specific requests. This assertion is incorrect—APHIS continues to work on and accept applications to permit product-specific requests. *See, e.g.*, Information From Foreign Regions Applying for Recognition of Animal Health Status, 77 Fed. Reg. 44107, 44108 (July 27, 2012) ("While this rulemaking addresses factors we consider when assessing the disease status of a geographic area, APHIS' regulations also include commodity-based requirements that allow for the importation of a variety of products from regions not considered free of diseases of concern. These requirements are contained largely in 9 CFR part 94.")) (USA-73); Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking, at p. 2 ("Initiation of the regionalization process: The regionalization process begins when the Office of the Deputy Administrator, VS, receives a request from the Chief Veterinary Officer (CVO) of a foreign government requesting recognition of status for a particular disease or seeking authorization to export animals and/or animal products to the United States.") (USA-74).

United States the FMD virus.[209] The process is a mutually interactive one and depends on the applicant's information to be timely, accurate, reliable, and credible.

126. The application asks the exporting country to provide information on the following eight elements:[210]

- 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;
- Diagnostic laboratory capabilities;
- Surveillance practices; and
- Emergency preparedness and response/[211]

The breadth and depth of information called for is intended to help APHIS understand the potential risk posed by the importation of the animal commodities from the applicant country.

ii. APHIS's Scientific Process of Assessing and Managing Risk

127. After receiving a country's application for import authorization, APHIS begins to evaluate the information contained within it. APHIS contacts the applicant country if the information raises additional questions, and APHIS often requests the applicant country to provide supplementary material. In nearly all cases, APHIS conducts site visits to the applicant country to verify the information contained in the application. Of course, APHIS cannot visit an applicant country unless the applicant's regulatory authorities agree to the visit. It some cases, APHIS conducts multiple site visits to a country or region within a country. This may occur because of an outbreak, which raises questions with respect to disease prevalence, the ability of

[209] *See generally* 7 U.S.C. § 8303(a) (". . . [T]he Secretary may prohibit or restrict - (1) the importation or entry of any animal, article, or means of conveyance, or use of any means of conveyance or facility, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock . . . .") (USA-75).

[210] 9 C.F.R. § 92.2 (2013) (USA-76); Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking, at p. 2 "Initiation of the regionalization process," publically available at APHIS' website at http://www.aphis.usda.gov/import_export/animals/downloads/regionalization_process.pdf. APHIS clearly defines the terms used in this application process in regulation at 9 C.F.R. § 92.1 (2013) (USA-72).

[211] 9 C.F.R. § 92.2(b) (2013) (USA-76).

the veterinary authority to prevent and control the disease, and the ability of the authority to comply with APHIS's certification requirements. This is the case with respect to Argentina.

128. APHIS follows international standards in evaluating the risk of disease from an applicant country. In the case of FMD, the assessment of risk addresses the following elements:

- (1) Release Assessment: This is an analysis of the biological pathway(s) necessary for an importation activity to introduce FMD into the United States, as well as the potential for introduction or re-introduction of FMD into the country seeking APHIS authorization. A key risk factor in the release assessment is the internal control system of the country seeking APHIS authorization. This includes the ability of the country to stop FMD from crossing its borders, as well as the capacity of the country's regulators and veterinary services to detect and respond to FMD outbreaks. Critical to this is the reliability and credibility of the country's system to report outbreaks and to be transparent as to the disease situation.

- (2) Exposure Assessment: This is an analysis of the biological pathway(s) necessary for exposure of animals and humans in the United States to FMD from potential imports from the exporting country. In this case, this analysis would examine the scientific attributes of FMD virus, as well as the ways in which the virus might enter the United States, for example, through recycling of imported products that could be used in feeding of swine.

- (3) Consequence Assessment: This is an analysis of the potential damage caused by the introduction of the pathogenic agent into the importing country, in this case, the introduction of FMD into the United States. This includes all forms of direct and indirect consequences, including costs of response, economic damage and loss, environmental damage, as well as social and psychology damage to agricultural communities. As discussed earlier, it is well established that the introduction and dissemination of FMD into the United States could potentially result in total damages in the billions of dollars, depending on the severity of the outbreaks.

- (4) Risk Estimation: This is the synthesis of the results of the release, exposure, and consequence assessments to produce an overall estimate of the risks associated with the hazards identified in the hazard identification. The risk estimation takes into account the whole of the risk pathway from the hazard identified to the unwanted outcome.

APHIS communicates the results of its risk assessment and any proposed risk management measures to the applicant country and other potentially affected and interested parties by publishing a proposed regulatory document in the Federal Register, the public, official journal of the U.S. federal government. This communication process is open and interactive; all potentially affected and interested parties are invited to respond to and submit comments on the proposed

regulatory document.[212] The public comment period varies, but is in most cases a minimum of 60 days.

129. After the expiration of the public comment period, APHIS collects all the comments, reviews them, and prepares responses. It reviews the proposed regulatory document in light of these comments and revises the regulatory document as appropriate. When the comments raise issues that need additional scientific review or require APHIS to re-assess its scientific evaluation, it does so. APHIS then issues the final regulatory decision on importation, which includes the risk assessment and the conditions under which imports are authorized in order to meet the appropriate level of protection of the United States.[213]

130. Currently, APHIS has determined that 56 countries or regions are free of FMD without vaccination (that is, determined to have the same animal health status as the United States). These countries and regions are listed on the APHIS website in accordance with 9 C.F.R. § 94.1(a)(1). Argentina was the first country without the same FMD-free status as the United States to obtain authorization to import fresh, chilled, or frozen bovine meat under certain conditions, when this occurred in 1997. As discussed in Part IV, supra, and in the following section, Argentina lost that authorization as a result of massive FMD outbreaks in 2000-2002.

3. Argentina's Recent Applications for Authorization to Import Beef and to Be Recognized as FMD-free

131. As detailed below, Argentina's multiple incomplete submissions, site visit cancelations and its ongoing failure to control FMD have affected the United States' evaluation of Argentina's applications.

i. Request for the Recognition of Argentina

132. The OIE removed Argentina from the list of countries free of FMD where vaccination is not practiced on May 30, 2001.[214] In November 2002, SENASA submitted to APHIS a request to attain recognition of Argentina as a region under 9 C.F.R. §92.[215] At the time Argentina submitted its application, it was suspended from the OIE list of FMD-free countries due to the

[212] OIE Article 2.1.7 states that the "participants" should include "authorities in the exporting country and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups." (USA-77)

[213] In the event of a loss of APHIS authorization to import animal commodities due to an outbreak of FMD, a country that has been recognized by APHIS as FMD-free can reapply to APHIS for reconsideration of its status. In the case of Argentina, its re-evaluation after repeal of its import authorization is governed by the same process that it underwent when it applied for import authorization. "Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking," at p. 5, released publicly in 2012 at http://www.aphis.usda.gov/import_export/animals/downloads/regionalization_process.pdf (USA-74)

[214] 69th General Session, at 96 (USA-38).

[215] Information provided by SENASA for recognition of Argentina as a region, as defined in Section 92.2, Title 9, of the Code of Federal Regulations for Foot and Mouth Disease (FMD), (Nov. 2002) (USA-32).

2000-2002 outbreak epidemic. Thus, the OIE had not restored Argentina's status when it applied to the United States for the same recognition.

133. Upon receiving SENASA's submission, APHIS engaged in an initial review process and initiated prompt communication with SENASA.[216] The application materials revealed the depth of the epidemic by detailing the number of outbreaks, affected animals, exposed animals and attack rate, exposing considerable flaws in SENASAs monitoring efforts.[217] APHIS offered to help SENASA resolve this issue by sending the director of APHIS' Colombia office to Argentina to assist SENASA in implementing a new surveillance system to detect FMD infected beef.[218] The following month, on December 16, the United States met with Argentina, and requested technical documents to allow for the initiation of a risk analysis.[219]

134. U.S. and Argentina animal health officials met on April 23, 2003 to discuss a range of issues.[220] During the meeting, the countries confirmed that a technical team would visit Argentina in September to discuss the status of FMD.[221] Thus, contrary to Argentina's contentions,[222] APHIS acted promptly in assessing SENASA's application by scheduling site visits and reopening the U.S. market to certain beef imports.

135. As SENASA attempted to control the FMD epidemic from 2000-2002, another outbreak emerged on August 29, 2003 in the Salta province.[223] A SENASA epidemiological report performed on September 2, 2003, revealed that 16 pigs were infected, 2 of which died.[224] The OIE responded to the outbreak report by immediately suspending Argentina's status as FMD-free with vaccination.[225] SENASA's inability to maintain a prolonged absence of FMD delayed an APHIS site visit, and consequently, SENASA's request for recognition of Argentina as a region.

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[216] *See* Fax from USDA/APHIS – Buenos Aires, Argentina Area Director Donald Wimmer to SENASA President Dr. Bernardo Cane, November 6, 2002 (USA-78).

[217] Information provided by SENASA for recognition of Argentina as a region, as defined in Section 92.2, Title 9, of the Code of Federal Regulations for Foot and Mouth Disease (FMD), 16 (Nov. 2002) (USA-32).

[218] Fax from USDA/APHIS – Buenos Aires, Argentina Area Director Donald Wimmer to SENASA President Dr. Bernardo Cane, November 6, 2002 (USA-78).

[219] Letter from SENASA President Dr. Bernardo Cane to APHIS, December 30, 2002 (USA-79).

[220] Fax from APHIS Rodolfo Acerbi to U.S. Embassy in Argentina Philip Schull, April 29, 2003 (USA-80).

[221] Fax from APHIS Rodolfo Acerbi to U.S. Embassy in Argentina Philip Schull, April 29, 2003(USA-80).

[222] *See* Argentina's First Written Submission, at Part IV (D)

[223] Report of the Meeting of the OIE Scientific Commission for Animal Diseases, Appendix VI at 31, Dec. 2003 (USA-81).

[224] Facsimile from Embassy of Argentina Minister Jose Molina to APHIS Peter Fernandez, September 5, 2003 (USA-51).

[225] Report of the Meeting of the OIE Scientific Commission for Animal Diseases, Appendix VI at 31, Dec. 2003 (USA-81).

136. APHIS arranged to perform a site visit in September 2003 to the Argentina region bordering Bolivia; however, the visit was canceled by SENASA.[226] APHIS reiterated its desire to conduct the site review because the visit was important to further its evaluation of FMD in Argentina,[227] An additional site visit was scheduled to occur on October 6, 2003; however, and SENASA notified APHIS of the FMD outbreak, forcing APHIS to cancel the site review.[228] On October 3, 2003, APHIS requested additional information from SENASA to continue assessing the status of FMD in Argentina.[229]

137. SENASA's initial submission lacked sufficient information related to the 2001 and 2002 FMD outbreaks, the status of adjacent regions, the vaccination and disease control programs within the region, animal movement control and biosecurity measures, adequacy of surveillance system and the diagnostic laboratory capabilities.[230] APHIS's October 2003 letter requesting additional information also notified SENASA of the model APHIS would use to assess the risk of FMD, and the ensuing requests for additional information to develop input parameters.[231]

138. APHIS and SENASA arranged a bilateral meeting to convene in Buenos Aires on October 30, 2003.[232] Following the meeting, APHIS continued corresponding with SENASA and scheduling site visits while awaiting Argentina's supplemental submission.

139. On February 18, 2004, SENASA responded to APHIS' request for a second bilateral meeting to reconvene in Buenos Aires on March 8, 2004.[233] SENASA and APHIS participated in an additional bilateral meeting on July 28, 2004 in Buenos Aires.[234] The repeated visits and meetings demonstrate the level of attention APHIS devoted to SENASA's requests, and the progress made in evaluating the risk of FMD contamination in Argentina beef.

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[226] Letter from APHIS Pablo Kalnay to SENASA President Dr. Jorge Amaya, October 14, 2003 (USA-82).

[227] Letter from APHIS Pablo Kalnay to SENASA President Dr. Jorge Amaya, October 14, 2003 (USA-82).

[228] Letter from SENASA Miguel Santiago Campos to APHIS, August 29, 2003 (USA-83); Letter from APHIS Deputy Administrator W. Ron DeHaven to SENASA President Dr. Jorge Nestor Amaya, October 3, 2003 (USA-84).

[229] Letter from APHIS Deputy Administrator W. Ron DeHaven to SENASA President Dr. Jorge Nestor Amaya, October 3, 2003 (USA-84).

[230] Letter from APHIS Deputy Administrator W. Ron DeHaven to SENASA President Dr. Jorge Nestor Amaya, October 3, 2003 (USA-84).

[231] Letter from APHIS Deputy Administrator W. Ron DeHaven to SENASA President Dr. Jorge Nestor Amaya, October 3, 2003 (USA-84).

[232] Facsimile from APHIS Assistant Area Director Thomas C. Schissel to SENASA President Jorge Amaya, October 23, 2003 (USA-85).

[233] Facsimile from SENASA to APHIS Area Director Theresa Boyle, February 18, 2004 (USA-86).

[234] Facsimile from SENASA to APHIS Area Director Theresa Boyle, July 30, 2004 (USA-87).

140. In October 2004, an OIE Ad Hoc Group evaluated SENASA's request to retain the status of FMD-free with vaccination for Argentina.[235] At this time, APHIS had not received responses from SENASA to the request for additional information. After more than one year from the U.S. request, SENASA submitted responses to the additional information requests in November 2004.[236]

141. APHIS evaluated the additional information SENASA provided, and, in February 2005, suggested a follow-up site visit in June 2005.[237] In a letter to SENASA, APHIS articulated that the purpose of the visit was to gather data for a quantitative risk analysis, and stated that APHIS could conduct the visit on May 30, one week earlier than previously suggested.[238] On April 21, 2005, prior to the scheduled visit, APHIS requested additional information from SENASA to assist in compiling data to be used in the quantitative and qualitative risk analysis of the Argentine region north of 42° parallel.[239]

142. APHIS conducted the scheduled site visit to the Argentina region north of 42° parallel on May 30, 2005 to June 3, 2005.[240] On June 7, 2005, APHIS sent a follow-up letter to SENASA summarizing comments and observations made by its veterinary services.[241] APHIS suggested that SENASA may have expedited disease control when it was first observed during the 2000 and 2001 period had the agency not substantially delayed reporting the disease for approximately 9 months.[242]

143. A strike by SENASA personnel prompted APHIS to make an additional information request on August 4, 2005.[243] Specifically, APHIS requested information regarding the scope and degree of the strike, to assess the potential impact on the agency's ability to pursue the mission of monitoring animal health and trade.[244]

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[235] Report of the Meeting of the OIE Ad Hoc Group for Evaluation of Country Status for Foot and Mouth Disease, at 86 (October 2004) (In January 2005, the Group recommended that Argentina be recognized as FMD free with vaccination) (USA-88).

[236] Further Information Requested by USDA-APHIS of the Information Provided by SENASA to Attain Recognition of Argentina as a Region, as Defined in Section 92.2, Title 9 of the Code of Federal Regulations for Foot and Mouth Disease (FMD), November 2004 (USA-89).

[237] Letter from APHIS John R. Clifford to SENASA Minister Dr. Jose Molina, March 17, 2005 (USA-90).

[238] Letter from APHIS John R. Clifford to SENASA Minister Dr. Jose Molina, March 17, 2005 (USA-90).

[239] Letter from APHIS Thomas C. Schissel to SENASA Arturo Ortiz, April 21, 2005 (USA-91).

[240] Letter from APHIS John R. Clifford to SENASA President Jorge Amaya, July 7, 2005 (USA-92).

[241] Letter from APHIS John R. Clifford to SENASA President Jorge Amaya, July 7, 2005 (USA-92).

[242] Letter from APHIS John R. Clifford to SENASA President Jorge Amaya, July 7, 2005 (USA-92).

[243] Letter from APHIS Deputy Administrator John R. Clifford to SENASA President Dr. Jorge Amaya, August 4, 2005 (USA-93).

[244] Letter from APHIS Deputy Administrator John R. Clifford to SENASA President Dr. Jorge Amaya, August 4, 2005 (USA-93).

144. Argentina reported yet another incidence of FMD to the OIE in February 2006, which resulted in the removal of the region north of 42° parallel from the list of FMD-free zones where vaccination is practiced.[245] SENASA recorded two FMD outbreaks, both occurring in the Argentine province of Corrientes.[246] These outbreaks occurred after APHIS produced an evaluation of Argentina's FMD risk in 2005. The subsequent outbreaks called into question APHIS's findings at that time, and thus required a revised analysis.

145. APHIS contacted SENASA on June 27, 2006 to arrange a visit to Corrientes to evaluate the area affected by the FMD outbreaks.[247] APHIS proposed to conduct the visit in August.[248] One month later on September 6-8, APHIS visited the areas affected by the FMD outbreaks and performed an audit.[249]

146. In February 2009, Congress passed the Omnibus Appropriations Act. Section 737 of the Act temporarily discontinued funding for individuals to that authorized the import of meat from Argentina. The section, however, preserved the Secretary of Agriculture's ability to review a request to import meat from Argentina.[250] The section also required the Secretary to submit a report of the review to the appropriate congressional committees.[251] The Act, including Section 737, expired in September 2009, less than a year after it was adopted. Because the section did not alter the Secretary's ability to review requests for import authorizations, and was in place for a short duration, APHIS's ability to evaluate Argentina's application was unaffected.

147. APHIS continued its efforts to conclude the evaluation, and maintained communication with Argentina. In a November 2012 meeting, the United States offered to conduct a site visit to Argentina.[252] SENASA, however, did not reply until July 2013, stating that it preferred that the site visit occur during the last week of October or the first week of November 2013.[253] Ultimately, at SENASA's request the visit was scheduled for November 2013.[254]

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[245] *See* 74th General Session at 45, 144 (USA-55).

[246] *See* 74th General Session at 45, 144 (USA-55).

[247] Letter from APHIS Area Director Thomas Schissel to SENASA President Jorge Amaya, June 27, 2006 (USA-94).

[248] Letter from APHIS Area Director Thomas Schissel to SENASA President Jorge Amaya, June 27, 2006 (USA-94).

[249] Letter from SENASA President Jorge Amaya to APHIS John Clifford, July 19, 2010 (USA-56).

[250] Omnibus Appropriations Act of 2009, H.R. 1105, 111th Congress (USA-95).

[251] Omnibus Appropriations Act of 2009, H.R. 1105, 111th Congress (USA-95).

[252] Letter from APHIS Acting Associate Administrator Dr. Peter J. Fernandez to SENASA President Marcelo S. Miguez, March 13, 2013 (USA-96).

[253] Letter from APHIS Administrator Kevin Shea to SENASA President Marcelo S. Miguez, July 15, 2013 (USA-97).

[254] Letter from APHIS Administrator Kevin Shea to SENASA President Marcelo S. Miguez, July 15, 2013 (USA-97).

148. Upon concluding the site visit, the United States looks forward to moving forward with its risk analysis, and to ensure that Argentina's request has been properly considered, pursuant to the thorough and transparent rulemaking process.

ii. Request for the Recognition of Patagonia

149. Because of the long, widespread FMD outbreak epidemic in Argentina from 2000 to 2002, SENASA implemented resolutions to attempt to prevent the disease from entering Patagonia. The April 2001 Eradication Plan introduced a regionalization scheme to divide the country into 6 distinct zones.[255] SENASA also adopted a resolution to implement a sanitary barrier at the 42° parallel line, the northern border of Patagonia South.[256] In May 2001, SENASA introduced measures to ban the internal transport of live animals into Patagonia South and Patagonia North B.[257] While these initial efforts to control the spread of FMD and prevent it from being introduced into Patagonia occurred before Argentina requested recognition as an FMD free region by the United States, Argentina continuously revised its animal sanitation regulations over the next decade. Consequently, the United States needed to consider and evaluate the alterations in assessing the risk of FMD with respect to Patagonia.

150. In July 2003, SENASA submitted a formal request to APHIS requesting the recognition of Patagonia as a region free of FMD.[258] Specifically, SENASA's request was for the recognition of the area of Argentina recognized as Patagonia South, which consists of the area south of 42° parallel and is comprised of 3 provinces: Chubut, Santa Cruz and Tierra del Fuego. Argentina's request addressed the 11 factors articulated in 9 C.F.R. §92.2, similar to the request SENASA submitted to APHIS with respect to the recognition of Argentina as a region free of FMD[259]

151. On November 6, 2003, APHIS contacted SENASA regarding a December 1, 2003 site visit to Patagonia.[260] APHIS outlined its plan to visit Buenos Aires laboratories to review surveillance measures, SENASA's local offices in Patagonia to assess border security, and a slaughter facility.[261] APHIS also requested additional information from SENASA regarding the

[255] SENASA Resolution No. 5, April 6, 2001 (USA-37).

[256] Risk Analysis: Risk of Exporting Foot-and-Mouth in FMD-Susceptible Species from Argentina, South of the 42° Parallel to the United States, 32, June 2005 (USA-58).

[257] SENASA Resolution No. 58, May 24, 2001 (USA-59).

[258] Information Requested by USDA-APHIS of the Information Provided by SENASA to Attain Recognition of Argentina's Patagonia as a Region, as Defined in Section 92.2, Title 9 of the Code of Federal Regulations for Foot and Mouth Disease (FMD), July 2003 (USA-98).

[259] See Information Provided by SENASA to Attain Recognition of Patagonia as a Region, as Defined in Section 92.2, Title 9 of the Code of Federal Regulations for Foot and Mouth Disease (FMD), July 2003 (USA-98)

[260] Facsimile from APHIS Area Director Theresa Boyle to SENASA President Dr. Jorge Amaya, November 6, 2003 (USA-99).

[261] Facsimile from APHIS Area Director Theresa Boyle to SENASA President Dr. Jorge Amaya, November 6, 2003 (USA-99).

request for regional recognition of Patagonia as FMD-free.[262] APHIS evaluated SENASAs information submitted to address the 11 factors to assess the risk FMD with respect to Patagonia South at the time.[263] SENASA's initial submission failed to provide sufficient information explaining the FMD status of adjacent regions, the vaccination and disease control programs within the region, animal movement control and biosecurity measures, adequacy of surveillance system and the diagnostic laboratory capabilities.[264]

152. From December 1 -5, 2003, APHIS conducted a site visit to Patagonia South and the Patagonia buffer zone consisting of Patagonia North A and B to continue its assessment of the status of FMD in the area.[265] In a follow-up letter sent to SENASA on March 2, 2004, APHIS informed SENASA that it would need to provide additional information to allow APHIS to proceed with the risk assessment.[266] The letter also contained recommendations for SENASA to improve its laboratory diagnostic procedures and the public awareness of biosecurity measures.[267]

153. SENASA finally responded nearly a year later, on November 16, 2004.[268] This delay prolonged the United States' evaluation process.

154. In June 2005, APHIS concluded and produced the risk analysis evaluating Patagonia South as a region free of FMD.[269] Although APHIS publicized the risk analysis in 2005, the conclusions drawn were based on observations conducted during the December 2003 site visit.

155. On January 5, 2007, APHIS published a proposed rule in the Federal Register to change the disease status of Patagonia South to FMD-free.[270] During the ensuing 60-day period, APHIS received comments on the proposed rule from interested parties. There was a recognizable time gap between the data collection period (2003) and the proposed rule (2007), and APHIS made continuous efforts to visit Patagonia South to ensure that it had the most accurate, current information pertaining to the zone's FMD status.

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[262] Letter from APHIS W. Ron DeHaven to SENASA President Dr. Jorge Amaya, November 6, 2003 (USA-100).

[263] Letter from APHIS W. Ron DeHaven to SENASA President Dr. Jorge Amaya, November 6, 2003 (USA-100).

[264] Letter from APHIS W. Ron DeHaven to SENASA President Dr. Jorge Amaya, November 6, 2003 (USA-101).

[265] Letter from APHIS W. Ron DeHaven to SENASA President Dr. Jorge Amaya, March 2, 2004 (USA-102).

[266] Letter from APHIS W. Ron DeHaven to SENASA President Dr. Jorge Amaya, March 2, 2004 (USA-102).

[267] Letter from APHIS W. Ron DeHaven to SENASA President Dr. Jorge Amaya, March 2, 2004 (USA-102).

[268] Further Information Requested by USDA-APHIS of the Information Provided by SENASA to Attain Recognition of Patagonia as a Region, as Defined in Section 92.2, Title 9 of the Code of Federal Regulations for Foot and Mouth Disease (FMD), November 2004 (USA-103).

[269] Risk Analysis: Risk of Exporting Foot-and-Mouth in FMD-Susceptible Species from Argentina, South of the 42° Parallel to the United States, June 2005 (USA-58).

[270] Change in Disease Status of the Patagonia South Region of Argentina with Regard to Rinderpest and Foot and Mouth Disease, 72 Fed. Reg. 475 (codified at 9 C.F.R. 94) (USA-104).

156. SENASA then submitted an application to the OIE for the recognition of Patagonia North B as FMD-free without vaccination. Patagonia South was previously recognized as an FMD-free zone with vaccination in 2002, and SENASA's application amounted to a request for OIE to extend this recognition to Patagonia North B.[271] On February 22, 2007, after completing its evaluation, the ad hoc group submitted its recommendations to the Scientific Commission.[272]

157. On May 22, 2007, the OIE enlarged zone recognized as FMD-free where vaccination is practiced to include Patagonia North B.[273] In 2007, SENASA passed numerous resolutions to create local offices in provinces across the country. Although these measures may have demonstrated SENASA's commitment to intensify FMD surveillance, introducing additional offices creates need to ensure that they are operating properly.

158. In March 2008, SENASA introduced measures to authorize conditional transport of live animals into Patagonia South from Patagonia North B.[274] Subsequently, on October 2, 2008, APHIS contacted SENASA to arrange a site visit to Patagonia South in December.[275] The following week, SENASA replied, expressing its displeasure with the duration of the FMD assessment process; SENASA did not address the proposed site visit, however.[276] Before responding to the APHIS site visit request, SENASA introduced a resolution to relax the border restrictions on transport of live animals susceptible to FMD into Patagonia South and Patagonia North B.[277]

159. The revisions applied under Resolution No. 1282, detailed above in Part IV, however, posed potential obstacles to Argentina's ability to conform with APHIS FMD sanitation requirements. Specifically, by relaxing the border measures to allow transport into Patagonia South and Patagonia North B, Argentina's ability to comply with the slaughtering facility requirements and commingling prohibitions became questionable.[278] Although the regulatory

[271] Report of the Meeting of the OIE Scientific Commission for Animal Disease, 5, February 2007 (USA-57).

[272] Report of the Meeting of the OIE Scientific Commission for Animal Disease, 5, February 2007 (USA-57).

[273] 75th General Session, at 23 (May 2007) (USA-105).

[274] SENASA Resolution No. 148, March 11, 2008 (requiring: animals must be transported in SENASA authorized trucks with a valid truck disinfection certificate; the owner of the farm must submit to SENASA the itinerary that the truck must follow; animals must be transported in sealed trucks and must not move through zones where FMD vaccination is practiced; if animals are destined to slaughter, the shipment will be authorized only to slaughterhouses inspected and authorized by SENASA; the owner of the farm receiving the animals must communicate to SENASA within 48 hours of arrival of the animals; upon arrival to the destination farm, the animals must remain separate from all other animals of FMD susceptible species for 21 days; during that time, animals may be sent to slaughter only if authorized by the local SENASA veterinarian) (USA-62).

[275] Letter from APHIS Yvette Perez to SENASA Oscar Astibia, October 15, 2008 (USA-106).

[276] Facsimile from SENASA Oscar Astibia to APHIS Yvette Perez, October 22, 2008 (USA-107); Facsimile from SENASA Oscar Astibiato to APHIS Yvette Perez, November 11, 2008 (USA-108).

[277] SENASA Resolution No. 1282, December 16, 2008 (USA-109).

[278] *See* Restrictions on importation of meat and other animal products from specified regions, 9 C.F.R. §94.11(c)(1) (USA-110).

revisions reduced barriers to animal movement in Patagonia, these measures posed potential FMD sanitation issues that the United States would need to assess further.

160. On December 17, 2008, two months after receiving the initial site visit request from APHIS, SENASA granted approval for APHIS to visit Patagonia South in February 2009.[279] In granting the site visit request, SENASA also requested that APHIS extend the mission to cover Patagonia North B because the zone was recognized by the OIE as a region free of FMD where vaccination is not practiced.[280]

161. In February 2009, APHIS conducted a site visit to Argentina for the purpose of updating the risk assessment for Patagonia and advancing the proposed rulemaking process.[281] At this time, the revisions introduced under Resolution No. 1282 had not been completely implemented. As a result, the United States was unable to assess the impact of the changes on Argentina's FMD status.

162. As stated above, the United States and Argentina discussed a proposal to have an APHIS technical team visit Argentina to continue its evaluation in November 2012.[282] SENASA postponed the visit to November 2013.[283] APHIS visited Argentina to conduct the site review during the first week of November 2013, demonstrating its effort to conclude its evaluation of FMD in the Patagonia zone. Upon finishing the site review, the United States believes that APHIS can continue and conclude its analysis the risk of FMD with respect to Patagonia.

163. In sum, this record demonstrates four key facts: (1) FMD is internationally recognized as one of the most easily transmitted and economically devastating animal diseases; (2) Argentina has a long history of the disease and has not shown that it is able to deal with the disease effectively and credibly, going so far as to conceal the FMD threat from the international community; (3) the United States has not had an FMD outbreak in over 80 years and an outbreak would do substantial economic damage; and (4) the United States employs a science-based system to evaluate the threat of FMD from other countries, and is reviewing the situation in Argentina closely.

[279] Facsimile from SENASA Oscar Astibia to APHIS Yvette Perez, December 17, 2008 (USA-111).

[280] Facsimile from SENASA Oscar Astibiato APHIS Yvette Perez, December 17, 2008 (USA-111).

[281] Facsimile from SENASA Oscar Astibiato APHIS Yvette Perez, January 30, 2009 (USA-112).

[282] Letter from APHIS Acting Associate Administrator Dr. Peter J. Fernandez to SENASA President Marcelo S. Miguez, March 13, 2013 (USA-96).

[283] Letter from APHIS Administrator Kevin Shea to SENASA President Marcelo S. Miguez, July 15, 2013 (USA-97).

IV. LEGAL CLAIMS

A. Measure at Issue, Relevant Disciplines, and Order of Analysis

1. Measure at Issue

164. For Argentina, this dispute centers on one core grievance: the United States "failed to finalize its regulatory processes"[284] to permit Argentina to export beef to the United States. In essence, Argentina alleges that the United States has breached its SPS obligation because it has failed to finalize U.S. regulatory processes within some unspecified period of time. This alleged failure to act in a timely manner involves two rulemaking processes: First, Argentina alleges that the United States failed to complete regulations that would allow Argentine fresh, chilled, and frozen meat to be sold in the United States. Second, Argentina alleges that the United States failed to complete regulations that would designate South Patagonia as a region free of foot-and-mouth disease.

165. Notably, Argentina does not allege – nor could it – that the 2001 U.S. measure was problematic at the time of adoption**.** This key fact distinguishes the current dispute from most other disputes that have arisen under the SPS Agreement. Rather, Argentina alleges that the United States failed to modify the 2001 measure in response to what Argentina alleges are changes in pertinent facts regarding FMD in Argentina.

166. With respect to the first complaint (concerning Argentina in general), Argentina is not complaining about the adoption of the 2001 measure due to outbreaks of foot-and-mouth disease. Indeed, Argentina itself "unilaterally suspended its exports" at the time, Argentina thus acknowledges both that products from regions with FMD outbreaks should not be traded, and the seriousness at that time of the situation within Argentina.[285] Nor is Argentina complaining about other periods in which Argentina suffered foot-and-mouth disease outbreaks between 2001 and today, as Argentina references other trade partners that imposed restrictions on imports.[286]

167. Instead, Argentina is concerned with the fact that the United States has not modified its 2001 measure in the period between Argentina's last FMD outbreak and today. Yet – pursuant to U.S. regulations and Argentina's request under those regulations – a proposal to change the 2001 measure is currently under review in the APHIS regulatory system. Thus, at its core, Argentina is complaining about the time taken to review and change a fully-justified measure in response to claims that the underlying facts have changed.[287]

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[284] Argentina's First Written Submission, at para. 8.

[285] Argentina's First Written Submission, at para. 107.

[286] Argentina's First Written Submission, at para. 118.

[287] Argentina's First Written Submission, at para. 110.

168. With respect to the second complaint (concerning Patagonia South), Argentina repeats many of its same concerns. For Argentina, what is at issue is that the United States has not issued a decision on its 2003 application with respect to Patagonia South.[288]

169. To a large extent, Argentina's specific legal claims present a fundamental mismatch between its allegations of untimely regulatory processes and the WTO obligations cited and discussed in Argentina's first submission. In particular, many of Argentina's specific claims under the SPS Agreement[289] presume that the alleged failure by the United States to complete the regulatory process serves as a substantive denial of Argentina's request for import authorization. But this premise is incorrect: The regulatory finalization process is a procedural mechanism, and the length of time to complete it is not a decision on the merits of Argentina's applications pending before the regulatory agency.

170. In this respect, Argentina's situation with respect to the APHIS application system is similar in structure to the situation in *EC – Biotech*. In that dispute, complaining parties alleged, in part, that a delay caused by the European Communities in the approval of certain biotechnology products was a decision to ban the product. The panel did not agree, finding that by applying "a general moratorium, the European Communities did not give a negative substantive reply to the question '[m]ay the biotech products with pending or future applications be marketed in the European Communities?' . . . [T]he decision to apply a general moratorium was a procedural decision not to make final and favourable substantive decisions . . ."[290] The panel concluded that the decision to apply the moratorium did not constitute a substantive decision to reject all applications.[291] Instead, the moratorium was part of a premarketing approval system that remained in effect until a final approval decision was made.[292] Accordingly, the Panel found that the relevant SPS disciplines were <u>not</u> those involving substantive decisions on product safety, but rather were disciplines on the timeliness of decisionmaking.

171. Taking into consideration the conclusions in *EC–Biotech*, the measure at issue, properly construed, is the alleged failure of the United States to render a final decision in a timely manner on Argentina's two applications for import authorization and designation of FMD-free status.

2. Relevant Disciplines and Order of Analysis

172. As discussed above, the nucleus of Argentina's complaint is this: Argentina applied for import authorization and "no decision on the matter has been made by the United States

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[288] Argentina's First Written Submission, at para. 135.

[289] Argentina's claims under the SPS Agreement include: 1.1; 2.2; 2.3; 3.1; 3.3; 5.1; 5.2; 5.4; 5.6; 6.1; 6.2; 8; 10.1, and Annex C(1), as well as GATT 1994 Article I:1 and Article XI:1.

[290] *EC – Biotech (Panel)*, at para. 7.1342.

[291] *Id.*, at para. 7.1343.

[292] *Id.*, at para. 7.1351

authorities to date."[293] At base, Argentina's allegations are related to measures that govern the timeliness of the U.S. process for reviewing and amending a measure that Argentina itself recognizes was warranted at the time of adoption. Argentina is arguing that the process provided for receiving and processing applications for import authorization and designations of FMD status was not concluded in a time consistent with obligations under the SPS Agreement.

173. The SPS Agreement has two relevant disciplines on the timeliness of decisionmaking: the Annex C(1)(a) requirement "that procedures are undertaken and completed without undue delay," and the Article 5.7 requirement that "Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the [SPS] measure within a reasonable period of time." Argentina's submission addresses both Annex C(1)(a) and Article 5.7, and these are the provisions that fit Argentina's stated concerns with the U.S. measure. Accordingly, those are the provisions that the Panel should examine to resolve this dispute.

174. Furthermore, to the extent that the Panel needs to reach the other claims raised by Argentina, the two provisions about the timeliness of decisionmaking (Annex C(1)(a) and Article 5.7) should be placed first in the Panel's order of analysis. This minimizes the complications in Argentina's attempting to contort procedural concerns into substantive ones. Similarly, in presenting the U.S. legal analysis in this submission, the United States will address Argentina's claims in this order: SPS Agreement Article 8 and Annex C(1); Article 5.7; Article 5.1; Article 5.2; Article 2.2; Article 5.4; Article 5.6; Article 2.3; Article 3.1; Article 3.2; Article 6.1; Article 6.2; Article 10.1; GATT 1994 Article I:1; and GATT 1994 Article XI:1.

B. Argentina Has Not Shown that the United States Breached Article 8 and Annex C(1) of the SPS Agreement with Respect to Argentina's Requests for The Recognition of Argentina and Patagonia as Independent FMD-free Regions

175. As discussed above, two arguably relevant provisions of the SPS Agreement address the timeliness of regulatory decisions: Annex C (1)(a), and Article 5.7. In its first written submission, Argentina presents most of its arguments about timeliness of decision-making under an Annex C framework. Accordingly, the United States will address Annex C first, before turning to similar issues under Article 5.7.

176. Nonetheless, Argentina's Annex C claim presents an important threshold issue namely, whether Article 8 and Annex C apply to Member's determinations of disease-free areas. As the United States explains in subsection 1 below, these types of determinations are not in fact "control, inspection, and approval procedures" within the scope of Article 8. In subsection 2 below, the United States will go on to explain that the United States has not operated its FMD regulatory procedures with "undue delay."

[293] Argentina's First Written Submission, at para. 102.

1. Article 8 Does Not Apply to Determinations Under Section 92

177. Argentina asserts, but does not show, that the type of determination at issue in this dispute falls within the scope of Article 8. Argentina cannot support this assertion. To the contrary, an examination of the text of the SPS Agreement shows that this type of determination – involving disease-free areas of potential exporters –does not fall within the scope of Article 8.

178. Argentina's first submission illustrates the weakness of its position. Argentina argues that the U.S. procedures under Section 92 are "approval procedures" according to the following logic: "Because imports of animals or animal products from a region or country are conditioned upon the evaluation of its animal health status under 9 C.F.R. § 92.2, these procedures are analogous to the types of procedures specifically articulated in Annex C."[294] Two points are notable here. First, Argentina does not even argue that disease-status determinations under Section 92 are in fact the specific types of procedures covered by Annex C; instead, the most Argentina can claim is that they are (in some unspecified sense) "analogous" to the types of procedures covered by Annex C. Second, Argentina's argument by analogy would prove far too much, and thus fails. Argentina's argument is that because Section 92 imposes conditions on imports, section 92 must be an "approval procedure." But this argument would make Annex C apply to nearly every SPS measure; that is, most conceivable SPS measures will relate to conditions on the import or sale of an agricultural product.

179. The United States recalls the text of Article 8, which provides:

> Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

180. Two aspects of the language of Article 8 are especially important for evaluating Argentina's claim of undue delay under Annex C(1)(a) :

181. First, Article 8 makes clear that Annex C does not apply to every SPS measure; rather, it only applies to a subset of SPS measures – namely, "control, inspection or approval procedures." In this regard, a contrast with the Article 7/Annex B transparency provisions is instructive. The drafters clearly intended for Article 7's transparency provisions to apply to all measures of general application,[295] because Article 7 applies to "SPS measures," and not to a specific subset of such measures. Thus, if – as Argentina appears to believe – the drafters intended for Article 8 to apply to any SPS measure, the drafters would have used broad language like that in Article 7.

[294] Argentina's First Written Submission, at para. 610.
[295] *See* SPS Agreement, fn. 5 (stating that Annex B applies to measures which are "applicable generally).

182. Second, Article 8 explicitly states that it applies only to three specific types of SPS procedures: namely, "control, inspection and approval procedures " Article 8 makes no mention of the type of procedure at issue in this dispute, which is the procedure used in determinations involving disease-free areas.

183. In addition, Annex C provides context for what is meant in Article 8/Annex C by "control, inspection, and approval procedures." First, Footnote 7 to Annex C states that the control, inspection, and approval procedures include "sampling, testing and certification" procedures.[296] Section 92, however, applies to the "animal health status of a region", not to the sampling, testing and certification of a particular product.

184. Second, Annex C provides two specific examples of the types of approval procedures covered by the provision. Annex C specifies (1) systems for approving the use of additives, and (2) systems for establishing tolerances for contaminants. Both of these examples relate to approving or controlling particular products or substances. In contrast, nothing in Article 8 indicates that control, inspection, or approval procedures were intended to involve an examination of disease-free status.

185. Third, the specific obligations in the subparagraphs of Annex C provide further context indicating that "control, inspection or approval" procedures involve particular products or substances, rather than an evaluation of the disease status of particular regions

- Paragraph (1)(a) provides that Members must ensure that "such [control, inspection, and approval] procedures are undertaken and completed without undue delay and in no less favourable [sic] manner for imported products than for like domestic products."

- Paragraph (1)(d) provides that Members must ensure that "the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected in a way no less favourable [sic] than for domestic products and in such a manner that legitimate commercial interests are protected."

- Paragraph (1)(e) provides that Members must ensure that "any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary."

- Paragraph (1)(f) provides that Members must ensure that "any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service."

[296] SPS Agreement, Annex C (1), fn. 7.

- Paragraph c(1)(g) provides that Members must ensure that "the same criteria should be used in the siting of facilities used in the procedures and the selection of samples of imported products as for domestic products so as to minimize the inconvenience to applicants, importers, exporters or their agents."

- Paragraph c(1)(h) provides that Members must ensure that "whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned."

186. Each of these obligations, as indicated, are aimed at procedures designed to check and ensure the fulfillment of SPS measures as applied to specific products. And none of these obligations make sense when applied to the type of measure involved in this dispute, which is to evaluate the disease status of particular regions.

187. For all of the above reasons, the Panel should reject Argentina's argument "by analogy" that procedures under Section 92 are approval procedures within the scope of Article 8 and Annex C.

2. The United States Did not Engage in Undue Delay in Evaluating the Argentina Applications

188. In this section, the United States will show that Argentina has failed to establish that United States has engaged in "undue delay" within the meaning of Annex C (1) (a). in evaluating Argentina's applications.

a. Definition of Undue Delay

189. In discussing the definition of undue delay, the United States will draw on the adopted panel report in *EC – Biotech*. The determination of whether an approval procedure has been conducted without undue delay "must be made on a case-by-case basis, taking into account of relevant facts and circumstances."[297] A determination cannot be based on an assessment made in the abstract. Rather, the determination involves a case-by-case analysis "as to the reasons for the alleged failure to act with appropriate dispatch, and whether such reasons are justifiable."[298]

190. The *EC - Biotech* Panel concluded that the phrase "without undue delay" in the context of Annex C (1) (a) "requires that approval procedures be undertaken and completed with no

[297] *EC – Biotech (Panel)*, at para. 7.1497.

[298] *Australia – Apples (AB)*, at para. 437.

unjustifiable loss of time."[299] Notably, Annex C (1) (a) applies narrowly to "undue" delays, which indicates that certain time periods ("delays") in the operation of a procedure to check or ensure fulfillment of an SPS measure are permitted under the annex. The panel clarified this distinction in its interpretation of the annex, stating that the language is clear that "not every delay in undertaking or completion of approval procedures which is caused by a Member is contrary to the provisions of Annex C (1) (a), first clause."[300] Thus, in considering an undue delay claim under Annex C (1) (a), the critical determination is not whether some period of time has elapsed (e.g., that a delay occurred), but rather whether the delay was unjustifiable. Further, it is the obligation of the complaining party to establish, based on record evidence, that alleged delays are not justifiable.

191. The Panel in *EC – Biotech* articulated various considerations to be utilized in the determining whether a delay was justifiable. The Panel noted that:

192. A Member is not legally responsible for delays which are not attributable to it. Hence, delays attributable to action, or inaction, of an applicant must not be held against the Member when a determination is made regarding whether that Member has undertaken or completed approval procedures "without undue delay."[301]

193. Thus, if an applicant causes delay in the undertaking or completion of an "approval procedure", then the delay may be justified. An applicant may not interrupt the approval procedure, only then to later allege that the approval procedure has been unduly delayed by the Member receiving the application. The delays caused by an applicant or other factors are not attributable to the Member receiving the application, and should not therefore be considered an undue delay under Annex C (1) (a).

194. The approval procedures serve to "check and ensure the fulfillment of SPS measures", and a Member must have reasonable time to complete the procedure.[302] In *EC – Biotech*, the Panel acknowledged the importance of the process, and of the fact that "Members applying such procedures must in principle be allowed to take the time that is reasonably needed to determine with adequate confidence whether their relevant SPS requirements are fulfilled, if these requirements are WTO-consistent."[303] As an example, the Panel stated that additional information becoming available at a late stage of the approval procedure, which may impact a

[299] *EC – Biotech (Panel)*, at para. 7.1495.

[300] *EC – Biotech (Panel)*, at para. 7.1495.

[301] *EC – Biotech (Panel)*, at para. 7.1497.

[302] *See EC – Biotech (Panel)*, at para. 7.1539.

[303] *EC – Biotech (Panel)*, at para. 7.1498.

determination, could justify a delay.[304] The Panel acknowledged the importance of allowing members to access complete information during the approval procedure. Thus, if additional time is necessary as part of the procedure for a Member to obtain complete information, the time elapsed while evaluating the issue may be justifiable.

3. Argentina has Failed to Show that the United States Acted Inconsistently with "Undue Delay" in the Evaluation of Argentina's Application for the Recognition of Argentina as Region Free of FMD

195. Argentina asserts that its application process suffered "undue delay" because the United States has not concluded the evaluation of Argentina's request to be recognized as a region free of FMD.[305] Argentina, however, has not provided any factual support for its claim. In fact, the record shows that any interruptions in Argentina's application process were due to changing FMD conditions in Argentina, such as additional FMD outbreaks, regulatory changes that altered sanitary boundaries, and time attributable to Argentina's preparation of responses to questions by the United States.

196. In November 2002, less than one year since a 19-month long FMD epidemic, Argentina submitted an application to the United States for the recognition of Argentina as a region free of FMD.[306] The submission contained detailed information regarding Argentina's FMD outbreak epidemic between July 2000 – January 2002, including data on *previously unreported* outbreaks. Argentina's request described its analysis of the internal remedial measures taken by the animal health regulatory authority SENASA.

197. Less than one week after Argentina submitted its request, the United States contacted Argentina in order to send an APHIS veterinarian to assist with implementing its surveillance system. The following month, on December 16, the United States met with Argentina, and requested technical documents, which would allow it to commence a risk analysis. The immediate action the United States undertook in evaluating Argentina's request is consistent with Annex C (1) (a), first clause.

198. Pursuant to the evaluation, the United States conducted multiple site visits to Argentina in 2003. The sole purpose of the site visits was to advance Argentina's application by assessing the status of FMD in the region. However, the United States' originally scheduled site visit to Argentina was delayed in 2003 because of the FMD outbreaks.

199. In 2006, as the United States continued its evaluation of Argentina's request, the country reported another outbreak, which called for an additional site visit by U.S. veterinary experts.

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[304] *EC – Biotech (Panel)*, at para. 7.1498.

[305] *See* Argentina's First Written Submission, at para. 620.

[306] SENASA Application: Argentina (November, 2002) (USA-32).

200. Notably, In 2012, the United States requested a site visit to advance its efforts in the regulatory process. Argentina did not arrange for the visit to occur until the first week of November 2013.[307] The United States will examine the outcome of this site visit and will proceed with its regulatory assessment of Argenina's applications.

201. The Panel in *EC – Biotech* explains that "delays which are justified in their entirety by the need to check and ensure the fulfilment [sic] of a Member's WTO-consistent SPS requirements should not be considered 'undue.'"[308] Although Argentina argues that the delay in its entirety is unjustified,[309] consistent with the *Biotech* panel's interpretation, the United States' conduct is not undue. The period of time required to make a decision on Argentina's application are a consequence of the United States need to conduct a thorough evaluation of Argentina's ability to meet its FMD-free control requirements. .

202. Argentina relies on the overall length of time (11 years) that have been involved in the evaluation process[310] But this type of argument – involving a total period of time – represents exactly the wrong type of analysis under Annex C(1)(a). It completely avoids any discussion of the specific facts and circumstances. It completely ignores, for example, that after submitting its application, Argentina had additional FMD outbreaks in 2003 and 2006. It fails to recognize that the United States has requested necessary follow-up information from Argentina, and that for part of this period the United States was waiting for Argentina's responses. And it unreasonably discounts standard U.S. regulatory procedures that check and ensure that all stakeholders – including potential exporting Members like Argentina – have an opportunity to review and comment on draft rules. In short, the total period of time involved in a regulatory process – standing alone -- is not determinative of undue delay.

203. The United States would like to highlight in particular Argentina's failure to mention its own impact on the time period involved in the regulatory process. In this regard, the United States recalls the finding in *EC – Biotech* that delays caused by an applicant cannot be legally attributed to a Member.[311] In other words, any interruption caused by the applicant is not the responsibility of the Member, and any consequential delays are justified. During the evaluation process, Argentina has caused numerous delays.

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[307] Letter from APHIS Administrator Kevin Shea to SENASA President Marcelo S. Miguez, July 15, 2013 (USA-97).

[308] *EC – Biotech (Panel)*, at para. 7.1498.

[309] Argentina's First Written Submission, at para. 632.

[310] Argentina's First Written Submission, at para. 639.

[311] *EC – Biotech (Panel)*, at para. 7.1497.

204. Argentina notes, Argentina submitted a request for recognition as a region free of FMD in November 2002.[312] Argentina fails to note, however, that outbreaks of FMD *after* Argentina submitted an application to the United States claiming that it had FMD under control raises obvious serious concerns, especially when combined with the fact that Argentina had concealed and misled the international community as to the nature of the massive 2000-2002 FMD outbreaks. In its November 2002 request, Argentina submitted information detailing the status of FMD in the country, and the regulatory framework in place to control the disease.[313] Argentina's submission suggested that it had eradicated the disease and that it had the proper prevention measures in place;[314] however, less than a year after submitting its application to the United States, the country reported another outbreak. Again, in 2006, Argentina reported additional outbreaks, calling into question the adequacy of its ability to prevent the disease from entering its borders. The continuous outbreak reports and revisions to its control measures resulted in new information that the United States would have to consider and evaluate in its assessment process.

205. The Biotech panel refers expressly to an example of when new or additional information becomes available. A logical extension of this permitted circumstance would be the awareness of new or additional information that may not be available at the time, but potentially impactful on a Member's determination. The 2003 and 2006 FMD outbreaks created the circumstances by which additional information was available that would directly impact the United States determination of Argentina's request. The outbreaks were attributable to Argentina, not the United States, and the delay caused is not undue.

206. For all of the above reasons, Argentina has failed to meet its burden of showing that the regulatory process of evaluating Argentina's application is affected by undue delay.

4. Argentina has Failed To Show that the United States Acted with "undue delay" in the Evaluation of Argentina's Application for the Recognition of Patagonia as Region Free of FMD

207. Argentina also has failed to demonstrate that the United States acted with "undue delay" in the evaluation of Argentina's application for the recognition of Patagonia as region free of FMD. As explained above, the Panel in *EC – Biotech* noted that "both the reason for a delay and its duration are relevant considerations in determining whether a delay is 'undue.'"[315] In examining the reasons for the interruptions in the evaluation process, the following will demonstrate the Argentina has no basis for claiming that the United States has engaged in undue delay.

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[312] Argentina's First Written Submissoin, at para. 620.

[313] *See generally* SENASA Application: Argentina (November, 2002) (USA-32).

[314] *See* SENASA Application: Argentina (November, 2002) (USA-32).

[315] *EC – Biotech (Panel)*, at para. 7.1495.

208. Argentina formally submitted the request for the recognition of Patagonia as a region free of FMD in July 2003.[316] Shortly after, in November 2003, the United States undertook the evaluation process, and contacted Argentina to schedule a site visit to Patagonia in December 2003.[317] Because Argentina's initial submission did not sufficiently detail the FMD status of adjacent regions, vaccination and control programs in Patagonia and the adequacy of surveillance system, the United States requested supplemental information.[318] After concluding the December 2003 visit, the United States contacted SENASA in March 2004 to request additional information with respect to the surveillance program, the live animal movement patterns between Patagonia South and Patagonia North B, and additional practices affecting the control of FMD in the area.[319] Argentina did not provide the additional information until November 2004, over one year after the United States requested it.[320]

209. Subsequent to receiving the additional information in November 2004, the United States drafted and issued a risk analysis in June 2005.[321] The United States then initiated the rulemaking process, which resulted in a proposed rule to change the disease status for Patagonia South.[322] Based on the risk analysis, the United States was prepared to add Patagonia South to the list of FMD-free regions. The authorization was conditional, due to the region's proximity to and trading relationship with FMD-affected countries.[323] The United States recognized that FMD continued to pose a risk to Patagonia South because of its geography and trading activity – a risk that continued to exist.

210. The proposed rule in 2007 reflected the United States' intention to finalize the evaluation and authorization process. After the United States received comments to the rule, Argentina passed numerous resolutions that impacted the country's efforts to control FMD. In March 2008, SENASA introduced Resolution No. 148, which modified a November 2005 resolution on the transport of commercial goods into Patagonia South.[324] In December 2008, the introduction of Resolution No. 1282 resulted in substantial changes to the methods of detecting and preventing

[316] SENASA Application: Patagonia (July, 2003) (USA-98).

[317] Facsimile from Boyle (USDA, APHIS) to Amaya (SENASA) (November 6, 2003) (USA-99).

[318] Letter from DeHaven (USDA, APHIS) to Amaya (SENASA) (November 6, 2003) (USA-100).

[319] Letter from DeHaven (USDA, APHIS) to Amaya (SENASA) (March 2, 2004) (USA-102).

[320] SENASA Application: Patagonia (November, 2004) (USA-103).

[321] USDA, Risk Analysis: Risk of Exporting Foot-and-Mouth Disease in FMD-Susceptible Species from Argentina, South of the 42° Parallel, to the United States (USA-58).

[322] 72 Fed. Reg. 475 (USA-104).

[323] 72 Fed. Reg. 475 (USA-104).

[324] SENASA Resolucion 148/2008 (USA-142).

the spread of the disease.[325] Specifically, the resolution introduced the following substantive revisions:

- Admission of animals susceptible to FMD from Patagonia North B to Patagonia South, to any destination and for any purpose;

- Animals must be transported in SENASA authorized trucks with a valid truck disinfection certificate;

- The owner of the farm must submit to SENASA the itinerary that the truck must follow;

- Animals must be transported in sealed trucks and must not move through zones where FMD vaccination is practiced;

- If animals are destined to slaughter, the shipment will be authorized only to slaughterhouses inspected and authorized by SENASA;

- the owner of the farm receiving the animals must communicate to SENASA within 48 hours of arrival of the animals;

- Upon arrival to the destination farm, the animals must remain separate from all other animals of FMD susceptible species for 21 days; during that time, animals may be sent to slaughter only if authorized by the local SENASA veterinarian; and

- Transit of animals through areas where FMD vaccination is practiced, under specific requirements[326]

211. Resolution No. 1282 was introduced, in part, to modify preexisting surveillance and slaughtering practices. [327] However, because of the ongoing risks posed by FMD in neighboring countries, examining the revisions of Argentina's surveillance and slaughtering regulations was critical to the U.S. assessment of FMD risk to Patagonia South. These border reduction measures called into question Argentina's ability to prevent FMD from penetrating its borders. With respect to the process, these resolutions presented new information during the later stages of the U.S. evaluation process, resulting in delay.

212. The United States performed a site visit to Patagonia in February 2009, and at the time, Argentina had not fully implemented Resolution No. 1282. Consequently, the United States was

[325] SENASA Resolucion 1282/2008 (USA-109).

[326] SENASA Resolucion 1282/2008 (USA-109).

[327] *See* SENASA Resolucion 1282/2008 (USA-109).

unable to adequately assess the impact that the revisions had on Patagonia's ability to control FMD.

213. The panel in *EC – Biotech* recognized that such a situation, in which new or additional information becomes available, may justify a delay. Here, the new information consisted of Argentina's revisions to its surveillance regulations and slaughter establishment standards.[328] As outlined above in Part. IV, these revisions may have affected the United States' ability to properly assess the status of FMD in Patagonia South. Furthermore, introducing the new standards required the United States to update its evaluation, causing a delay that is justified under Annex C (1) (a).

214. Further, As noted above, the *EC – Biotech* panel acknowledged that any delays caused by the applicant are not legally attributable to the Member. Here, the delay between the receipt of application and the submission of additional information is attributable to Argentina. Argentina's initial request lacked adequate information necessary for the United States to perform and complete the evaluation process. Therefore, the delay was attributable to Argentina, and thus not undue.

215. The United States continued efforts to progress and complete the evaluation of Argentina's request by corresponding with SENASA to arrange a visit. In October 2008, the United States communicated its intention to visit Patagonia South, for Patagonia South was the only area designated in Argentina's 2003 request for regional recognition as FMD-free.[329] Two months later, Argentina responded to the request and agreed to allow the United States to visit in February 2009.[330] At this time, Argentina asked the United States to extend its evaluation to Patagonia North B.[331] This was the first time Argentina articulated a request for the United States to evaluate the FMD status of Patagonia North B. Thus, after more than 5 years from the time Argentina requested the regional recognition of Patagonia South, Argentina delivered an informal request to essentially restructure its initial application. The request was not accompanied by supporting documentation to address the factors listed under 9 C.F.R. §92.2. The request undoubtedly altered and delayed the process because the United States would need to revise its evaluation to account for the distinct geographical differences between Patagonia South and Patagonia North B. The differences affected the region's susceptibility to FMD, and the United States needed to perform a new site visit to assess the risk.

216. Because the United States' 2009 site visit did not allow it to properly evaluate Patagonia, the United States needed to schedule another visit. The United States and Argentina arranged a

[328] *See* SENASA Resolucion 1282/2008 (USA-109).

[329] Letter from Perez (USDA, APHIS) to Astibia (SENASA) (October 15, 2008) (USA-106).

[330] Facsimile from Astibia (SENASA) to Perez (USDA, APHIS) (December 17, 2008) (USA-111).

[331] Facsimile from Astibia (SENASA) to Perez (USDA, APHIS) (December 17, 2008) (USA-111).

site visit to Patagonia during the first week of November 2013[332] – a visit that will advance the United States' efforts to finalize the evaluation of Argentina's request.

217. Ultimately, Argentina has the burden to demonstrate that the evaluation process was delayed because of unjustifiable actions of the United States. Argentina has failed to do so. Argentina has drawn the legal conclusion that the delays have been undue because Patagonia South and Patagonia North B have not experienced recent FMD outbreaks and the OIE has recognized the area as FMD without vaccination. However, Argentina neglects to evaluate the circumstances involved in the regulatory process, nor has Argentina indicated a period by which the evaluation should have been concluded. The foregoing circumstances demonstrate that the United States has acted appropriately in its efforts to conclude the risk assessment, and the delays it experienced are justified and are not undue.

5. Argentina has Failed to Show that Section 737 of 2009 Omnibus Appropriations Act or Any Other Proposed Legislation has Resulted in an Undue Delay under Annex C (1)(a), First Clause, and Article 8

218. Argentina has failed to demonstrate that legislation, which has expired years ago, and legislation that was never enacted into law, results in undue delay in the evaluation process. Neither Section 737 of the 2009 Omnibus Appropriations Act nor the Foot and Mouth Disease Prevention Act of 2008 resulted in any delay, and therefore did not cause an undue delay under Annex C (1)(a), first clause, and Article 8.

i. A 2008 Legislative Proposal is Not a Measure, Never Affected Argentine Beef Imports, and Could Not Have Resulted in Undue Delay

219. Argentina has no basis for its assertion that the Foot and Mouth Disease Prevention Act of 2008 resulted in undue delay in the evaluation of Argentina's applications. In fact, the bill was a proposal that never became law.

220. Argentina nonetheless alleges that the United States has utilized political objections and legislative measures to delay the evaluation of Argentina's applications,[333] and that legislative interest is somehow supportive of Argentina's claims. Argentina has no basis for this contention. The proposed legislation was introduced to ensure the confirmation of Argentina's FMD-free status prior to authorizing meat imports, and was not, as Argentina implies, some sort of proposal for a protectionist measure.[334] Moreover, as Argentina acknowledges, the "bill was not brought

[332] Letter from Shea (USDA, APHIS) to Miguez (SENASA) (July 15, 2013) (USA-37).

[333] Argentina's First Written Submission, at para. 122 – 124 ("Argentina nonetheless alleges that the United States has utilized political objections and legislative measures to delay the evaluation of Argentina's applications").

[334] H.R. 6522, 110th Congress (2008) (USA-113).

to a vote". Because the proposed bill was never passed by the U.S. Congress or signed into law by the U.S. President, it never served as a measure affecting Argentina beef imports.[335]

ii. Section 737 of the 2009 Omnibus Appropriations

221. Because Section 737 of the 2009 Omnibus Appropriations Act has expired, it does not – as Argentina asserts -- impose a ban on import of meat from Argentina. Moreover, contrary to Argentina's claims, Section 737 did not delay the evaluation process.[336] In short, Argentina's interpretation of Section 737 is incorrect, and is based on a mischaracterization of the language.

222. The Act reads as follows:

> None of the funds made available by this Act may be used to pay the salaries and expenses of any individual to conduct any activities that would allow the importation into the United States of any ruminant or swine, or any fresh (including chilled or frozen) meat or product of any ruminant or swine, that is born, raised, or slaughtered in Argentina: *Provided*, That this section shall not prevent the Secretary from conducting all necessary activities to review this proposal and issue a report on the findings to the Committees on Appropriations of the House and Senate: *Provided further*, That this section shall only have effect until the Secretary of Agriculture has reviewed the domestic animal health aspects of the pending proposal to allow the importation of such products into the United States and has issued a report to the Committees on the findings of such review.[337]

223. Argentina neglects to recognize the provisional language in the section, which modifies the limitation on funding that Argentina alleges is an essential ban. The section preserves the USDA Secretary's ability to conduct "all necessary activities to review" a pending proposal and "issue a report on the findings" to the appropriate congressional committees.[338] Furthermore, the section no longer had any operative effective after the Secretary had reviewed the domestic animal health aspects of a pending proposal to allow imports of Argentine meat into the United States.[339]

224. Contrary to the manner in which Argentina frames Section 737, the section does not delay the Secretary of Agriculture in conducting an evaluation of a request for authorization to import meat from Argentina.. The act essentially preserved the review process USDA conducts

[335] *See* Argentina First Written Submission, at para. 124.

[336] *Contra* Argentina First Written Submission, at para. 126.

[337] Omnibus Appropriations Act of 2009 (USA-95).

[338] Omnibus Appropriations Act of 2009 (USA-95).

[339] Omnibus Appropriations Act of 2009 (USA-95).

in assessing the FMD status of a requesting country under 9 C.F.R. §92.2. Notwithstanding the provisional funding limitations, the Secretary maintained the ability to review a proposal and issue a report to congress in furtherance of proposal.

225. Argentina argues that Section 737 is analogous to Section 727 (involving poulry) of the Omnibus Appropriations Act of 2009 because Section 727 imposed a funding restriction on the USDA to establish or implement a rule that would allow importation of a product.[340] Argentina cites the panel report in *US – Poultry* to support the argument that Section 737 served as an import ban, and consequently resulted in undue delay.[341] In examining the panel report in *US – Poultry*, it is evident that Argentina failed to acknowledge the significant difference between Section 727 and Section 737. The sections imposed different measures, applied to different products and resulted in different effects on USDA's ability to review an import application.

iii. Section 737 is not similar to Section 727

226. Under Section 727, no funds could be used to "establish or implement a rule allowing poultry products to be imported into the United States" from China.[342] Also, at the time of the dispute, the funding prohibition was still in effect. The Panel in *US – Poultry* concluded that the section thereby eliminated the possibility for the Food Safety and Inspection Service (FSIS) to complete its equivalence determination process.[343] Because Section 727 "completely foreclosed the possibility for 'completion' of the FSIS equivalence process" in an unjustifiable manner, the delay was undue.[344] In contrast, Section 737 has long expired. And, even when it was in effect, it did not completely foreclose the Secretary's ability to complete the review process. In fact, the section explicitly provided that it "shall not prevent the Secretary from conducting all necessary activities to review" a proposal and "issue a report."[345] Thus, Section 737, unlike Section 727, did not prohibit the Secretary's ability to establish or implement of a rule; Section 737 actually preserved the Secretary's capacity to conduct necessary activities to review a proposal and issue findings.[346]

227. Furthermore, for these reasons, Argentina has no basis for asserting that Section 737 results in undue delay. As stated above, Section 737 did not eliminate the Secretary's ability to

[340] Argentina's First Written Submission, at para. 702.

[341] *See* Argentina's First Written Submission, at para. 712 – 714.

[342] Omnibus Appropriations Act of 2009 (USA-95).

[343] *US – Poultry (Panel)*, para. 7.385.

[344] *US – Poultry (Panel)*, para. 7.392.

[345] Omnibus Appropriations Act of 2009 (USA-95).

[346] Omnibus Appropriations Act of 2009 (USA-95).

review Argentina's applications. In fact, the United States visited Argentina in February 2009 to continue the assessment of FMD. After the visit, the United States continued its evaluation process, demonstrating that Section 737 did not stall the assessment, contrary to Argentina's assertions. Thus, Section 737 did not restrict the United States' ability to continue assessing Argentina's applications, and therefore did not impose a delay.

C. U.S. Measures with Respect to Argentina Are Justified Under Article 5.7

228. This dispute is about the length of time required to issue a regulatory decision on Argentina's applications for import authorization and FMD-free status. As noted, Annex C contains an obligation with respect to the timeliness of decisionmaking. However, as explained in Section B above, Annex C does not apply to the type of disease-free determination at issue in this dispute. Accordingly, in evaluating Argentina's complaints, the Panel may consider it appropriate to apply the obligation in Article 5.7 with respect to the timeliness of the review of SPS measures.

229. In particular, Article 5.7 of the SPS Agreement provides that "[i]n cases where relevant scientific evidence is insufficient," Members may take provisional measures based on "available pertinent information." In those instances, Members "shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly, within a reasonable period of time."

230. As discussed in Part IV.A, *supra*, Argentina's complaints concern the alleged failure of the United States to complete a regulatory process based on an application submitted by Argentina for (1) authorization to import fresh, chilled and frozen beef and (2) designation of Patagonia South as an FMD-free region under APHIS regulation. In short, Argentina seeks the completion of the rulemaking phase and issuance of the authorization.

231. Argentina's allegations are directed at the APHIS application system, which in this case, based on the pertinent information available about the FMD outbreaks in Argentina, provisionally considers Argentina to continue to be a potential FMD infection threat until APHIS reviews additional information derived from the application submitted by Argentina seeking import authorization.

232. The Appellate Body articulated four prongs to determine whether a measure was properly deemed provisional: (1) the measure was imposed in a situation where relevant scientific information is insufficient to conduct a risk assessment; (2) the measure was adopted on the basis of available pertinent information; (3) the Member imposing the measure seeks additional information necessary for a more objective assessment of risk; and (4) the Member reviews the measure within a reasonable period of time.[347]

1. Application of the APHIS System to Argentina with Respect to Fresh, Chilled, and Frozen beef was proper under Article 5.7

[347] *Japan–Agricultural Products II (AB)*, at para. 89.

233. The application of the APHIS system and the 2001 Regulations, which removed Argentina's prior authorization for the importation of certain meat products due to the 2000-2002 FMD outbreaks and required it to show that it could export product consistent with maintaining the FMD-free status of the United States, were clearly justified when adopted as Argentina implicitly concedes. Subsequent to their adoption, Argentina submitted applications in which it claimed to have regained disease-free status for parts of its territory. While the U.S. review of Argentina's requests for recognition as disease-free is ongoing, the regulations are justified under Article 5.7 and fully conform to the procedural obligations of that article.

234. First, the APHIS system and the 2001 Regulations were effective during a period in which Argentina had been experiencing FMD outbreaks for a series of months. Based on a series of outbreaks between July 2000 and January 2002, affecting 152,619 animals and exposing 2,783,642 animals to FMD, removing Argentina's authorization was clearly appropriate.[348]

235. Argentina itself voluntarily ceased exporting to other Members.[349] Other Members such as the European Union and Chile also removed their import authorizations in place for Argentina. The OIE itself formally suspended the FMD-free with vaccination designation that it granted Argentina in 2001.[350] Subsequently, Argentina experienced additional outbreaks in 2003 and 2006 further justifying those measures. Argentina has made applications in which it argues that its disease status and risk profile have changed. However, the scientific evidence to accept or reject those applications must be developed and evaluated; therefore, from the time of those applications, the regulations have been imposed in a situation of insufficient information to complete a risk assessment.

236. Second, the measures were based on available information—namely the reports and acknowledgment by Argentina of serious FMD outbreaks. As noted above, the outbreaks were large and sustained, and it was not clear when and how they would be contained. At the time of Argentina's applications alleging a change in disease status, the regulations were based on available pertinent information until such time as the change in status could be accepted or rejected.

237. Third, upon Argentina's request for re-authorization to import in November 2002, the United States, through the provisions of 9 C.F.R. § 92.2, sought and requested additional information to ascertain the FMD status of Argentina. APHIS and Argentina's regulatory authority, SENASA, were exchanging information when Argentina suffered additional outbreaks in 2003 and 2006.

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[348] *See* Part III.B.

[349] Argentina's First Written Submission, at para. 107.

[350] OIE 69th General Session Final Report, at 96 (USA – 114).

238. After these outbreaks, APHIS sought additional information through its application process from Argentina, including explanations of the FMD status of adjacent regions, the vaccination and disease control programs within the region, animal movement control and biosecurity measures, adequacy of the surveillance system and the diagnostic laboratory capabilities.[351] Additionally, Argentina's concealment of outbreaks, as described in more detail in Part III.B, raised serious issues. Outbreaks in 2003 and 2006 in Argentina also complicated the understanding of FMD in Argentina. (The OIE again suspended Argentina's status in both those instances.) APHIS arranged visits to areas affected by the 2003 and 2006 outbreaks, and requested information regarding a labor strike by SENASA personnel in 2005.[352] These instances demonstrate the complexities the United States has encountered during its evaluation of FMD in Argentina.

239. In order to finalize the process, APHIS requested in November 2012 that SENASA allow it to conduct a site visit.[353] SENASA did not reply until July 2013 and suggested that APHIS travel to Argentina in November 2013.[354] Thus, the United States has sought and is seeking additional information for a more objective assessment of risk from imports of Argentine beef.

240. Fourth, considering the ongoing attempt of the United States to seek information from Argentina, and the latter's response time, the period for review has been reasonable. The legal and factual issues raised under Article 5.7 are similar to those articulated in Part IV.B above concerning allegations of undue delay in connection with Article 8 and Annex C(1). For the same reasons articulated in Part IV.B, incorporated here by reference, Argentina has not established that the United States has not sought to obtain necessary information and review a measure within a "reasonable period of time". The United States is committed to completing the review process, of which a necessary step is the site visit which it will conduct in November 2013.

2. The Review of Argentina's Application with Respect to Patagonia South was Proper Under Article 5.7

241. Similarly, the continuing review of Argentina's request to consider Patagonia South as disease-free also fulfills the Article 5.7 criteria discussed above. First, at the time of Argentina's application to APHIS to consider that the region of Patagonia South as disease-free, the United States had insufficient data to make any judgment on the status of Patagonia South. Until the time of Argentina's application, Patagonia South had been considered to be part of the larger sanitary region of Argentina. In fact, Argentina's application for authorization to import fresh, chilled, and frozen beef was to cover the whole country, including Patagonia South. It was in August 2003 that Argentina submitted initial information under 9 C.F.R. § 92.2 to APHIS for

[351] APHIS, Clarification of Information Requested for Recognition of a Region (USA-115).

[352] *See* Part III.D.

[353] Letter from Fernandez (USDA, APHIS) to Miguez (SENASA (March 13, 2013) (USA-96)

[354] Letter from Shea (USDA, APHIS) to Miguez (SENASA) (July 15, 2013) (USA-97)

purposes of determining whether Patagonia South (not Patagonia North B) was a region free of FMD.[355]

242. Second, the U.S. review of Argentina's application is clearly designed to obtain the additional information from Argentina necessary to conclude whether Patagonia South is FMD free and review the 2001 Regulations accordingly within a reasonable period of time. The review is based on scientific information—that FMD is an internationally recognized highly contagious and dangerous disease—and that Argentina has experienced outbreaks of FMD during a relevant period. The OIE provides that the animal health status of the exporting country must be determined before imports are to be permitted.[356] Given Argentina's record of FMD outbreaks, and the fact that Argentina itself had, until this time, considered Patagonia South as part of the larger Argentina region, the need for more information was clear.

243. Third, APHIS sought information from Argentina through its review of Argentina's application. It continued to seek information after the draft rule on Patagonia South because of the changing sanitary conditions in Patagonia South and Patagonia North B, which are addressed extensively at Part III.B and Part III.D. In short, Argentina established areas called "Patagonia South" and "Patagonia North B" in 2001 through resolutions that imposed various conditions on the entry and exit of FMD-susceptible animals. These conditions were altered a number of times in 2002, 2005, and 2008. The effects and implications of these changing conditions are important, since it involves the movement of FMD-susceptible animals. Moreover, Argentina's initial request for APHIS recognition was for Patagonia South, not Patagonia North B. It then expanded its request to cover Patagonia North B. APHIS is reviewing this expanded request.

244. Fourth, given the complex procedural process and historical timeline, the period for review has been reasonable. The facts and issues raised claims under Article 8 and Annex C(1) are similar in nature to the ones discussed under Article 5.7. For the same reasons articulated in Part IV.B, there is no basis for the panel to find that APHIS violated the "reasonable period of time" standard. As stated earlier, APHIS approached Argentina in November 2012 with respect to conducting a site visit that would address the whole Patagonia region. Argentina did not respond in the affirmative until July 2013, at which time it proposed November 2013 as an acceptable date. The United States is committed to completing the review process, of which a necessary step is the site visit which it will conduct in November 2013.

245. For the foregoing reasons, the U.S. measures fulfill the requirements of Article 5.7.

D. U.S. Actions with Respect to Argentina's Importation of Beef Are Consistent with Articles 5.1 and 5.2 of the SPS Agreement

246. As noted above, the core concern articulated by Argentina is that the United States has not completed its review of Argentina's requests for import authorization due to an alleged

[355] Argentina's First Written Submission, at para. 135.

[356] OIE Terrestrial Animal Health Code Chapter 5.3.3 (USA-19).

change in disease status. That procedural concern is one that may be examined in the light the procedural obligations in Article 5.7 of the SPS Agreement. Because it is justified under Article 5.7, the U.S. 2001 Regulations currently under review are consistent with Articles 5.1 and 5.2.[357]

247. While it should not prove necessary to undertake a review of the U.S. measures under Articles 5.1 and 5.2, the United States nonetheless in this part explains that at the time of adoption the regulations were based on an assessment of risks as appropriate to the circumstances, and those circumstances have not been demonstrated to have changed.

248. Article 5.1 of the SPS Agreement states that "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations." The Appellate Body clarified that compliance with Article 5.1 requires an evaluation of whether there is a "rational or objective relationship between the SPS measures and the scientific evidence and between the SPS measures and the risk assessment."[358] The U.S. measures are rationally and objectively connected to both the scientific evidence and the risk assessment.

249. Elaborating upon Article 5.1's assessment of risks, Article 5.2 provides that "Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and other treatment." Article 5.2 "sheds lights on the elements that are of relevance in the assessment of risks foreseen in paragraph 1."[359] Article 5.2 lists various factors that a Member shall "take into account," but the Appellate Body has, in interpreting the similar phrase "taking into account" in Article 5.1 has found that it means that "failure to respect each and every aspect . . . would not necessarily, per se, signal that the risk assessment on which the measure is based is not in conformity with the requirements of Article 5.1."[360]

1. The 2001 Regulations Removing Argentina's Authorization to Export Fresh, Chilled, and Frozen Beef Is Consistent with Articles 5.1 and 5.2

250. The 2001 Regulations that removed Argentina's authorization to export fresh, chilled, and frozen beef occurred during the midst of the largest FMD outbreak in Argentina in recent history. The removal of this authorization was directly a consequence of the FMD series of outbreaks in Argentina during the period 2000-2002. Between July 2000 and January 2002,

[357] Were the Panel to consider the review of the 2001 regulations under Article 8 and Annex C, the United States has also demonstrated that there is no inconsistency with these provisions either.

[358] *Australia – Apples (AB)*, at para. 208.

[359] *Australia – Apples* (Panel), at para. 7.211.

[360] *Japan – Apples (Panel)*, at para. 8.241.

outbreaks in Argentina affected approximately 152,619 animals and exposed approximately 2,783,642 animals to FMD.

251. In response to the 2000-2002 outbreak of substantial proportions, which had exceeded the control of the Argentine veterinary authorities, Argentina itself voluntarily ceased export.[361] The OIE removed Argentina from the list of FMD free with vaccination countries. The implication of this was to treat Argentina as an "FMD infected country" because an FMD infected country is defined by the OIE as "a country that does not fulfill the requirements to qualify as . . . an FMD free country where vaccination is practiced."[362] These facts were sufficient for the United States to remove Argentina's authorization to export fresh, chilled, and frozen beef due to the outbreak. When it had removed the authorization, the outbreaks were still ongoing, and so the FMD situation and Argentina's inability to control FMD was apparent.

252. In removing the import authorization, the United States was not permanently prohibiting Argentina from regaining its import authorization. Instead, the removal returned Argentina to the *status quo ante* that if Argentina sought to export to the United States, it would have to demonstrate that it had reduced the risk of FMD to a level that would not allow the introduction and dissemination of FMD into the United States. This is the very same process—loss of designation followed by reapplication—that the OIE employed.

253. Argentina argues in paras. 249-252 that the SPS Agreement required the United States to undertake a "risk assessment" at the time before implementing the 2001 Regulations. The assessment appropriate to the circumstances with respect to the 2001 Regulations is the well-established body of scientific evidence discussed at length at Part III that shows that FMD is one of the most highly contagious and devastating animal disease. These facts together with the facts of the outbreak in Argentina discussed in Part III.B, were a sufficient assessment of the risk to animal life or health. In fact, Argentina itself acknowledged the risk of transmission of FMD in 2001 by voluntarily ceasing export of its <u>own</u> product.[363] The removal of Argentina's authorization was clearly based on a scientific assessment "appropriate to the circumstances."

254. In its submission, Argentina also introduces an irrelevant and potentially misleading discussion regarding the administrative process in the United States. Argentina states that the first step taken by the United States to prohibit Argentine beef was taken in June 2001 and was an interim or "provisional measure."[364] It then implies that the December 2001 final rule was a "permanent ban" and thus required a risk assessment.[365]

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[361] *See, e.g.*, the acknowledgment at paragraphs 99 and 107 in Argentina's First Written Submission.

[362] OIE Terrestrial Animal Health Code Chapter 8.6.7 (USA-23).

[363] *Id.*

[364] Argentina's First Written Submission, at paras. 250 and 251.

[365] *Id.*, at paras. 250-252.

255. Argentina is mistakenly reading terms of art of U.S. domestic law as though they were terms in SPS Article 5.1 requirements. The "interim rule" issued in June 2001 is "interim" for U.S. law purposes because it was a rule issued by APHIS made effective less than 30 days after publication in the Federal Register and without prior public notice and comment. The Federal Register is the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations. The "interim" designation was necessary to comply with the exception under the Administrative Procedure Act,[366] 5 U.S.C. § 553(b)(3)(A), for issuance of rules that would otherwise not satisfy the procedural requirements of U.S. law. The exception was applicable because of the fast moving nature of Argentina's FMD outbreak. The "final" rule was issued in December 2001 in accord with the U.S. Administrative Procedure Act.

256. For purposes of this dispute however, the status of the APHIS action under U.S. law does not invoke any different requirement under the SPS Agreement. The 2001 Regulations certainly did not mean that the United States was required to conduct a further inquiry into the situation in Argentina. It may have even been the case that Argentina might not have been interested in exporting its animal and animal products until such time that it felt comfortable that it had regained control of its sanitary situation.

2. The 2001 Regulations Are Consistent with Articles 5.1 and 5.2 with Respect to Argentina's Request to Export Fresh, Chilled, and Frozen Beef

257. The 2001 Regulations were justified as a response to the massive FMD outbreak that spanned 2000-2002. They continue to be justified by the assessment made at the time as APHIS is in the process of reviewing and evaluating Argentina's application. This current review and evaluation by APHIS is the basis for the position of the United States that claims under Article 5 are more appropriately addressed by Article 5.7, discussed above. In the alternative, the 2001 Regulations are appropriate to the circumstances pending the completion of the review of Argentina's application.

258. As discussed in Part III.D, after Argentina submitted an application for authorization to export, the United States began the process of reviewing Argentina's application materials. The record is lengthy with respect to the back and forth between the two countries. The record also demonstrates that it takes a substantial amount of time to conduct these inquiries, ask questions, and obtain replies. For example, Argentina submitted its application for recognition of Argentina as a region free of FMD to APHIS in November 2002. The application materials included information and supporting data detailing Argentina's FMD control infrastructure.[367] The United States performed a site visit in February 2003 and was evaluating all the data when a subsequent FMD outbreak in Argentina in August 2003 forced the United States to reconsider

[366] The Administrative Procedure Act (APA) governs the process by which Federal agencies propose and establish new regulations. The APA generally requires agencies to provide public notice and seek comment prior to enacting new regulations.

[367] SENASA Application: Argentina (November, 2002) (USA-32).

Argentina's situation, thereby complicating the review process. In October 2003, the United States requested additional information from Argentina to supplement its application. Argentina did not provide this information until November 2004.

259. In the case of Argentina in particular, the ability of regulatory authorities to control FMD within its borders is a valid and open question. Argentina's actions in the 2000-2002 outbreak period reflected a clear policy of concealment of FMD and a problem in maintaining border and internal controls to contain and eliminate the virus. Throughout the 2000s, Argentina's situation with respect to FMD was unstable. Argentina applied to the OIE in 2002 for FMD free status and obtained it in May 2003, only to lose it 3 months later due to an outbreak in Argentina. It then regained its OIE designation in May 2005, only to lose it again a short time later in 2006. Argentina finally regained its most recent designation in 2007.

260. The assessment that supported the 2001 Regulations is still appropriate to the circumstances pending the conclusion of the evaluation by APHIS of Argentina's request for import authorization. To suggest differently, as Argentina's interpretation does, would not be reasonable as it would require a country to allow in product from a country with demonstrated FMD infection. Argentina's interpretation would be contrary to all the scientific evidence that shows the high risk of FMD transmission due to its highly contagious nature. In the case of Argentina, given the subsequent outbreaks of FMD in 2003 and 2006, following Argentina's interpretation would have meant that FMD-contaminated product could have entered the United States.

261. As stated in Part III, the United States has sought to obtain information from Argentina to assess the current state of regulatory controls and the sanitary situation there. The United States made an offer in November 2012 to Argentina to conduct a site visit,[368] and Argentina did not accept that offer until July 2013.[369] Then, at the request of Argentina, the site visit date was set for early November 2013.[370] The United States is looking forward to the opportunity to obtain the data necessary for a current risk assessment and to move forward with its regulatory process.

3. The 2001 Regulations with Respect to Patagonia Are Consistent with Articles 5.1 and 5.2

262. First, as discussed above, the 2001 Regulations were a response based on an assessment of risks based on the substantial and undeniable scientific evidence of an unchecked FMD large scale outbreak in Argentina. The substantial and undeniable scientific evidence included the facts elaborated at length in Part III.A, Part III.B, and Part III.D, with respect to the dangerous nature of FMD and the failure of Argentina to control it. Patagonia is a part of Argentina and was subject to the same overall internal controls as the rest of the country at that time. These

[368] Letter from Fernandez (USDA, APHIS) to Miguez (SENASA (March 13, 2013) (USA-96).

[369] Letter from Shea (USDA, APHIS) to Miguez (SENASA) (July 15, 2013) (USA-97).

[370] Letter from Shea (USDA, APHIS) to Miguez (SENASA) (July 15, 2013) (USA-97).

were national controls that had been breached repeatedly. Accordingly the application of the 2001 Regulations based on the outbreak situation was consistent with Article 5.1 and Article 5.2.

263. Second, as stated above, the assessment of the risk raised by the situation in Argentina made with respect to the 2000-2002 series of outbreaks is appropriate pending the conclusion of APHIS evaluation of the Patagonia South application. In the case of Patagonia, the risk assessment process has not been completed because of the changing nature of Argentina's application with respect to that region.

264. In 2003 Argentina requested recognition of FMD freedom for the specific region known as Patagonia South, which is the region south of the 42nd parallel. This application resulted in an APHIS site visit in December 2003, a draft risk assessment document in 2005 (based on the 2003 site visit) and an APHIS proposed rule that was published in 2007, based on the 2005 risk assessment. This proposed rule was premised on Argentina's proffer that Patagonia South would be separated, in sanitary terms, from North B. At that time, Patagonia North B, in the view of Argentina, was a region described as a "buffer area" in which vaccination was alleged not to be practiced. As described in Part III.B and Part III.D, in 2008, Argentina began the process of reducing requirements for the movement of live bovine between Patagonia North B and Patagonia South by amending various Resolutions. While there was no implementation yet of any reduction of the border between the two areas, the changing sanitary conditions proposed by Argentina would affect the situation in Patagonia South, which was the subject of APHIS examination. Argentina rejected requests for an APHIS site visit throughout 2008. It was not until APHIS requested a site visit in October 2008 did Argentina finally respond positively, in December 2008. The site visit took place in February 2009 in Patagonia South and Patagonia North B.

265. This procedural history is necessary to understand because APHIS was working with a moving target on the Argentina side. APHIS had to re-evaluate the situation in Patagonia South because the regulatory conditions in 2007-2008 were likely to change in the region. (This conclusion is clearly validated by the fact that Argentina went on to merge Patagonia North B into Patagonia South and seek OIE recognition of that combined area.) In order to complete the assessment of the current situation in Patagonia, a site visit was necessary, but Argentina did not grant permission until December 2008.

266. As in the case of Argentina's application for authorization to import certain beef products, the application for Patagonia was not a simple situation. There were a number of moving parts in a rather complex FMD sanitary situation. Argentina points out multiple times that South Patagonia had not had an FMD outbreak since 1976—that fact alone is not dispositive of the inquiry. The fact is that an inquiry into the risks posed by a particular region is one into the sanitary controls and the changes in that landscape.

267. All this points to the fact that APHIS requested permission from Argentina to conduct a site visit to review the system and situation in Argentina in 2012. As discussed, Argentina did not respond until July 2013, and requested that the site visit occur in November 2013. Argentina

insists on pursuing litigation, when the United States is moving forward with its regulatory process.

E. U.S. Measures with Respect to Argentina's Importation of Beef Are Consistent with Article 2.2 of the SPS Agreement

268. Article 2.2 provides that "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal, or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5."

1. Because U.S. Measures are Consistent with Article 5.7, They are Consistent with Article 2.2

269. The United States maintains that its measures are consistent with Article 2.2 because they are consistent with Article 5.7, for the reasons elaborated in the previous sections. As set out in Article 2.2, the obligation not to maintain a measure without sufficient scientific evidence expressly sets out an exception: "except as provided for in paragraph 7 of Article 5." Therefore, a measure that is consistent with Article 5.7 will not be inconsistent with Article 2.2.[371]

2. Argentina Has Not Met its Burden of Proof to Show that the United States Is Taking Measures Inconsistent with Article 2.2

270. Article 2.2 contains three separate requirements: "(i) the requirement that SPS measures be applied only to the extent necessary to protect human, animal or plant life or health; (ii) the requirement that SPS measures be based on scientific principles; and (iii) the requirement that SPS measures not be maintained without sufficient scientific evidence."[372]

271. It is well established that "it rests upon the complaining party to 'establish a prima facie case of inconsistency with a particular provision of the SPS Agreement'"[373] Argentina simply has not met its burden.

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[371] As noted above, the United States considers that the procedural concerns raised by Argentina are better analyzed under Article 5.7. Were the Panel to consider them under Articles 5.1 and 5.2, however, we have explained in the alternative that the measures would be consistent with those provisions. As Argentina's Article 2.2 is based on the same arguments as those for its claims under Articles 5.1 and 5.2, Argentina's Article 2.2 claim would fail for the same reasons.In addition, U.S. measures are consistent with Articles 5.1 and 5.2 of the SPS Agreement, and, as a result, cannot be held to be inconsistent with Article 2.2 on those grounds. *Australia – Apples (AB),* at para. 262.

[372] *US – Poultry (Panel),* at para. 7.144.

[373] *Japan – Apples (AB),* at para. 152.

3. U.S. Measures are Consistent with Article 2.2's Obligation to be Applied Only to the Extent Necessary to Protect Animal Health

272. Argentina's only argument for satisfying the first requirement of Article 2.2 is this: "The circumstances that motivated the withdrawal of the authorization of imports of fresh beef from Argentina . . . are outdated by several years."[374] This is mere assertion, without any relevant scientific evidence for support. Argentina states that its last outbreak was in 2006—yet this is not dispositive of the matter. The FMD risk of a country is not only determined by when was its last outbreak, but also by a series of other factors described in Part III.D, including the quality of the country's internal controls and its credibility in disease surveillance and reporting. Argentina provides no scientific evidence or assessments.

4. U.S. Measures Are Based and Maintained on Scientific Principles

273. The second requirement under Article 2.2 is that SPS measures be based on scientific principles and this "requires that there be a rational or objective relationship between the SPS measure and the scientific evidence."[375]

274. The 2001 Regulations and the requirement that Argentina obtain re-authorization for importation has a "rational or objective relationship" to the scientific evidence because all parties, including Argentina, agree with the OIE that FMD is an extremely dangerous, contagious and debilitating animal disease. As the OIE Code itself provides: "Before trade in animals or their products may occur, an importing country must be satisfied that its animal health status will be appropriately protected."[376] Argentina has presented no argument or evidence different than that addressed under sections addressing Articles 5.7, 5.1, and 5.2 previously. Maintaining the 2001 Regulations in the meantime is based on scientific principles related to transmissibility and consequences of the disease. Therefore, Argentina has not established that the U.S. measures are not based on scientific principles.

5. U.S. Measures Are Consistent with Article 2.2 for Argentina's Application Regarding Authorization for Importation of Fresh, Chilled, or Frozen Bovine Meat

275. The third requirement under Article 2.2 is that that SPS measures not be maintained without sufficient scientific evidence. Where a Member is provisionally applying a measure and seeking to obtain additional information necessary for a more objective assessment of risk, the obligation does not apply. This is the situation here as the United States reviews the requests of Argentina asserting a change in its disease status. Thus, the United States would not see this obligation of Article 2.2 as pertinent in this dispute.

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[374] Argentina's First Written Submission, at para. 268.

[375] *Japan – Agricultural Products (AB)*, at para. 84.

[376] OIE Terrestrial Animal Health Code Chapter 5.3.3 (USA-19).

276. In relation to the adoption of the 2001 regulations and the requirement that Argentina obtain import re-authorization, the record is replete with sufficient scientific evidence to support those measures. As was discussed at length in Part III.B regarding Argentina's history of FMD, Argentina's recent experience with respect to FMD is checkered. After submitting its application for import authorization in late 2002, mere months after the devastating outbreaks of 2000-2002, which were exacerbated by its own cover ups, Argentina had an outbreak in 2003. This was then followed by another outbreak in 2006. It is fully consistent with the scientific record for APHIS to maintain the 2001 Regulation while APHIS conducts a review of Argentina's FMD situation and the credibility of its internal controls.

277. Again, Argentina has provided no scientific evidence to meet its burden of proof. Argentina returns to the point that there were favorable risk assessments in 1997 and 2000—and obliquely acknowledges the massive outbreaks in 2001 with the nuanced phrase "events in 2001."[377] Argentina should not hide now as it hid then—the outbreaks in 2001 clearly showed that there was a large and unchecked problem, which were confirmed by further outbreaks after Argentina declared itself to be "all clear" of FMD.

278. With respect to Patagonia, not only are the above considerations relevant because Argentina's SENASA exercises regulatory authority over the whole country, but also the record provides an additional basis for support of the U.S. measures. The fact is that Argentina itself had altered the sanitary conditions in Patagonia South and Patagonia North B, requiring the United States to reassess the situation prior to issuing any regulatory determination on FMD status.

279. First, Argentina applied for FMD-free status for the region of Patagonia South. This region was bounded by the 42nd parallel. APHIS completed a risk analysis on this region in 2005 based on data in 2003. A proposed rule was promulgated in 2007 based on that risk analysis. Argentina began in 2008 to alter sanitary conditions between Patagonia South, for which it had originally applied for APHIS authorization, and another area, Patagonia North B.

280. This change in sanitary conditions raised issues of compliance with APHIS requirements. Under these circumstances, APHIS sought to conduct another site visit, which Argentina only reluctantly agreed to in December 2008. Given the many changing variables with respect to Argentina's Patagonia South and Patagonia North B regions, APHIS measures were based and maintained on science.

281. For the reasons elaborated above, Article 2.2 is not relevant in the circumstances of this dispute where the United States is reviewing the requests of Argentina asserting a change in its disease status and seeking to obtain additional information necessary for a more objective assessment of risk. However, in addition, Argentina has failed to meet its burden to show that the measures in question are not consistent with Article 2.2.

[377] Argentina's First Written Submission, at para. 264.

F. Measures Taken by the United States Are Consistent with Article 5.4

1. Article 5.4 Does Not Impose Affirmative Obligations on Members

282. Article 5.4 states that a Member "should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects." Argentina simply does not read this text according to its plain meaning. The provision, by its terms, does not impose affirmative obligations on Members.

283. First, the operative verb form is "should", which expresses exhortation and not obligation, and not "shall". Second, the operative verb is "take into account" which relates to a consideration and not an outcome of that consideration. Third, what "should" be "take[n] into account" is an "objective", which indicates a goal or aim, not an outcome. As Argentina recognizes in its own written submission at paras. 292 and 483, the panel in *EC–Hormones* considered these elements and concluded that there is no affirmative obligation imposed on Members under Article 5.4. It found that the use of "should" as opposed to "shall" and Article 5.4's aspirational use of the term "objective" were clear evidence that Members did not have an affirmative obligation with respect to this provision.

284. Argentina urges the Panel to disagree with the conclusion of the panel in *EC–Hormones* because Argentina "considers that it must have operative meaning."[378] This is mere assertion, without basis in reasoning or law.

285. The rest of Argentina's discussion in this section shoots blindly—it finds the U.S. system to be "confusing" and makes unsubstantiated allegations that review of regulation for economic effects in a rulemaking process makes it "susceptible to non-science-based political and economic pressures."[379] And it never even links these allegations to the object of Article 5.4, "determining the appropriate level of sanitary … protection." In the end, Argentina's insinuations do not add up: nowhere in APHIS regulations is APHIS empowered to take action on non-scientific grounds, and Argentina does not point to any legal authority that states otherwise. The APHIS application system and its relationship to the FMD events in Argentina from 2000-2002 period is clearly established and supported by international standard and practice.

2. Measures Taken by the United States Take Into Account the Objective of Minimizing Negative Trade Effects

286. Minimizing negative trade effects in the context of FMD threats means that appropriate regulatory pathways should be in place to ensure that the importation of animals and animal products does not lead to the spread of FMD. The review of Argentina's requests for import reauthorization in relation to the 2001 Regulation is not only consistent with the OIE's own

[378] Argentina's First Written Submission, at para. 294.

[379] Argentina's First Written Submission, at para. 297.

approach, but also consistent with the OIE's own larger strategy to support economic and human development.

287. As stated by the OIE, FMD is a threat because "lost trade opportunities for affected countries are a global economic burden and a hindrance on human development."[380] It is "[t]he aim of the FMD Global Strategy . . . to decrease the impact of FMD worldwide by reducing the number of disease outbreaks in infected countries until they ultimately attain FMD-free status, as well as by maintaining the official FMD-free status of countries that are already free."[381] In fact, according to the OIE, "the risk of FMD for countries free from the disease has increased due to the increased global movement and trade of livestock and animal products."[382]

288. The opportunity to review Argentina's application upon a request setting out the necessary evidence of a change in disease status takes into account the objective of minimizing negative trade effects by only applying to those products and regions that pose a risk of FMD. This regulatory pathway permits an applicant country, upon successful review by APHIS, to export animal and animal products to the United States. This is in line with OIE principles and standards. The very premise of having countries apply for FMD status designation mirrors the OIE system in which countries apply and receive one of several possible FMD status designations.[383] That the FMD status bestowed upon an applicant country comes with associated restrictions on animal and animal product exports also mirrors the OIE system.[384] For example, a country which applies to the OIE and receives the "Foot and Mouth Disease Infected Country" status designation[385] would be subject to OIE import restrictions associated with that FMD status.[386]

289. The regulatory pathway described above is also consistent with the OIE's principle, expressed in the OIE Global Foot and Mouth Disease Control Strategy, that "countries free from [FMD] place reliance on a policy of preventing entry of the virus through strict control of the importation of livestock and animal products."[387] Like the OIE, APHIS has adopted the view

[380] OIE, "FAO and OIE unveil Global Strategy for control of foot-and-mouth disease," June 27, 2012, at http://www.oie.int/for-the-media/press-releases/detail/article/fao-and-oie-unveil-global-strategy-for-control-of-foot-and-mouth-disease/ (emphasis added).

[381] *Id.*

[382] OIE Global Foot and Mouth Disease Control Strategy, at 14 (emphasis added) (USA-5).

[383] OIE Terrestrial Animal Health Code Chapter 1.6.5 (USA – 116).

[384] OIE Terrestrial Animal Health Code Chapter 8.6. Articles 8.6.22, 8.6.23, 8.6.25, and 8.6.26 (USA-23).

[385] *Id.* at Article 8.6.7 (USA-23).

[386] *Id.* at Article 8.6.26 (USA-23).

[387] OIE Global Foot and Mouth Disease Control Strategy Annex 6 at 2 (USA-12).

that, "control of FMD is…a public good"[388] and has worked to prevent the spread of FMD in the United States and beyond.[389]

G. Measures Taken by the United States Are Consistent with Article 5.6

290. Article 5.6 provides that "when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility."

291. A breach of Article 5.6 can only be found once "there is a measure, other than the contested measure," that satisfies these three conditions: (1) the alternative measure is "reasonably available taking into account technical and economic feasibility"; (2) the alternative measure "achieves the Member's appropriate level of sanitary or phytosanitary protection"; and (3) the alternative measure is "significantly less restrictive to trade than the SPS measure contested."[390]

1. The U.S. Review of Argentina's Requests for Recognition of Disease-Free Status Will Identify Terms and Conditions under which Animal and Animal Products from Argentina can Enter the United States, Consistent the SPS Agreement and OIE Approach

292. Argentina's claim does not succeed because the measure in question, the alleged failure of APHIS to complete the process under its application system, is not a measure that "achieves" an "appropriate level of sanitary protection" of the United States. Argentina's complaint is that the United States has not completed the regulatory process provided for under the APHIS application system to issue a decision on the terms under which animal and animal products can enter the United States. It is that decision containing those terms which are the "measures to achieve the appropriate level of sanitary or phytosanitary protection" of the United States. As discussed at the beginning of the legal argument in this dispute, the APHIS review of Argentina's various requests for import authorization after the introduction of the 2001 regulations is in a similar position to that of the European Communities system for biotechnology approval, in which delays for approvals were found not to be "measures to achieve their appropriate level of sanitary or phytosanitary protection."[391] Thus, as noted above, it is appropriate to consider Argentina's procedural concerns pursuant to Article 5.7.

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[388] OIE Global Foot and Mouth Disease Control Strategy at 14-15 (USA-5).

[389] "A country that fails to control FMD may negatively impact…its neighbors and trading partners," OIE Global Foot and Mouth Disease Control Strategy at 15 (USA-5).

[390] *Australia – Apples (AB)*, at para. 337.

[391] *EC – Biotech (Panel)*, paras. 7.1402-7.1406.

293. In addition, Argentina persists in inaccurately defining the U.S. approach of reviewing Argentina's requests as a "total prohibition." The United States does not seek to impose and has not imposed a permanent, "total prohibition"—it is simply implementing due diligence with respect to a region, Argentina, whose regulatory authorities, in the recent past, knowingly and intentionally engaged in an intentional scheme to mislead other countries with respect to a series of massive FMD outbreaks. Those outbreaks lasted from July 2000 and January 2002, affecting 152, 619 animals and exposing 2,783,642 animals to FMD.[392] Argentina's record includes 3 suspensions of OIE-designated FMD free status since 2000. Thus, as explained above, maintaining the 2001 regulations while reviewing Argentina's requests achieves the U.S. appropriate level of protection, given available and pertinent scientific information, while additional information is sought.

294. The U.S. approach to reviewing Argentina's requests is consistent with the approaches suggested in the SPS Agreement and by the OIE. Article 6.3 states that a Member claiming that it is disease-free shall provide the necessary evidence to demonstrate that it is, and is likely to remain, disease-free. The United States is assessing the scientific evidence related to Argentina's assertion and will conform its SPS measures to the results of that more objective assessment of risk. In addition, the U.S. review of Argentina's requests to revise the 2001 regulations is a process that is consistent with the international standard for handling trade in animals and animal products that can spread FMD. Accordingly, it is not "more trade-restrictive than required,"[393] since, in the words of the OIE, "[b]efore trade in animals or their products may occur, an importing country must be satisfied that its animal health status will be appropriately protected."[394] The OIE Code outlines a number of different approaches for importation of product depending upon a determination of the FMD situation in an applicant country—the point here is that the importing country must ascertain the situation in the applicant country through a systematic review.

295. This systematic review starts with an application by an exporting country that provides information about the status of FMD and the country's internal controls. APHIS reviews this and must also conduct its own independent due diligence in order to ascertain the situation in the exporting country. These decisions are very sensitive, because inaccurate judgments can lead to an epidemic. Argentina's own FMD situation with respect to its border is a cautionary tale about how easily FMD can be spread, and how difficult it is to eradicate.

296. Whether there are appropriate alternative measures for safe importation of beef from Argentina depends on what the factual situation on the ground in Argentina is with respect to not simply its geography and disease status but the credibility of its regulatory and control system. While the U.S. review of Argentina's requests is ongoing to permit a more objective assessment of risk, maintaining the 2001 regulations is not more trade-restrictive than required to achieve the

[392] *See* Part III.B.

[393] SPS Agreement, Art. 5.6.

[394] OIE Terrestrial Animal Health Code Chapter 5.3.3 (USA-19).

U.S. appropriate level of protection. Argentina has not established any inconsistency with Article 5.6 in the absence of the gathering of necessary information for that more objective assessment.

2. Argentina Merely Asserts that Measures that Apply to Uruguay and Santa Catarina are Applicable to Itself

297. Argentina asserts that measures applied to Uruguay's exports to the United States are appropriate and readily available to be applied to Argentina. However, Argentina has not established the premise of the argument—that Uruguay is a proper basis of comparison for Argentina. In fact, Argentina asserts that Uruguay's measures are applicable to it since "the sanitary situations are essentially similar."[395] Argentina provides no reasoning as to why this is the case. The differences between Uruguay and Argentina are discussed at length in considering Argentina's argument under Article 2.3. On this basis alone, Argentina's argument in relation to measures on Uruguayan exports fails.

298. The above argument applies as well to Santa Catarina and Patagonia. The difference here is the fact that Argentina first applied for recognition of Patagonia South, which had a separate sanitary status from Patagonia North B. In considering Argentina's argument under Article 2.3, statements made by APHIS in 2007 pertaining to Patagonia South were predicated on a situation in Patagonia South that was changing by 2008. The changing nature of the sanitary situation in these two regions, require APHIS to complete the analysis before drawing a conclusion as to the appropriateness of the import authorization terms applied to Santa Catarina. Again, Argentina has not established a sufficient basis to make out an Article 5.6 claim.

3. OIE Guidelines for FMD-Free with Vaccination Status are not Applicable Because the United States ALOP is Higher

299. OIE guidelines for importation of products from countries that are FMD-free with vaccination do not meet the acceptable level of protection (ALOP) of the United States. 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 therefore still be present in certain animals in a vaccinated population.[396] In addition, the United States is concerned that current FMD vaccines may have residual Non Structural Proteins- NSP (depending on the manufacturing process) that could result in the detection of NSP antibodies in vaccinated animals, which in turn would not

[395] Argentina's First Written Submission, at para. 308.

[396] Parida, *Vaccination Against Foot-and-Mouth Disease Virus: Strategies and Effectiveness* (USA – 117).

allow the differentiation between vaccinated and infected animals.[397] As a result, importation of beef from areas that are designated as FMD-free with vaccination could result in importation of beef derived from infected animals. This would not satisfy the U.S. standard of safe importation. For these reasons, use of OIE guidelines for exports from a Member with FMD-free with vaccination status would not meet the U.S. appropriate level of protection.

H. Measures Taken by the United States Are Not Inconsistent with Article 2.3 Because Argentina Is Not Being Arbitrarily or Unjustifiably Discriminated Against

300. Argentina fails to show that its situation is identical or similar to that of Uruguay, Japan or the United Kingdom, and thus it cannot sustain its challenge under Article 2.3. As the discussion below illustrates, Argentina's record on issues such as geography and history are distinct from those of Uruguay, Japan, or the United Kingdom for purposes of Article 2.3.

301. Article 2.3 of the SPS Agreement states in relevant part that "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail . . . . Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade."

302. To find a breach of Article 2.3's provision against arbitrary or unjustifiable discrimination, Argentina must show: (1) "the measure discriminates between the territories of Members other than the Member imposing the measure[;] (2) the discrimination is arbitrary or unjustifiable; and (3) identical or similar conditions prevail in the territory of the Members compared."[398]

1. Argentina Fails to Establish That It Meets the Article 2.3 Criteria for Arbitrary or Unjustifiable Discrimination

a. Argentina Does Not Establish Discrimination or Arbitrary or Unjustifiable Discrimination

303. Argentina's complaint is that it has not completed the APHIS regulatory process in the same time that other countries have completed it. However, in the first instance, the review by the United States of Argentina's requests is not a "sanitary or phytosanitary measure" subject to Article 2.3. An SPS measure (in pertinent part) is "applied" to "protect animal … life or health" and may include "provisions on … methods of risk assessment" (Annex A, para. 1). But Argentina is not challenging a method of risk assessment that discriminates against it, and there is nothing in U.S. law or regulations on risk assessment that discriminates. Furthermore, the

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[397] Lee, et al., *Presence of Antibodies to Non-Structural Proteins of Foot-and-Mouth Disease Virus in Repeatedly Vaccinated Cattle* (USA – 118).

[398] *Australia – Salmon (21.5 Panel)*, at paras. 7.110-7.111.

U.S. review of Argentina's requests will obtain additional information for a more objective assessment of risk; the United States will adopt a measure following that review, and it is that measure that will be "applied" to "protect animal … life or health". Thus, the process of seeking additional information is not itself an SPS measure within the meaning of Annex A, and the obligation in Article 2.3 applies only to "sanitary or phytosanitary measures." For this reason alone, Argentina's claim under Article 2.3 fails.

304. In substance, Argentina's claim of discrimination based simply on alleged differences in time to review its requests is not a sufficient basis to establish discrimination. A determination of a country's FMD situation is not the same as inspecting automobiles on a factory assembly line. As described earlier, the process for reaching conclusion on an application for FMD status depends upon a variety of factors, not all of which are in the control of the United States.

305. For example, in this case, the review of an application is dependent upon the comprehensiveness of the submission of the applicant, and the responsiveness in the applicant in providing answers to follow up questions. Argentina, in this case, in one instance, took over one year (from October 2003 until November 2004) to respond to APHIS follow up questions on the Argentina application.[399] As detailed in Part III.D, with respect to the Patagonia South application, a request for documents and responses in March 2004 was left unanswered until November 2004. Reviewing applications that are particularized to the animal health status in a specific country necessarily proceed at different rates. Some country situations are straightforward, others are complex. As can be seen by Argentina's history of FMD, described in Part III.D, Argentina's situation and its own response to that situation was not simple. Nor is it a simple matter when, during the course of the application process, Argentina suffered two more outbreaks of FMD (2003 and 2006), necessitating further consideration.

306. In many different sorts of application processes, applicants can be reviewed more or less quickly, due to individualized circumstances. Argentina has not established, merely by asserting a difference in review time, that discrimination occurred in relation to any of its applications. Thus, for this additional reason, Argentina's claim under Article 2.3 fails.

b. Argentina Fails to Show That Its Situation Is Identical or Similar to Uruguay

307. As discussed above, review of an application is dependent on many factors, and is a particularized review of the animal health status of a country or region with very specific characteristics. Argentina devotes substantial space to describing the conditions under which Uruguay is permitted to import animal products into the United States. It merely asserts, however, that "the physical situation and the institutional structures are similar in Uruguay and Argentina."[400] Argentina then proceeds to recite a few superficially similar passages of language

[399] *See* Part III.D.

[400] Argentina's First Written Submission, at para. 334.

to justify its position. Argentina's Article 2.3 claim cannot be sustained on the basis of its selective and meager facts.

308. First, Uruguay and Argentina are not similarly situated in terms of geography and risks of cross-border FMD introduction, populations of livestock susceptible to FMD, and volume of veterinary resources. Uruguay is a small country (176,215 sq. km; slightly smaller than the U.S. state of Washington) bordered only by the Atlantic Ocean (660 km), Brazil (1,068 km), and Argentina (580 km).[401] Uruguay also has a relatively small population of animals susceptible to FMD, including 10,400,000 heads of cattle; 13,000,000 sheep; 360,000 pigs; and 15,000 goats.[402] Finally, Uruguay has infrastructure to carry out FMD control and eradication programs, with 299 veterinarians in the General Directorate of Livestock Services (DGSG).[403] Within the agency specifically responsible for animal health control and eradication programs (the Division of Animal Health) there are 99 veterinarians.[404] This translates to 105,051 heads of cattle for every veterinarian.

309. Argentina, on the other hand, is 2,780,400 sq. km (over 15 times larger than Uruguay) and is bordered by Chile (5,308 km), Bolivia (832 km), Paraguay (1,880 km), Brazil (1,261 km), and Uruguay (580 km).[405] Of these neighbors, two have had recent FMD outbreaks.[406] Argentina also has a significantly larger livestock population, with 52,500,000 heads of cattle; 13,800,000 sheep; 2,500,000 pigs; and 2,400,000 goats.[407] Finally, Argentina's infrastructure to carry out FMD control and eradication programs is less vis-à-vis its large livestock population, with only 576 permanent veterinary physicians.[408] Within the agency specifically responsible for animal health control and eradication programs (the National Animal Health Office) there are only 237 veterinary physicians.[409] This translates to 221,519 heads of cattle for every veterinarian (110% more cattle per veterinarian than Uruguay).

310. Another key difference between the two countries is each one's recent FMD history. Prior to the 2000-2001 FMD outbreaks in each country, Uruguay's prior FMD outbreak was in 1990. The outbreak in 2001 was believed to be traceable to a strain of FMD virus in Argentina

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[401] World Fact Book, "Uruguay" (USA – 119).

[402] USDA, APHIS, VS, Foot and Mouth Disease in Uruguay at 7 (USA – 120).

[403] USDA, APHIS, VS, Site Visit Report: Uruguay – Foot and Mouth Disease (September, 2002) at 5 (USA – 121).

[404] *Id.*

[405] World Fact Book, "Argentina" (USA – 122).

[406] OIE, Foot and Mouth Disease, Paraguay (2011) (USA – 123); OIE, Foot and Mouth Disease, Paraguay (2011-2012) (USA – 124); OIE, Foot and Mouth Disease, Bolivia (2007) (USA – 125).

[407] Argentina's First Written Submission, at para. 22; SENASA Application: Argentina (November, 2002) at 48 (USA-32).

[408] SENASA Application: Argentina (November, 2002), at 92 (USA-32).

[409] *Id.*, at 4.

at the time.[410] Each country's veterinary authorities also reacted differently to the FMD outbreak. Uruguay reported promptly and was transparent to APHIS authorities.[411] As Argentine officials acknowledged and as the general scientific community recognizes, Argentina embarked on a deliberate campaign of concealment of FMD infection from 2001-2002.

311. In fact, difference between the two countries can be encapsulated by the fact that since the 2001 outbreak, there has not been a reported outbreak in Uruguay. On the other hand, Argentina suffered two more outbreaks in the same period after 2000-2001. Based on the facts above, Argentina cannot sustain a claim under Article 2.3 on either substance or process.

c. Argentina Fails to Establish that Its Situation is Identical or Similar to Japan

312. Argentina's claim with respect to Japan should fail based on its own admission that "[t]he point here is not that the substantive situation of Argentina, on the one hand . . . and Japan, on the other, are identical."[412] In fact, that is the point: one key prong of the Article 2.3 analysis is "that identical or similar conditions prevail in the territory of the Members compared."[413]

313. A notable difference between Argentina and Japan is the fact that Japan is an island chain comprised of 6,852 islands.[414] Because of its island geography, land crossings of infected FMD animals over a long border (such as that which occurred in Argentina during the decade of the 2000s) is not possible. Moreover, Japan's FMD history is quite different from Argentina's. Japan had an FMD outbreak in 2010, but it was limited to one of the islands in the island chain. Prior to that, the last outbreak was in 2000. The 2000 outbreak had only 22 cases, according to the OIE database.[415] Prior to that, the last reported outbreak of FMD in Japan was in 1908. The same cannot be said of Argentina. It is reasonable that the process for a country with an FMD history like Japan would be less complex from a review standpoint than that of Argentina. Japan's situation is so different from Argentina's such that Argentina's claim against the application process must fail.

d. Argentina Fails to Establish that Its Situation is Identical or Similar to the United Kingdom

314. As with the comparison to Japan, Argentina's claim with respect to the United Kingdom should fail based on its own admission that "[t]he point here is not that the substantive situation

[410] USDA, APHIS, VS, Site Visit Report: Uruguay – Foot and Mouth Disease (September, 2002) at 7 (USA – 121).

[411] 68 Fed. Reg. 6673 (USA-126).

[412] Argentina's First Written Submission, at para. 344.

[413] *Australia – Salmon (21.5 Panel)*, para. 7.111.

[414] USDA, APHIS Evaluation of the Foot and Mouth Disease Status of Japan (USA – 127).

[415] *See* OIE Handistatus website for data prior to 2005. The website is located at: http://www.oie.int/en/animal-health-in-the-world/the-world-animal-health-information-system/data-before-2005-handistatus/

of Argentina, on the one hand and the United Kingdom . . . , on the other, are identical."[416] In fact, that is the point: one key prong of the Article 2.3 analysis is "that identical or similar conditions prevail in the territory of the Members compared."[417]

315. Similar to Japan, the United Kingdom is an island, and thus land crossings of FMD animals over a long border (such as that which occurred in Argentina) is not possible. The United Kingdom's FMD history includes an outbreak in 2000- 2001, and an outbreak in 2008. While the 2000 outbreak was significant, it differed in a number of respects from the one in Argentina. Other than that, the OIE database records the last outbreak as 1981.[418] The source of the smaller 2008 outbreak was an official laboratory conducting research into the FMD virus.

316. It is reasonable that the process for a country with an FMD history like the United Kingdom would be less complex from a review standpoint than that of Argentina. The United Kingdom's situation is so different from Argentina's such that Argentina's claim against the application process must fail.

e. Argentina Fails to Establish that Patagonia's Situation Is Identical or Similar to Santa Catarina

317. The review of an application for FMD free designation is based on a consideration of the eight factors listed in 9 C.F.R. § 92.2 and is discussed at length in the section addressing claims under Article 3, and throughout this submission. Many parts of this process are dependent on the cooperation and response by the applicant. With respect to Patagonia, as noted above, an APHIS request for more information in March 2004 was only answered in November 2004, a lag of 8 months.

318. The key differentiation between Santa Catarina's situation and that of Patagonia was the fact that Argentina had introduced new changes to the sanitary boundaries between Patagonia South and Patagonia North B in 2008. This factor added a new confounding element because Argentina's application in 2003 was for the region defined as Patagonia South, which was premised on certain controls with Patagonia North B. The reasons and implications of this were discussed in detail in Part III.B and Part III.D. Santa Catarina, by contrast, had no sanitary boundary changes during the period of consideration, simplifying the process. It is reasonable, based on these facts, to understand how such changes could result in a difference in review periods and to see why Argentina's claim on this point must fail.

[416] Argentina's First Written Submission, at para. 344.

[417] *Australia – Salmon (21.5 Panel)*, para. 7.111.

[418] *See* OIE Handistatus website for data prior to 2005. The website is located at: http://www.oie.int/en/animal-health-in-the-world/the-world-animal-health-information-system/data-before-2005-handistatus/

2. Argentina Fails to Establish that the APHIS Application System Is A "Disguised Restriction"

319. Article 2.3 provides that SPS measures not be "applied in a manner which would constitute a disguised restriction on international trade." As this phrase calls upon the chapeau of Article XX of the GATT, it is worth noting that no "single test might uniformly apply in all cases to determine the existence of a 'disguised restriction on international trade.'"[419]

320. A "disguised" restriction on international trade may mean "hidden" or "dissimulated". This is not the case with respect to Argentina's applications. The record as described in Part IV and Part VI is clear as to Argentina's FMD history, the series of outbreaks since 2000, the deliberate cover-up of outbreaks, and shifting sanitary boundaries within the country. The process of reviewing the conditions in Argentina to determine under what terms that country can safely export to the United States must be thorough based on that record. These are objective concerns on their face, and so the process is not one that the United States has embarked upon to promote a "hidden" or "dissimulated" purpose. It is a process of review that the United States takes very seriously, given the fact that an FMD outbreak in the United States would lead to severe economic and social damage, as described at length in Part III and Part V. It is a process that the United States undertook in "the principle of good faith"[420] consistent with its obligations under the SPS Agreement.

I. U.S. Application System to Prevent FMD Is Consistent with Article 3 of the Agreement on Sanitary and Phytosanitary Measures

321. In its submission, Argentina identifies the application of 9 C.F.R. § 94.1 and the 2001 Regulations to it as inconsistent with Article 3 because they are allegedly not measures based on international standard. However, 9 C.F.R. § 94.1 (together with 9 C.F.R. § 92.2) represent an approach that is entirely consistent with the OIE. In fact, with respect to the handling of animals and animal products that are susceptible to FMD infection from countries, the OIE Code lays out a system that is fundamentally the same in structure and approach to that of the APHIS application system. The preceding discussion illustrates how the OIE approach and the APHIS application system mirror each other such that the latter can be said to be based on the former. "Based on" does not mean that the United States must necessarily reach the same result on individual applications, and at the very same time, as the OIE makes recommendations on disease-free status.

1. The APHIS Application System is Based On International Standard and Consistent with Article 3.1

322. This section demonstrates that the APHIS application system is founded upon the approach taken by the OIE in the Code and in the OIE's internal process to determine the FMD

[419] *Brazil – Tyres (Panel)* at para. 7.320.

[420] *Brazil – Tyres (Panel)* at para. 7.321 ("[T]he chapeau is 'but one expression of the principle of good faith.'").

status of a country or zone for purposes of the OIE's own designations list. Because the APHIS application system and the OIE approach reflected in the Code and in its internal process are so similar, it is clear that the former is "based on" the latter. Argentina's claim under Article 3.1 must fail.

323. Article 3.1 of the SPS Agreement provides that "Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations where they exist, except as otherwise provided for in this Agreement[.]" The Appellate Body, in *EC-Hormones* observed that "A thing is commonly said to be 'based on' another thing when the former 'stands' or is 'founded' or 'built' upon or 'is supported by' the latter."[421]

a. OIE Code Establishes and the OIE's Designation System Is An Application System

324. To show that the APHIS application system is "based on" the OIE Code and OIE's own approach to reaching FMD designations, we first turn to the OIE Code itself. The OIE Code states that "[t]he animal health situation in the *exporting country*, in the *transit country* or *countries* and in the *importing country* should be considered before determining the requirements for trade."[422] Again, at Article 5.3.3, the OIE Code states: "Before trade in *animals* or their products may occur, an *importing country* must be satisfied that its *animal health status* will be appropriately protected."[423] In the case of FMD, this reflects the overwhelming scientific consensus that FMD is a highly dangerous, devastating, and contagious animal disease.[424] Before trade can commence, it is sensible and necessary for the importing country to determine whether the exporting country can export on terms that protect the importing country's animal health status.

325. In fact, this is how the OIE generally approaches the designation of a country or zone. As reflected in Chapter 1.6 of the OIE Code, the OIE operates a "recognition" system in which a country voluntarily applies for OIE designation of FMD free status. OIE recognized status can only be obtained after (1) a country submits an application for it to be recognized; (2) the Ad hoc sub-committee under the Scientific Commission of the OIE completes its review of the application and is satisfied that the OIE requirements for that designation are met; (3) the Ad hoc sub-committee recommends a decision to the Scientific Commission; (4) the Scientific Commission recommends a designation to the OIE General Assembly; (5) the OIE General Assembly adopts the resolution containing the list of countries with a recognized status.

326. An applicant country seeking OIE designation provides paper responses to a questionnaire that addresses topics such as the geography of the country, the livestock industry,

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[421] *EC – Hormones (AB)* at para. 163.

[422] OIE Terrestrial Animal Health Code Chapter 5.1.1 (USA – 69).

[423] OIE Terrestrial Animal Health Code Chapter 5.3.3 (USA-19).

[424] *See* Part III.A.

the veterinary system (including legislation), history and situation related to FMD surveillance, prevention, and control measures.[425] In certain limited cases, OIE may conduct site visits, with the applicant country bearing the cost.[426]

327. Under the approach taken by the OIE, a country is considered to be an "FMD infected country" if it "does not fulfill the requirements to qualify as an FMD free country where *vaccination* is not practiced or an FMD free country where *vaccination* is practiced."[427] An "FMD infected zone" is a zone "that does not fulfill the requirements to qualify as either an FMD free zone where vaccination is not practiced or an FMD free zone where vaccination is practiced."[428]

328. Accordingly, for purposes of OIE's own system designating FMD status, the OIE itself does not differentiate between "no status" and "FMD infected." For example, in the reproduction of the OIE map of the Far East region, *infra*, you will note that a country such as Russia, which has had a number of recent outbreaks of FMD,[429] has the same "no recognized status" as Papua New Guinea, which has not recently reported outbreaks of FMD.

[425] OIE Terrestrial Animal Health Code Chapter 1.6.5 (USA – 116).

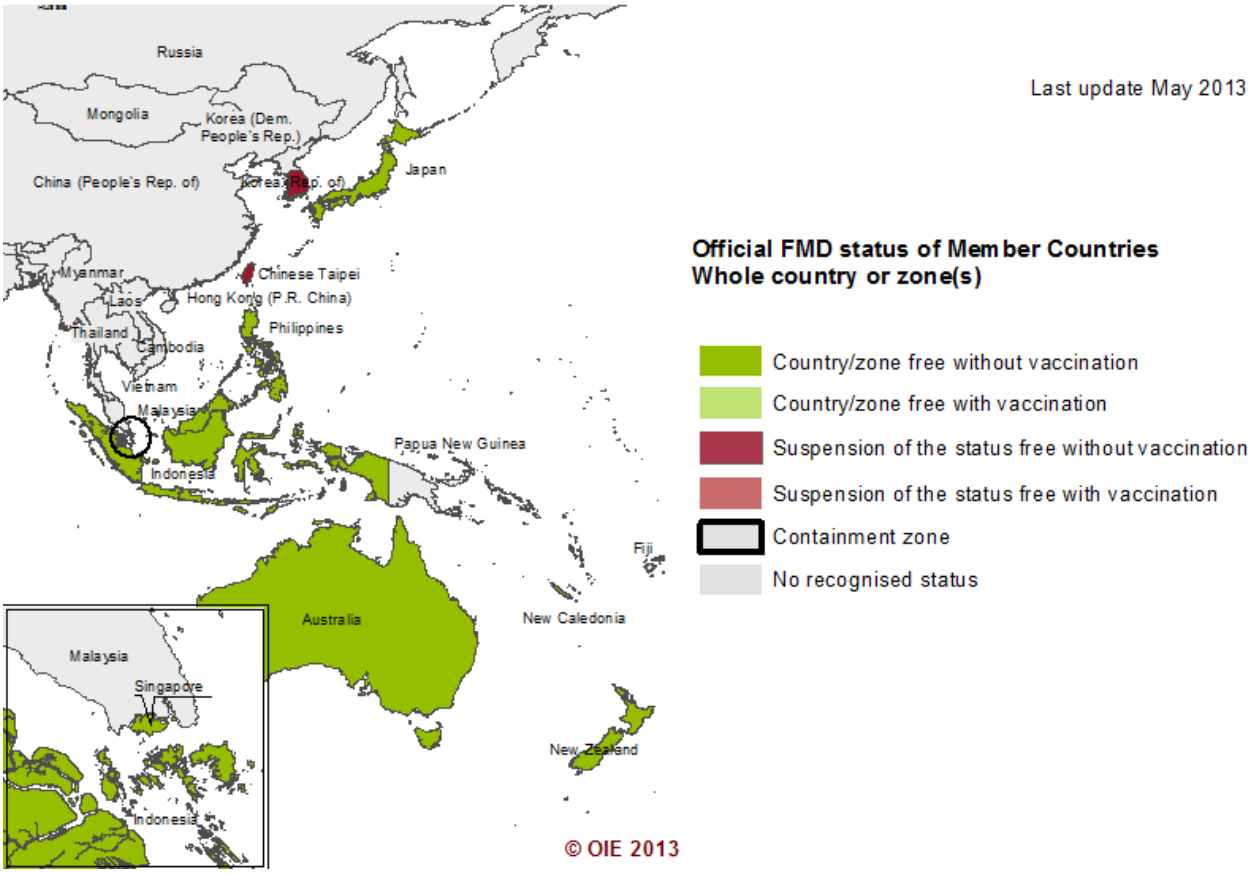
[426] OIE Standard Operating Procedures (USA – 22).

[427] OIE Terrestrial Animal Health Code Chapter 8.6.7 (USA-23).

[428] OIE Terrestrial Animal Health Code Chapter 8.6.7 (USA-23).

[429] Russia reported FMD in 2013 and in its 2012 report. See OIE Website at http://www.oie.int/wahis_2/public/wahid.php/Reviewreport/Review/viewsummary.

FAR EAST ASIA AND PACIFIC: OIE Member Countries' official FMD status map



329. When a country or zone with an FMD-free designation has an FMD outbreak, the OIE immediately strips that country or zone of its FMD-free status and it becomes an FMD-infected country or zone. For it to recover its designation, it must follow the procedure under Article 8.6.9 of the OIE Code, which outlines waiting periods before a country can reapply to the OIE for a designation of status. This is the process that Argentina followed each time it suffered an FMD outbreak in 2001, 2003, and 2006.

330. OIE's recommendations for importation from FMD infected countries or zones includes the requirement that, for meat products of domestic ruminants and pigs, "the meat has been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.6.34." The procedures in Article 8.6.34 are canning, thorough cooking, or drying after salting. That is, it does not recommend the importation of fresh, chilled, or frozen meat.

331. In brief, under the OIE approach, unless a country can show that it does not have FMD, it is to be categorized as FMD infected, and the meat products that can be exported from it should be canned, cooked, or dried after salting.

b. APHIS Application System Is "Based On" OIE Code and Application System

332. Under the APHIS application system, the same principled framework applies:

333. First, just as in the OIE approach, 9 C.F.R. § 94.1(a) establishes that a country or region is to be considered the equivalent of an "FMD infected zone" unless it has been determined to be free of FMD after an examination of an application provided under 9 C.F.R. § 92.2. This is consistent with the OIE's approach and the underlying science that FMD is a dangerous, highly contagious animal disease.

334. Second, just as in the OIE approach, no decision is made about a country's FMD situation until an application is made by a country. APHIS does not take action in the abstract, in the absence of an application. The process outlined in 9 C.F.R. § 92.2 permits APHIS to authorize the importation of animals and animal products after the submission by an applicant country is received, reviewed, and a conclusion is reached. The topics that APHIS asks applicants to respond to include: Geographic description, disease history, veterinary system, history and situation related to FMD surveillance, prevention, and control measures. The topics requested mirror those asked by the OIE. Unlike the OIE, APHIS almost always conducts site visits to the applicant country, and APHIS bears its own costs for the site visit.

335. Third, just as in the OIE approach, an outbreak can result in the removal of authorization under 9 C.F.R. § 94.1(a)(2). In that provision, APHIS states that it "will remove a region from the list of those it has declared free of . . . foot-and-mouth disease upon determining that the disease exists in the region based on reports APHIS receives of outbreaks of the disease from veterinary officials of the exporting country, from the World Organization for Animal Health (OIE), or from other sources the Administrator determines to be reliable." A region can be reauthorized by resubmitting its information under 9 C.F.R. § 92.2 or § 92.4 as appropriate. The OIE also has a process for re-application.

These similarities are illustrated in the table provided for below:

U.S. Standard (APHIS Regulations)	**International Standard (OIE Code)**
Application Process (9 C.F.R. § 92.2(b)) 1. A request for APHIS recognition of the FMD status of a foreign region (country, zone or other configuration) must include information pertaining to: • A. The scope of the evaluation being requested. • B. Veterinary control and oversight. • C. Disease history and vaccination practices. • D. Livestock demographics and traceability. • E. Epidemiological separation from potential sources of infection. • F. Surveillance. • G. Diagnostic laboratory capabilities. • H. Emergency preparedness. *FMD Status Designations (9 C.F.R. § 92.2 and 9 C.F.R. Part 94)* 1. The outcome of the application evaluation process is the granting of one of two FMD statuses: • A. Foreign region (country, zone or other configuration) free of FMD. ➔ Imports permitted • B. Animal commodity approval with conditions to protect United States animal health status. ➔ Imports permitted	*Application Process (Article 1.6.5*) 1. A request for OIE recognition of the FMD status of a country or zone[430] must include information pertaining to: • A. Introductory information. • B. The veterinary system. • C. FMD eradication. • D. FMD diagnosis. • E. FMD surveillance. • F. FMD prevention. • G. Control measures and contingency planning. • H. Compliance with the Terrestrial Code. *FMD Status Designations (Articles 8.6.2 – 8.6.5, 8.6.7)* 1. The outcome of the application evaluation process is the granting of one of several FMD statuses: • A. FMD free country/zone where vaccination is not practiced. ➔ Import terms (Article 8.6.22). • B. FMD free country/zone where vaccination is practiced. ➔ Import terms (Article 8.6.23).

[430] For countries/zones where vaccination is not practiced *and* where vaccination is practiced.

• C. Foreign region not free of FMD. ➔ No fresh, chilled, or frozen meat. *Recovery of FMD Free Status (9 C.F.R. 92.4)* 1. If a foreign region free of FMD experiences an outbreak, it will lose its status as a foreign region free of FMD (9 C.F.R. 92.4(a)). This results in halting imports. 2. APHIS may later reassess the situation to determine whether interim prohibitions are still necessary. APHIS will consider OIE procedures and other relevant information received (9 C.F.R. 92.4(b)). 3. APHIS decides on reinstatement. (9 C.F.R 92.4(c)).	• C. FMD infected country or zone. ➔ No fresh, chilled, or frozen meat (Article 8.6.26 and Article 8.6.34) (mitigation). *Recovery of FMD Free Status (Article 8.6.9)* 1. If a FMD free country or zone (with or without vaccination) experiences an outbreak, it will lose its FMD free status. This results in the suspension of corresponding import recommendations. 2. Following a reinstatement application, OIE may reassess the situation according to the relevant OIE criteria. 3. The OIE decides on reinstatement.

336. From 2000-2001, Argentina suffered massive, widespread outbreaks of foot and mouth disease that it delayed reporting, as discussed exhaustively in Part III.B and Part III.D. After it finally notified these outbreaks, it voluntarily stopped the export of beef to the United States. Because of the outbreaks, APHIS removed Argentina's authorization to export fresh, chilled, and frozen beef. In 2002, Argentina applied again in accordance with 9 C.F.R. § 92.2 for reauthorization. While the United States has not made a final determination with respect to this application, the application system of the United States is based on the approach taken by the OIE for purposes of its system of designation.

337. In sum, the APHIS application system used to determine the terms and conditions of importation of animals and animal products is clearly "based on" the OIE Code and the approach used by the OIE in making its own designations for FMD status. Accordingly, Argentina's claim based on Article 3.1 must fail.

2. The U.S. Application System Is Not Inconsistent with Article 3.3

338. Argentina has submitted applications for authorization to import fresh, chilled and frozen bovine meat from the whole country and for the recognition of Patagonia as an FMD free region for purposes of 9 C.F.R. § 94.1. In a process that is based on the OIE approach, the APHIS application system provides that APHIS reviews Argentina's application and then makes a determination based on it. In this matter, APHIS has not come to a final resolution of the process.

339. It may be the case (and, in fact, it may often be the case) that the timeframe upon which OIE makes its designation might not be synchronized with the timeframes of the appropriate regulatory authorities in Member countries. There could be many reasons for this: for example, as noted above, the OIE generally does not conduct site visits to countries that are applying for an FMD designation.[431] Moreover, some countries might seek OIE designation but not seek particular import authorization from a specific Member state. These are procedural and policy issues that, at least in this context, cannot be swept into the ambit of an Article 3.3 legal analysis. In fact, the OIE itself does not specify the appropriate time period for review of applications regarding disease-free status.

340. Argentina is a good example of the problem in synchronized designations. As discussed in Part III.B and Part III.D, Argentina's designation status has fluctuated significantly because of its unstable FMD situation. The OIE suspended Argentina's status once Argentina ceased concealing the 2000-2002 outbreaks and finally notified the OIE. It regained its OIE status in 2003 for only a month before losing it again due to another outbreak. It then regained its OIE status in 2005, but lost it again 2006 due to another outbreak. This OIE status was regained in 2007.

341. Even if this Panel were to find that Article 3.3 applies to the U.S. measures despite the fact that the United States has not rejected the specific OIE designation, Article 3.3 provides that such measures are consistent with Article 3 "if there is a scientific justification." Based on the facts of this dispute, the U.S. measures at issue in fact are fully justified. As discussed above in connection with Article 5.7, Article 5.1, and Article 5.2, , U.S. measures suspending shipments in the face of FMD outbreaks are supported by extensive scientific evidence.

J. The APHIS Application System Permits Adaptation of Measures to the Sanitary or Phytosanitary Characteristics of an Area Consistent with Article 6.1

342. Article 6.1 states that Members shall "ensure that their sanitary and phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area" and that Members "shall take into account *inter alia*, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations." The United States, in adopting the 2001 regulations, ensured that its measures were adapted to the SPS characteristics of Argentina in light of its FMD outbreak. Since Argentina's request to recognize a change in its disease status, particularly for Patagonia, the United States has been undertaking to ascertain, inter alia, the level of prevalence of the disease and Argentina's control procedures in light of the evidence Argentina, as the party seeking to establish that disease status, must present pursuant to Article 6.3.

[431] OIE Standard Operating Procedures (USA – 22).

343. Argentina specifically alleges at para. 534 that the United States did not take into account factors listed in Article 6.1. The phrase "take into account" used in Article 6.1 has been elaborated upon with regard to Article 5.1 of the SPS Agreement. According to the Panel in *Japan – Apples*, "[t]his expression does not impose that a risk assessment under Article 5.1 be 'based on' or 'in conformity with' such risk assessment techniques; this suggests that such techniques should be considered relevant, but that a failure to respect each and every aspect of them would not necessarily, per se, signal that the risk assessment on which the measure is based is not in conformity with the requirements of Article 5.1."[432] In other words, the Panel was stating that it is not necessary to follow, solely and exactly, the risk assessment techniques referred to in Article 5.1 in order to "take them into account." This Panel should conclude from this that the criteria listed in Article 6.1, including the OIE guidelines, may be considered similarly.

344. The similar phrase "take account of" has also been examined in the context of Article 10.1 of the SPS Agreement. The Panel in *EC – Biotech* stated that this phrase does not require or prescribe a specific result, saying that "the obligation laid down in Article 10.1 is for the importing Member to "take account" of developing country Members' needs. The dictionary defines the expression 'take account of' as 'consider along with other factors before reaching a decision'. Consistent with this, Article 10.1 does not prescribe a specific result to be achieved." (internal citation omitted).[433] Following from this review of relevant previous reports, the Panel should conclude that the phrase "take into account" in Article 6.1 does not require an importing Member to completely base its analysis on the OIE guidelines.

345. In addition, Article 6.1 uses the term "*inter alia*." This term indicates that the listed criteria are not the only criteria that may be taken into account. For example, the Appellate Body in *Australia – Apples* stated that the use of the term "*inter alia*" in a list of measures "emphasizes that the list is only indicative."[434] This term indicates that the elements listed are not exclusive or complete, and that other criteria, such as prior experience with a country and its credibility might be applicable.

346. The United States is currently applying the process laid out in Article 6.1 with respect to Argentina's Patagonia application. Under 9 C.F.R. § 92.2, an applicant country that seeks designation of a region as free of FMD submits documentation to address the following eight factors:

- Scope of the evaluation (the region)
- Veterinary control and oversight

[432] *Japan – Apples (Panel)*, para. 8.241.

[433] *EC – Biotech (Panel)*, para. 7.1620.

[434] *Australia – Apples (AB)*, para. 176.

- Disease history and vaccination practices
- Epidemiological separation from potential sources of infection
- Surveillance
- Diagnostic laboratory capabilities
- Emergency preparedness and response

These factors track the elements listed in Article 6.1.

347. The APHIS application system takes into account appropriate criteria or guidelines developed by international organizations including the WTO and the OIE.

348. In fact, the APHIS application system tracks closely the SPS Committee's "Guidelines to Further the Practical Implementation of Article 6 of the Agreement on the Application of Sanitary and Phytosanitary Measures" (the "Guidelines").[435] The Guidelines illustrate "typical" steps in the process of recognition. These steps include:

- Exporting country requests information about procedures;
- Importing member explains requirements;
- Exporting member provides documentation;
- Importing member evaluates the documentation and, if necessary, requests additional information;
- Exporting Member responds to feedback;
- Importing Member evaluates any additional information and, if required, seeks further clarifications;
- Importing Member conducts on-site verification;
- Exporting Member responds to inspection report; and
- Importing Member makes determination

349. The APHIS process tracks these typical steps. The requirements for the recognition process are provided for in the APHIS document "Clarification of Information Requested for

[435] Guidelines to Further the Practical Implementation of Article 6 of the Agreement on the Application of Sanitary and Phytosanitary Measures (USA – 128).

Recognition of a Region" and in 9 C.F.R. § 92.2. These requirements are the basis for the documentation request of the exporting member. APHIS then conducts a review process and asks follow up questions of the exporting member. APHIS conducts a site visit, and then aggregates the information received. It then performs an analysis and then makes a determination.

350. As discussed above in the section addressing Article 3, the APHIS process is based on and tracks the structure of the OIE process. This includes the use of an application system and the consideration of science-based factors in reaching a determination on FMD prevalence. Argentina alleges that the OIE designation of Patagonia must be taken into account, however, it has not established that such a designation is in fact a "criteria" or a "guideline." A "criteria" or "criterion" is "A principle, standard, or test by which a thing is judged, assessed, or identified."[436] A "guideline" is "a directing or standardizing principle laid down as a guide to procedure, policy, etc."[437] In no sense is it reasonable to say that the OIE designation of Patagonia a "principle, standard, test" or as a "directing or standardizing principle" in the ordinary meaning of those words.

351. As described in earlier sections, Argentina's application of the Patagonia region is under review. Argentina is submitting an application to the United States for FMD free recognition. Argentina has vouched for its status in the past, and was found to have concealed FMD outbreaks. "The importing Member should take into account any relevant knowledge of and prior experience with the authorities of the exporting Member."[438]

352. Argentina first submitted an application to APHIS for the designation of Patagonia South as an FMD free region. That application did not include Patagonia North B, which was not formally the subject of an application. Nevertheless, Argentina signaled that it was changing the sanitary conditions between Patagonia South and Patagonia North B after the 2007 proposed rule was released for Patagonia South. After that, Argentina stalled in approving an APHIS site visit until late 2008, and the site visit was not completed until early 2009. The complexities of Argentina's application are discussed at length in Part III.D.

353. A review of the record clearly demonstrates that the United States is taking into account factors consistent with Article 6 of the SPS Agreement with respect to Argentina's application for Patagonia. The United States is committed to completing the process for Patagonia, consistent with Article 6.1., and requires that Argentina provide the necessary information, including access within Argentina, pursuant to Article 6.3.

[436] Oxford English Dictionary (1993), "Criteria" (USA – 129).

[437] Oxford English Dictionary (1993), "Guideline" (USA – 130).

[438] Guidelines to Further the Practical Implementation of Article 6 of the Agreement on the Application of Sanitary and Phytosanitary Measures at para. 9 (USA – 128).

K. The APHIS Application System Recognizes the Concepts of Pest- or Disease-free Areas Consistent with Article 6.2

354. Argentina believes that the United States does not "recognize the concept of pest- or disease-free areas" because the United States does not at this time categorize the Patagonia region as a region free of FMD with vaccination. Argentina's complaint is that the APHIS process has not been completed, and not against a definitive rejection of the application. It is clear that the United States does recognize the concept of pest- or disease-free areas in 9 C.F.R. § 94.1 and in the definition of "region" in 9 C.F.R. § 92.1.

355. Section 94.1(a)(2) states that "APHIS will add a region to the list of those it has declared free of . . . . foot-and-mouth disease . . . after it conducts an evaluation of the region in accordance with Section 92.2." 92.1 defines a region as "[a]ny defined geographic land region identifiable by geological, political, or surveyed boundaries. A region may consist of . . . [a] national entity[,] [or] [p]art of a national entity . . . ." The evaluation referred to in Section 92.2 is based upon an application that considers factors such as "livestock demographics and traceability," "disease history and vaccination practices," "veterinary control and oversight," "epidemiological separation from potential sources of infection," "surveillance," "diagnostic laboratory capabilities," "emergency preparedness and response." These factors cover the factors listed by Article 6., such as "geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls."

356. The APHIS system recognizes these concepts in practice. To date, it has recognized 56 regions as regions free of foot-and-mouth disease.[439] It has recognized regions in continents across the world:

- Americas: Bahamas, Barbados, Belize, Bermuda, Canada, Chile, Costa Rica, Dominican Republic, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, St. Pierre and Miquelon, Santa Catarina (Brazil), Trinidad and Tobago.

- Asia-Pacific: Australia, Japan, New Zealand, New Caledonia, Papua New Guinea, Fiji, Trust Territories of the Pacific Islands

- Europe: Austria, Belgium, Channel Islands, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Greenland, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom

- Africa: Namibia (north of the veterinary cordon fence)

[439] USDA, APHIS, Countries/Regions Free of Foot and Mouth Disease (FMD) and Rinderpest (USA – 131).

357. With respect to the application for the Patagonia region, the United States is in the process of reaching a determination according to the criteria that are consistent with Article 6.2. As discussed in Part III.D, Argentina seeks to obtain an APHIS determination for a region that is comprised of both Patagonia South and Patagonia North B. However, Argentina's application to APHIS in 2003 and subsequent regulatory activity concerned Patagonia South. In Argentina, Patagonia North B was regulated as a separate zone. Due to the extensive changes described in Part III.B and Part III.D, the scope of the larger region needs to be considered. As a result, APHIS has been working to complete the process and update its information.

358. As discussed earlier in this submission, the most recent outreach by the United States to Argentina to request a site visit to Argentina was made in November 2012. The United States received no answer from Argentina until July 2013—and that answer was to allow for a site visit in November 2013. The United States is looking forward to finalizing these applications.

L. The United States Sufficiently Accounts for Developing Country Interests Under SPS Article 10.1

359. Argentina asserts that the United States has not accorded Argentina "special and differential treatment" with respect to application of SPS measures.

360. First, it must be remembered that "the obligation laid down in Article 10.1 is for the importing Member to 'take account' of developing country Members' needs. The dictionary defines the expression 'take account of' as 'consider along with other factors before reaching a decision.' Consistent with this, Article 10.1 does not prescribe a specific result to be achieved."[440]

361. The United States, to the extent possible, takes into account developing country members' needs in meeting its obligations under the SPS Agreement. Many countries at or even below Argentina's income level obtain import authorization and have been designated as FMD free.

362. According to World Bank data, Argentina reports Gross Domestic Product (GDP) of US$ 470 billion (2012) and Gross National Income (GNI) per capita $5,170 (2006). (This data is drawn from the World Bank.)

363. Countries at or below Argentina's GDP or GNI level and have obtained APHIS import authorization and designation as FMD free include:

i. Belize, GDP US$ 1.448 billion (2011); US$ 4,180 (2011)

ii. Dominican Republic, GDP US$ 58.95 billion (2012); GNI US$ 5,470 (2012)

iii. El Salvador, GDP $23.86 billion (2012); GNI US$ 3,580 (2012)

[440] *EC – Biotech (Panel)*, at para. 7.1620.

iv. Guatemala, GDP US$ 50.54 billion (2012); GNI US$ 3,140 (2012)

v. Haiti, GDP US$ 7.843 billion (2012); GNI US$ 760 (2012)

vi. Honduras, GDP US$ 18.53 billion (2012); GNI US$ 2,070 (2012)

vii. Jamaica, GDP US$ 14.84 billion (2012); GNI US$ 5,140 (2012)

viii. Namibia, GDP US$ 13.07 billion (2012); GNI US$ 5,640 (2012)

ix. Nicaragua, GDP US$ 10.51 billion (2012); GNI US$ 1,650 (2012)

All data for the countries above are drawn from the World Bank's Country database at http://data.worldbank.org/country.

364. In implementing its system to protect itself from FMD, the United States continues to remain open to imports from countries with income levels at or below those of Argentina. It is not credible for Argentina to assert that the United States is inconsistent with Article 10.1.

365. Second, Article 10.1 specifically points out "special needs" to be taken into account, however, nowhere in Argentina's discussion does it assert what "special needs" related to its status it is claiming. In fact, the United States has provided support to Argentina in combating FMD through technical assistance and other aid programs. For example, as noted in Part III.C, the United States, in the past, provided technical assistance to Argentina in training its veterinary services and economic assistance in building veterinary infrastructure. Moreover, prior to the massive outbreaks of FMD in 2000-2002, the United States in 1997 had granted authorization for Argentina to import fresh, chilled, and frozen beef.

366. The fact is that Argentina suffered a series of substantial FMD outbreaks from 2000-2002, as well as in 2003 and 2006. Argentina endangered global animal health through its deliberate official strategy of concealment of the disease. APHIS is reviewing the applications submitted by Argentina, and, based on the appropriate information obtained from a site visit to be conducted in November 2013, it intends to finalize the regulatory process.

367. For these reasons, the panel should reject Argentina's claims under Article 10.1.

M. The United States' Application System is consistent with Article I:1 and Article XI :1 of the GATT 1994

1. The Application System is Consistent with the SPS Agreement and is Therefore Justified under Article XX(b) exception to Article I:1 and Article XI:1of the GATT 1994

368. Argentina argues that the United States' Application System violates Article I:1 and Article XI:1 of the GATT 1994 because the system offers other Members advantages that are not accorded immediately and unconditionally to Argentina.[441] The Application System, however, is necessary to protect animal life or health, consistent with the SPS Agreement, and the disciplines of Article XX (b). Pursuant to Article 2.4 of the SPS Agreement, if a measure conforms to the SPS Agreement, then it is presumed to comply with Article XX(b). The Application System does not constitute a means of arbitrary or unjustifiable discrimination, or a disguised restriction on international trade against Argentina. Because the United States has satisfied its obligations under the SPS Agreement and Article XX (b), it has not breached Article I:1.

369. The pertinent part of Article I:1 provides:

> . . . with respect to all rules and formalities in connection with importation and exportation . . . any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.

370. The article is subject to the *General Exceptions* under Article XX of the GATT 1994. The relevant provision is subsection (b), which, read together with the chapeau, provides:

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:
>
> (b) necessary to protect human, animal or plant life or health.

371. Article XX (b) applies specifically to measures utilized to protect animal life or health, and is thereby interrelated with the SPS Agreement. The Preamble to the SPS Agreement declares an objective of "[d]*esiring* . . . to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary and phytosanitary measures, in particular the provisions of Article XX (b)."[442] In *Argentina – Footwear*, the Appellate Body stated that the WTO Agreement and its constituent provisions must be interpreted in a "way that gives meaning to all of them, harmoniously."[443] In interpreting Article XX (b) within the context of the SPS Agreement, the Panel in *US – Poultry* reiterated that the agreement "elaborates and thus explains the provisions of Article XX (b) in further detail when dealing with SPS measures."[444] The

[441] Argentina's First Written Submission, at para. 590.

[442] SPS Agreement.

[443] *See Argentina – Footwear (AB)*, at para. 81.

[444] *US – Poultry (Panel)*, at para. 7.479.

Panel explained that the interpretation "gives meaning to both Article XX (b) of the GATT 1994 and the *SPS Agreement* in a harmonious manner."[445]

2. The Application System is Consistent with Article 2.4 of the SPS Agreement, and is Thus Presumed to be Consistent with the GATT, Particularly Article XX(b)

372. An SPS measure found consistent with provisions of the SPS Agreement that are disciplines of Article XX (b) may be justified under the exception to the GATT 1994. Article 2.4 of the SPS Agreement provides support for the understanding that an SPS measure, which conforms to the SPS Agreement, is presumed to be consistent with Article XX (b).[446] Article 2.4 reads:

> Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

373. As addressed above, Section 92 conforms to Articles 5.7, 5.1, 5.2, 2.2, 5.4, 5.6, 2.3, 3.1, 3.2, 6.1, and 10.1 of the SPS Agreement. Therefore, the Application System is justified by Article XX(b) of the GATT 1994. The Panel is not compelled to perform a three-step test to determine the applicability of Article I:1, as Argentina suggests.[447] If the Panel determines that the Application System is consistent with the SPS Agreement, then, consequently, the Application System may be justified under Article XX (b).

a. The Application System Falls under the Scope of Article XX (b) of the GATT 1994

374. Aside from the presumption created by Article 2.4 of the SPS Agreement, the Application System falls within the scope of and is justified by Article XX (b). To fall within the scope of Article XX (b), previous panels have determined that two factors must be satisfied: (1) the policy in respect of the measure for which the provision is invoked must fall within the range of policies designed to protect human, animal or plant life or health; and (2) the inconsistent measure for which the exception is invoked must be necessary to fulfill the policy objective.[448]

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[445] *US – Poultry (Panel)*, at para. 7.479.

[446] *See* SPS Agreement, Article 2:4 ("Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).")

[447] Argentina's First Written Submission, at para. 574.

[448] *Brazil – Tyres (Panel)*, para. 7.40; *EC – Asbestos (Panel)*, para. 8.169.

i. The United States Introduced the Application System to Protect Animal Life and Health

375. In *Brazil – Tyres*, the Panel adopted the following analytical approach to determine whether a measure pursues a policy to protect human and animal or plant life or health: (1) the presence of a risk to human and animal life and health; and, if a risk is found, (2) whether the policy has the objective to reduce the risk.[449] As established above in PartA, FMD presents a significant risk to the life and health of animals – specifically, to cloven-hoofed animals such as bovines, sheep, and pigs. Generally, the objective of the Application System is to reduce (or eliminate) this risk by preventing the introduction of the disease into the United States. Specifically, as applied to all applicants including Argentina, the Application System is intended to assess the status of FMD in a particular region and to determine the permissible conditions under which animals may be safely exported into the United States. Thus, based on the recognized risk of FMD, and the stated objective of preventing the disease from entering the United States, the policy objective behind Application System was to protect the life and health of cloven-hoofed animals.

ii. The Application System is Necessary to Protect Animal Life and Health

376. The Application System falls within the scope of Article XX (b) because the system is necessary to protect animal life and health from the established risk of FMD presented by the import of fresh (frozen and chilled) beef.

377. To fall within the scope of Article XX (b), the measure must be necessary to achieve the aforementioned objective. In *Korea Beef*, the Appellate Body stated that "[t]he word 'necessary' normally denotes something 'that cannot be dispensed with or done without, requisite, essential, needful'"[450] Upon analyzing a standard law dictionary, the Appellate Body noted that, in the context of Article XX (d), "the reach of the word 'necessary' is not limited to that which is 'indispensable' or 'of absolute necessity' or 'inevitable'."[451]

378. To determine whether a measure is necessary under Article XX (b), the Appellate Body has directed panels to consider the "relevant factors."[452] In *Brazil – Tyres*, the Appellate Body suggested that a panel should consider 3 particular factors: (1) the importance of the interests or values at stake; (2) the extent of the contribution to the achievement of the measure's objectives; and (3) the measure's trade restrictiveness.[453] Upon concluding that the measure is necessary, a panel must confirm the finding by "comparing the measure with possible alternatives –

[449] *See Brazil – Tyres (Panel)*, at para. 743.

[450] *Korea—Beef (AB)*, at para.160 (citing The New Shorter Oxford English Dictionary).

[451] *Korea—Beef (AB)*, at para.161.

[452] *Brazil –Tyres (AB)*, at para. 178.

[453] *Brazil –Tyres (AB)*, at para. 178.

considering whether less trade restrictive alternatives exist that provide "an equivalent contribution to the achievement of the objective."[454]

1. Importance of the Interests or Values at Stake

379. The United States has some concerns about an analytical approach under which a WTO panel or the Appellate Body would make judgments on the importance of the interests or values of a Member sought to be protected by a measures. Nonetheless, there is no question in this dispute that the U.S. objective of preventing introduction of FMD is critical to safeguarding animal life or health. As stated above in Part III, the OIE considers the prevention and control of FMD to be an essential responsibility for countries, for the disease is the most contagious disease of mammals and has the potential to cause devastating financial loss. Because the disease spreads easily and rapidly, it is of vital importance that countries take measures to respond to FMD outbreaks, and to prevent the disease from entering its borders. The very establishment of the OIE and its dedication to assisting countries in preventing FMD illustrate the vital importance of controlling the disease.

2. The Contribution to the Achievement of the Measure's Objectives

380. The Application System has contributed significantly to the United States' ability to effectively prevent the entry of FMD into the country. The United States last detected FMD in over eighty years ago in 1929, illustrating the continued effectiveness of the regulatory regime and the Application System. The Application System ensures that a country requesting authorization to import fresh meat sufficiently details the status of FMD so that the United States can assess the risk that FMD will enter the country. As explained above in Part III, FMD is recognized by the OIE as a highly contagious disease that has devastating effects on cloven-hoofed animals across the globe. Thus, before permitting animal exports, the OIE recommends that countries be satisfied that its animal health status will be appropriately protected.

381. Here, the Application System has continued to contribute to achieving the stated objective of assessing the risk of FMD posed by Argentina beef. The United States has proceeded to collect information about the FMD status in Patagonia, and has arranged a site visit to work towards concluding a risk assessment. Throughout the evaluation process, the United States has maintained the goal of finishing and publishing Patagonia's risk assessment. The application process serves the stated objective to assess the risk of FMD posed by the authorization of beef exports into the United States and to set out conditions for safe imports. To date, the Application System has contributed substantially to the United States' efforts to achieve this objective.

3. Trade Restrictiveness

[454] *Brazil –Tyres (AB)*, at para. 178.

382. The third factor a panel considers is the degree to which the measure restricts trade. In assessing the trade restrictiveness of a measure to determine whether it is "necessary", the Panel evaluates whether less trade restrictive alternatives are reasonably available.[455] In *US – Gambling*, the Appellate Body explained that "it is not the responding party's burden to show, in the first instance, that there are no reasonably available alternatives to achieve its objectives."[456] In fact, the burden "rests upon the complaining Member to identify possible alternatives to the measure at issue that the responding Member could have taken."[457] Furthermore, "a responding party need not identify the universe of less trade-restrictive alternative measures and then show that none of those measures achieves the desired objective" because it is an "impracticable and, indeed, often impossible burden."

383. Argentina has not met its burden. Argentina suggests that the United States' system has restricted trade; however, Argentina fails to present an alternative. Because Argentina has neglected to present an alternative, the Panel need not consider the qualifying components of an alternative.

384. For the foregoing reasons, the Application System has the objective to protect animal life and health, and is necessary to achieve that stated objective. Therefore, the Application System provisionally qualifies under the exception set out in Article XX (b) of the GATT 1994.

b. The Application System Meets the Requirements of the Chapeau of Article XX of the GATT 1994

385. The Appellate Body has explained that a responding party must show that a measure meets the requirements of the Article XX chapeau to be justified under Article XX (b) of the GATT 1994.[458] Specifically, the chapeau requires that a measure may not be "applied in a manner which would constitute a means of arbitrary and unjustifiable discrimination between countries where like conditions prevail, or a disguised restriction on international trade . . ."[459] Because the Application System is not a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, and is not a disguised restriction on international trade, the system meets the requirements of the chapeau of Article XX.

[455] *See US – Gambling (AB)*, at para. 309.

[456] *US – Gambling (AB)*, at para. 309.

[457] *Brazil – Tyres (AB)*, at para. 156.

[458] *See, e.g., US – Gasoline (AB)*, at para. 22; *US – Shrimp (AB)*, at para. 119-120.

[459] Chapeau, Article XX of the GATT 1994.

i. The Application System is not a means of Arbitrary or Unjustifiable Discrimination Between Countries Where the Same Conditions Prevail

386. In *Brazil – Tyres*, the Appellate Body explained that a measure may be determined to be arbitrary and unjustifiable discrimination if (1) the application of the measure results in discrimination; (2) the discrimination is arbitrary or unjustifiable in character; and (3) the discrimination occurs between countries where the *same* conditions prevail.[460] All three conditions must be met to find arbitrary and unjustifiable discrimination.

387. The Application System applies to all countries applying to the United States for the recognition of a region free of FMD. The process depends largely on the information provided by the requesting country in its application. Because different countries have different experience with FMD and different control systems, the application process may not proceed in precisely the same manner. Nonetheless, Argentina has not demonstrated that any variations experienced during the process are neither arbitrary nor unjustifiable.

388. The Appellate Body has recognized that a responding party may show that a measure is not arbitrary or unjustifiable by demonstrating that it is not capricious or random.[461] Furthermore, the Appellate Body stated that this may be shown by focusing on the "cause of the discrimination, or rationale" for the measure.[462] In the instant dispute, the United States has a stated, compelling rationale for having the Application System in place. As stated above, FMD poses a significant risk to a country's cloven-hoofed animals, due to the disease's ease of transmission and potentially devastating impact on animal health. The Application System is in place to ensure that each requesting country does not pose a significant risk of introducing FMD into the United States. Considering Argentina's long history in battling FMD and proven record of concealment, the Application System is in place to ensure that the country provides sufficient information on its FMD status and the measures taken to prevent the disease from spreading to the United States.

389. The Application System is also not a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail because Argentina's conditions are unique. Part III explains the extensive history of FMD in Argentina, and details the various outbreaks across the country. Patagonia has not reported an FMD outbreak since submitting its application; however, the region north of 42° parallel has. Argentina has introduced multiple resolutions to rearrange geographic borders and revise control measures effecting Patagonia. Additionally, unlike any other requesting countries, Argentina did not immediately reveal the presence of FMD to the international community. As illustrated in Part III above, Argentina has

[460] *Brazil – Tyres (AB)*, at para. 215.

[461] *Brazil – Tyres (AB)*, at para. 215.

[462] *See Brazil – Tyres (AB)*, at para. 226.

a unique history with FMD, which indicates that the conditions therein are not the same as other requesting countries.

ii. The Application System is Not a Disguised Restriction on International Trade

390. The final requirement to justify a measure under the chapeau of Article XX of the GATT is that the measure must not be a disguised restriction on international trade. The Application System does not serve a protectionist objective and is therefore not a disguised restriction on international trade.

391. In *EC – Asbestos*, the Panel considered whether a Decree satisfied the chapeau of Article XX of the GATT 1994. The Panel recognized that the "key to understanding what is covered by 'disguised restriction on international trade' is not so much the word 'restriction', inasmuch as, in essence . . . the word "disguised".[463] Furthermore, the Panel stated that "a restriction which formally meets the requirements of Article XX (b) will constitute an abuse if such compliance is in fact only a disguise to conceal the pursuit of trade-restrictive objectives."[464]

392. The United States has no trade-restrictive objective. As explained above in Part D, the Application System was installed to achieve one stated objective: ensure that a requesting country does not introduce FMD to the United States through imports. The objective is strictly to satisfy an animal life and health concern and the United States has granted beef access for dozens of exporting countries. Because the Application System does not have the trade-restrictive objective, it is not a disguised restriction on international trade.

393. For the forgoing reasons, the Application System meets the requirements of the chapeau of Article XX, and is thus justified under Article XX (b).

3. Argentina Fails to Substantiate a Basis for a Finding under Article XI:1 of the GATT 1994

394. Argentina argues that the Application System applies and maintains a prohibition on the importation of animals, meat and other animal products from Patagonia, and operates as a "zero quota", in violation of Article XI:1.[465] However, Argentina relies entirely on the presumption that the Application System is inconsistent with the SPS Agreement, specifically Article 2 and Article 5.[466] As indicated above, the Application System is consistent with the SPS Agreement, and is therefore justified under Article XX (b).

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[463] *EC – Asbestos (Panel)*, at para. 8.236.

[464] *EC – Asbestos (Panel)*, at para. 8.236.

[465] Argentina's First Written Submission, at para. 592.

[466] Argentina's First Written Submission, at para. 593.

395. Article XX (b) permits Members to adopt and enforce measures necessary to protect animal life and health, provided that the measure does not constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade. The Application System does not serve the prohibited purposes, and is necessary to protect animal life and health. Thus, Argentina has failed to substantiate a basis for a finding under Article XI:1 of the GATT 1994.

V. CONCLUSION

396. For the reasons elaborated upon above, Argentina's claims must be rejected in their entirety.