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

(DS447)

EXECUTIVE SUMMARY OF THE FIRST WRITTEN SUBMISSION AND OPENING STATEMENT AT THE FIRST MEETING OF THE PANEL OF THE UNITED STATES OF AMERICA

March 4, 2014

OPENING STATEMENT

A. KEY FACTS AND CIRCUMSTANCES UNDERLYING THIS DISPUTE

1. FMD is considered widely to be one of the most infectious and economically devastating livestock diseases. Argentina is no stranger to FMD. FMD has been present in Argentina since the 19th century. And Argentina has struggled for decades to control the disease. The United States has not had a single case of FMD for over 80 years. Today, livestock in the United States is not vaccinated against FMD. The record shows that the APHIS review of Argentina's applications is active and, while the pace may not be to Argentina's liking, it is fully justified.

2. There has been no denial of any of Argentina's pending applications. Rather, the regulatory process is moving forward, and the time involved is reasonable in light of unstable FMD conditions in Argentina, the changes in Argentina's applications, and its history with respect to transparency and ability to control FMD.

B. THE CORE LEGAL ISSUE IN THIS DISPUTE RELATES TO THE TIME TAKEN TO CONSIDER ARGENTINA'S APPLICATIONS

3. The core legal issue in this dispute relates to the time taken to consider Argentina's two pending applications. This conclusion is supported by the Argentina's own arguments, by the factual record, and the relationship between the relevant provisions of the SPS Agreement.

4. Although there is no prescribed way for analyzing a number of inter-related SPS provisions, in this instance, the most helpful approach is to start with the language of Article 6. Given that this dispute involves Argentina's pending applications for disease free status, Article 6 is most directly relevant. Articles 6.1 and 6.2 set out the general principles that measures must be adapted to regional conditions, and that Members must recognize the concept of disease-free areas. Article 6.3 sets out the process for making determinations under Article 6.

5. Although Article 6.3 does not say that the evaluation must be completed in any particular time period, the United States does agree with the general proposition – as presented by Argentina – that an importing Member cannot take unlimited time to review an application. The SPS Agreement does contain disciplines on timeliness of decision-making, most notably in Article 5.7 and in Annex C. The United States and Argentina, while agreeing that timeliness is addressed by the SPS Agreement, disagree on which provision applies.

C. U.S. MEASURES ARE JUSTIFIED UNDER ARTICLE 5.7

6. The actions of the United States to verify and to ensure that FMD from Argentina is not introduced and established in the United States are envisioned by Articles 5.2 and 5.3, and are fully justified under Article 5.7 as a provisional measure.

7. The United States, in seeking to make a scientific determination of the present FMD threat from Argentina, is in the process of obtaining and analyzing scientific information related, to factors including: (1) the FMD situation in the country; (2) the capacity of the country's regulatory structure to prevent and control FMD outbreaks; and (3) the reliability of those responsible agencies to implement oversight and reporting obligations, including disclosure.

8. At the time of Argentina's 2002 request, it was clear that: (1) FMD was highly contagious and dangerous; (2) Argentina's systems had recently failed to control FMD on a massive scale; and (3) it was not known whether Argentina had FMD and whether its internal systems could control FMD such that exports to the United States would not pose a threat.

9. The Appellate Body recognized in *Japan – Agricultural Products II* that what is a "reasonable period of time" to review a provisional measure "depends on the specific circumstances of each case." In this case, the Panel should look to what is reasonable given the total circumstances of the record, particularly (1) Argentina's delays in responding to requests by the United States for site visits and answers to questions, (2) Argentina's three relatively recent FMD outbreaks, and (3) the country's history of intentional concealment and delayed reporting of outbreaks. Based on this record, the pace of APHIS review and analysis is reasonable.

D. APHIS' REGULATORY APPROVAL PROCESS IS BASED ON INTERNATIONAL STANDARD AND CONSISTENT WITH ARTICLE 3

10. With regard to Argentina's claim under Article 3.1, Argentina has failed to provide any legal or factual basis. The record shows that APHIS has created and implemented a system to control FMD based on the OIE's framework, consistent with Article 3.1. Argentina has the burden to demonstrate that the APHIS system is inconsistent with Article 3.1, a burden that Argentina has failed to satisfy.

11. The Appellate Body stated that a measure under Article 3.1 may embody some but not necessarily all of the elements of an international standard. Unlike Article 3.2, a measure that is based on an international standard does not need to conform to or embody the standard completely.

12. The record shows that the U.S. system for controlling FMD is built upon the relevant international standard established by the OIE. Three core principles common to both the OIE and the APHIS approach are the following: (1) Unless a country can show it does not have FMD, it is to be treated as an FMD-infected zone; (2) No decision is made about a country's FMD situation until an application is made by a country. In that application, both APHIS and the OIE consider the ability of the country in question to control and eradicate FMD as critical to the determination; and (3) An outbreak can result in the removal of FMD freedom.

13. The United States has acted consistently with Article 3.

E. APHIS ACTIONS WITH RESPECT TO PATAGONIA ARE CONSISTENT WITH ARTICLE 6.1 AND ARTICLE 6.2

14. Article 6.1 sets out the general principle that Members have an obligation to ensure that their measures are adapted to the conditions of the region from which products originate. Article 6.2 of the SPS Agreement provides that Members are required to recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence.

15. APHIS regulations at 9 C.F.R. Section 92.2 direct it to consider applications from foreign countries to determine regions to be free of FMD. Section 92.2 sets forth the factors that it will consider in its determination and for which it requires documentation from the applicant country.

These factors closely match those listed in Article 6, including geography, status of the disease in the country, extent of the country's disease control program, and structure and effectiveness of veterinary services. Thus, APHIS's regulations demonstrate that the United States recognizes the concepts of disease-free areas, consistent with Article 6.2.

16. The application process described in Section 92.2 is also consistent with reading Article 6.3 together with Article 6.1 and Article 6.2. As discussed earlier, Article 6.3 requires Members claiming that a region is free of a disease to provide necessary evidence. Section 92.2 is consistent with this understanding.

17. Further evidence that the United States recognizes the concept of disease-free areas is evident in relation to Argentina's applications. On January 23, 2014, APHIS promulgated a regulatory notice advising the public that it has determined that the Patagonia region is free of FMD, consistent with Section 94.1 of APHIS's regulations.

18. The risk analysis addresses the factors that the SPS Agreement asks members to "take into account" under Article 6.1—namely, the level of prevalence of FMD, the control program in Patagonia, and appropriate criteria of guidelines from the OIE. The risk analysis also considers the factors identified in Article 6.2, such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary controls.

19. For these reasons, the United States has acted consistently with Articles 6.1 and 6.2.

F. ARGENTINA INTRODUCES NO SCIENTIFIC EVIDENCE TO SUPPORT A CLAIM UNDER ARTICLE 5.6

20. With regard to Argentina's claim under Article 5.6, Argentina fails to meet its evidentiary burden or otherwise to explain the basis for its claim. Rather, Argentina's claim is based on hypothetical factual scenario unsupported by the record in this dispute.

21. Argentina has not made this showing. It merely asserts that either the OIE guidelines or the set of measures applied to Uruguay would meet the appropriate level of sanitary protection of the United States. But Argentina has not submitted any scientific evidence in the record that establishes that the scientific analysis that applies to Uruguay is applicable to Argentina and that therefore the measure is scientifically appropriate. As the Appellate Body also stated in *Australia –Apples*, "we cannot conceive of how a complainant could satisfy its burden of demonstrating that its proposed alternative measure would meet the appropriate level of protection under Article 5.6 *without* relying on evidence that is scientific in nature."

G. ARGENTINA CANNOT MEET ITS BURDEN TO SUPPORT A CLAIM UNDER ARTICLE 2.3

22. Because Argentina fails to show how its FMD circumstances and FMD control systems are similar to that of Uruguay, Santa Catarina (Brazil), Japan, and the United Kingdom, Argentina's claim under Article 2.3 too must fail.

23. Just as with Argentina's claim under Article 5.6, Argentina makes broad conclusions about the similarity between it and other countries. But nowhere does Argentina rely on specific evidence that shows that its regulatory infrastructure, disease history, geographical position, and

any other host of factors compel the same conclusion as reached by APHIS with respect to those countries. And in none of those countries was there shown to be a systematic failure to disclose FMD and to limit information as to its spread.

FIRST WRITTEN SUBMISSION

24. Argentina's first written submission starts with the assertion that "This is a simple dispute." 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 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 – FMD. One wonders what, exactly, is "simple" in this dispute.

25. The United States believes 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.

26. 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.

27. 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, Argentina has no basis for arguing that U.S. regulators should cut corners and rush to conclusions about Argentina's current FMD status.

28. Third, the record will show that time is of the essence in preventing and controlling FMD outbreaks. As 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 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.

29. Fourth, while Argentina argues that its FMD status is radically different than when it had outbreaks in 2000-2002, 2003, or 2006, Argentina presents the U.S. regulatory situation as static. The record shows, 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

30. 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. Only Argentina knows the answer to this question. The United States would note, however, the following publicly available information: On May 25, 2012, the EU requested consultations with Argentina regarding Argentina's wide-ranging non-automatic import licensing measures. Within several weeks, 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, 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.

31. 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 believes that this is the question that this Panel should tackle first under Annex C(1) and Article 5.7 of the SPS Agreement.

A. RELEVANT DISCIPLINES AND ORDER OF ANALYSIS

32. 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 authorities to date." 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.

33. 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 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.

B. ARGENTINA HAS NOT SHOWN THAT THE UNITED STATES BREACHED SPS ARTICLE 8 AND ANNEX C(1) WITH RESPECT TO ARGENTINA'S REQUESTS FOR THE RECOGNITION OF ARGENTINA AND PATAGONIA AS INDEPENDENT FMD-FREE REGIONS

34. Argentina asserts, but does not show, that the type of determination at issue in this dispute falls within the scope of SPS 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

35. The approval procedures serve to "check and ensure the fulfillment of SPS measures", and a Member must have reasonable time to complete the procedure. 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." As an example, the panel stated that additional information becoming available at a late stage of the approval procedure, which may impact a determination, could justify a delay.

36. 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. 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.

37. Argentina relies on the overall length of time (11 years) that have been involved in the evaluation process 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. In short, the total period of time involved in a regulatory process – standing alone – is not determinative of undue delay.

38. 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. 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. 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.

39. 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. Argentina has no basis for claiming that the United States has engaged in undue delay.

40. Argentina has failed to demonstrate that legislation, which has expired years ago and 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.

C. U.S. MEASURES WITH RESPECT TO ARGENTINA ARE JUSTIFIED UNDER ARTICLE 5.7

41. SPS Article 5.7 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."

42. 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.

43. In *Japan – Agricultural Products II*, 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.

44. The application of the APHIS system and the 2001 Regulations 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.

45. First, the APHIS system and 2001 Regulations were effective during a period in which Argentina had been experiencing FMD outbreaks for months. Second, the measures were based on available information – the reports and acknowledgment by Argentina of serious FMD outbreaks. 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. 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 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.

46. Similary, 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.

47. 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.

48. 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.

49. 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, there is no basis for the panel to find that APHIS violated the "reasonable period of time" standard. The United States is committed to completing the review process, of which a necessary step is the site visit which it conducted in November 2013.

50. 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

51. 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 change in disease status. That procedural concern is one that may be examined in the light the procedural obligations in SPS Article 5.7. 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.

52. Article 5.1 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." In *Australia – Apples*, 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." The U.S. measures are rationally and objectively connected to both the scientific evidence and the risk assessment.

53. 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."

54. 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.

55. The 2001 Regulations were justified as a response to the massive FMD outbreak from 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

56. 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.

57. 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. 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

58. The United States maintains that its measures are consistent with Article 2.2 because they are consistent with Article 5.7. 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.

59. 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."

60. 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." 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 including the quality of the country's internal controls and its credibility in disease surveillance and reporting.

61. 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" Maintaining the 2001 Regulations in the meantime is based on scientific principles related to transmissibility and consequences of the disease.

62. 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. After submitting its application for import authorization in late 2002, months

after the devastating outbreaks of 2000-2002, which were exacerbated by 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.

63. 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.

64. 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.

65. 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. Argentina simply has not met its burden.

F. MEASURES TAKEN BY THE UNITED STATES ARE CONSISTENT WITH ARTICLE 5.4

66. 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.

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

G. MEASURES TAKEN BY THE UNITED STATES ARE CONSISTENT WITH ARTICLE 5.6

68. 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."

69. 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."

70. 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. 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.

71. 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.

72. 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 U.S. appropriate level of protection.

73. 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." 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.

H. MEASURES TAKEN BY THE UNITED STATES ARE NOT INCONSISTENT WITH ARTICLE 2.3 BECAUSE ARGENTINA IS NOT BEING ARBITRARILY OR UNJUSTIFIABLY DISCRIMINATED AGAINST

74. 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.

75. 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."

76. 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 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.

77. 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. 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.

78. 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." Argentina's Article 2.3 claim cannot be sustained on the basis of its selective and meager facts.

79. 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. Another key difference between the two countries is each one's recent FMD history. 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.

80. 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." 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." A notable difference between Argentina and Japan is the fact that Japan is an island chain comprised of 6,852 islands. 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. Japan's situation is so different from Argentina's such that Argentina's claim against the application process must fail.

81. 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 of Argentina, on the one hand and the United Kingdom . . . , on the other, are identical." 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. The source of the smaller 2008 outbreak was an official laboratory conducting research into the FMD virus. The United Kingdom's situation is so different from Argentina's such that Argentina's claim against the application process must fail.

82. 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. 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.

83. 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.'"

84. A "disguised" restriction on international trade may mean "hidden" or "dissimulated." This is not the case with respect to Argentina's applications. The record 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. It is a process that the United States undertook in "the principle of good faith" consistent with its SPS obligations.

I. U.S. APPLICATION SYSTEM TO PREVENT FMD IS CONSISTENT WITH ARTICLE 3 OF THE AGREEMENT ON SANITARY AND PHYTOSANITARY MEASURES

85. 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. 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.

86. Under the APHIS application system, the same principled framework applies:

87. 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.

88. 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.

89. 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). 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.

90. 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, the OIE generally does not conduct site visits to countries that are applying for an FMD designation. 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.

91. Argentina is a good example of the problem in synchronized designations. 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.

92. 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.

J. THE APHIS APPLICATION SYSTEM PERMITS ADAPTATION OF MEASURES TO THE SANITARY OR PHYTOSANITARY CHARACTERISTICS OF AN AREA CONSISTENT WITH ARTICLE 6.1

93. 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.

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 factors: (1) Scope of the evaluation (the region); (2) Veterinary control and oversight; (3) Disease history and vaccination practices; (4) Epidemiological separation from potential sources of infection; (5) Surveillance; (6) Diagnostic laboratory capabilities; and (7) Emergency preparedness and response. These factors track the elements listed in Article 6.1.

94. The APHIS application system takes into account appropriate criteria or guidelines developed by international organizations including the WTO and the OIE. 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".

95. 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.

K. THE APHIS APPLICATION SYSTEM RECOGNIZES THE CONCEPTS OF PEST- OR DISEASE-FREE AREAS CONSISTENT WITH ARTICLE 6.2

96. 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. 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."

L. THE UNITED STATES SUFFICIENTLY ACCOUNTS FOR DEVELOPING COUNTRY INTERESTS UNDER SPS ARTICLE 10.1

97. The United States, to the extent possible, takes into account developing country Members' needs in meeting its SPS obligations. Many countries at or even below Argentina's income level obtain import authorization and have been designated as FMD free. Also, 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.

M. THE UNITED STATES' APPLICATION SYSTEM IS CONSISTENT WITH ARTICLE I:1 AND ARTICLE XI :1 OF THE GATT 1994

98. 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. 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.