United States — Measures Affecting the Importation of Animals, Meat and Other Animal Products from Argentina

(DS447)

OPENING STATEMENT OF THE UNITED STATES OF AMERICA AT THE SECOND SUBSTANTIVE MEETING OF THE PANEL

September 4, 2014

1. Mr. Chairman, members of the Panel: on behalf of the United States, we would like to thank you for your ongoing work in this panel proceeding.

I. Introduction

2. You have asked us to focus today on the critical issues raised at this phase of the dispute.

3. The core factual issues involve two regulatory proceedings: one involving Patagonia, one involving Northern Argentina. Argentina's basic complaint is that the failure to complete these processes "is a straightforward restriction on international trade" without scientific justification, and constitutes "arbitrary discrimination" *vis-à-vis* other WTO Members.[1] However, the factual landscape has fundamentally shifted since this dispute was initiated. Both regulatory processes have moved forward, as reflected in the formal notices that the United States has provided to the Panel.

4. First, the United States has issued a formal determination that recognizes Patagonia as a region that is FMD free.[2] As a practical matter, the completion of this administrative procedure moots Argentina's complaints regarding the handling of Argentina's Patagonia application.

5. Second, the United States has issued a proposed rule to allow imports from Northern Argentina,[3] with appropriate control measures that Argentina acknowledges would be acceptable. In association with the proposed rule, the United States has also issued a draft of a

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[1] Argentina's First Written Submission, para 2.

[2] Exhibit USA-167.

[3] Exhibit USA-168.

detailed risk assessment of Northern Argentina, explaining why trade in products from Northern Argentina would meet the U.S. level of protection.[4]

6. The issuance of these decisions confirms what the United States has maintained throughout this dispute: namely, the U.S. regulatory process is not, as Argentina alleges, some regulatory "black hole" that will restrict trade in perpetuity. Rather, the U.S. process has been moving forward, based on established processes that involve a detailed scientific evaluation. And that process has been entirely completed for one region, and has reached an important milestone for the other region, in a manner that belies any allegation that the United States is intent on maintaining restrictions on animal products from Argentina.

7. With respect to the legal framework of Argentina's challenge, the critical issue in this dispute has been and continues to be this: what obligations apply under the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement") and how do they operate when an exporting Member claims either that its territory, in whole or in part, is free of disease, or that it is of low disease prevalence in relation to a disease of concern to an importing Member?

8. The SPS Agreement addresses this through Articles 2, 5, and 6. The provisions of these three articles must be read together, in a manner that reflects the drafters' intention of providing a coherent, workable set of obligations governing claims of disease-free or low-disease-prevalence status. Under these provisions, the process starts when the Member making the claim of a certain disease status makes a request to the importing Member. The importing Member

[4] Exhibit USA-169.

then must begin an assessment and seek to obtain necessary information from the exporting Member. At the same time, the exporting Member is obligated to provide the necessary information to validate its claim. Pending the completion of the information collection and review process, the importing Member may maintain provisionally a measure affecting the importation of the product that is based on pertinent available information. During this period, the importing Member collects information necessary for a more objective assessment of the risk and reviews its existing SPS measure accordingly within a reasonable period of time. Once the importing Member has completed its risk assessment, it adopts a measure that is based on the assessment and achieves its appropriate level of protection ("ALOP").

9. As the United States understands it, Argentina's view – at least for the purpose of this proceeding – is the opposite. According to the logic of Argentina's arguments, when an exporting Member claims it is free of disease, the importing Member must either immediately produce an assessment specific to that Member or permit the product to enter. However, this view is not grounded in the text of the SPS Agreement, does not make sense of the inter-relationship of the relevant provisions, and is not the approach taken by any responsible regulatory authority.

10. And, as was confirmed during the meeting with the individual experts and the World Organisation for Animal Health ("OIE"), neither is this view reflected in the practice of other Members nor the procedure and practice of the OIE.

11. In fact, Members such as the European Union ("EU") and Australia, as well as the United States, conduct investigations to assess claims made as to disease status before accepting those claims as valid. Argentina itself "acknowledges the right of each WTO Member to conduct its

own sanitary evaluation."[5] This evaluation process is a crucial step for an importing Member, because it is the importing Member that bears the ultimate responsibility and the consequences of an authorization to permit imports of products that are, in this case, capable of causing substantial biological and economic damage.

12. The expert consultation process further confirms the need for importing Members to make careful assessments of disease-free or low-disease-prevalence status, and the complexity of this task. For example, at the expert session, the individual experts stated that importing Members conducting an evaluation process must assess the effectiveness of a multitude of complex systems within a country. In the case of assessing the foot and mouth disease ("FMD") status in an exporting Member, an importing Member would examine systems such as:

- the veterinary infrastructure of the importing Member to evaluate its capacity to control FMD;
- border measures to evaluate the ability of the exporting Member to prevent entry of FMD from other countries;
- surveillance systems to monitor the existence of the disease;
- programs such as systematic vaccination to confirm that the medicines are applied appropriately and effectively; and
- where relevant, mitigation techniques such as deboning and maturation to reduce the likelihood of FMD virus in beef.

[5] Argentina's Responses to Panel Question No. 53, para. 202.

13. Furthermore, the OIE itself stated that its country designations do not constitute an import risk assessment. The OIE also confirmed that the paper dossier – that is, the factual submission of the Member seeking an official disease status – is not shared with other OIE Members. Nor are other OIE Members privy to the working papers, the deliberations, or the detailed analyses of the OIE *ad hoc* group that reviews the dossier. Rather, the only information publicly available in this process is typically a short summary document, ranging from a few paragraphs to no more than a page or two.

14. The individual experts also discussed the lack of transparency of the OIE process for making disease status designations. Indeed, the experts explained how the lack of transparency makes it very difficult for importing Members to place substantial weight on the OIE's designations. The experts also noted that the OIE's designation process does not involve the preparation of a full risk assessment. For example, we heard from Dr. Bonbon that he observed that a risk assessment is a detailed evaluation, and must take account of the particularized situation of both the exporting and importing Members.

15. To conduct this type of thorough risk assessment, importing Members such as the United States conduct site visits, often multiple times, to the exporting Member to collect data and evaluate the exporting Member's disease status and internal controls. In contrast, as the OIE confirmed, the OIE itself does not routinely or regularly conduct site visits.

16. A thorough risk assessment of an exporting Member is an extensive and deliberate process. At the time of the first meeting of the Panel in this dispute, the United States noted that on January 23, 2014, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service ("APHIS") had published a proposed notice to designate the region of Patagonia as free

of FMD. Together with that proposed notice, APHIS published its 87-page risk analysis, based on a careful examination of the scientific evidence related to the disease and region. In the intervening months, APHIS received, analyzed, and answered comments provided by the public. And, on August 29, 2014, APHIS published its final notice, which determines that Patagonia is a region free of FMD.

17. As also noted, APHIS has taken action on the second regulatory proceeding at issue in this dispute. On August 29, APHIS published a proposal to permit the importation of fresh beef from the Northern Argentina region under certain conditions. The 103-page draft risk analysis is based on a careful examination of the scientific evidence related to the disease and this region. And, as with all regulatory actions, this proposal is now open for the public, as well as for Argentina, to provide comment.

18. As the United States has pointed out from the start, the core of Argentina's complaint is one of time and timeliness. It is these issues – time and timeliness – that underlay the scientific, technical, and legal questions raised by the dispute.

19. While it took the United States time to reach preliminary and final decisions for Northern Argentina and Patagonia, respectively, length of time is not the appropriate standard with which to reach a legal conclusion on the issue of timeliness. Rather, under Article 5.7 of the SPS Agreement, the legal question is whether the period of time taken "to seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly" is "reasonable." The United States has elaborated in prior submissions on the process of collecting information from Argentina in connection with these

two applications. A review of the record shows that the exchange of views and information and the time taken to consider them was reasonable.

II. This Dispute Should Be Analyzed In Light of the Obligations of Articles 2.2, 5.7 and 6.3 of the SPS Agreement

20. The SPS Agreement – through Articles 2.2 and 5.7, as informed by Article 6 and Article 6.3 in particular – addresses the situation raised by this dispute.

21. Article 2.2 states that Members shall ensure that SPS measures are not maintained without sufficient scientific evidence, except as provided in Article 5.7. Article 5.7 in turn sets out the rules that apply when "scientific evidence is insufficient" to complete an assessment of risks.

22. When an assertion of the disease status of the exporting Member is made, the importing Member is not likely to have all the scientific information it will need to review its existing measure and determine whether changes are appropriate, as was the case here. No Member and not even the OIE could determine immediately, at the moment that Argentina made a claim of disease-free status, whether to accept or reject that claim. In particular, no regulatory authority or organization had immediate access to Argentina's regulatory experts and the wide range of scientific information necessary to form a basis for an assessment.

23. Recognizing this, Article 5.7 obligates the importing Member to "seek to obtain the additional information necessary for a more objective assessment of the risk," and to "review the SPS measures accordingly." In the context of an assessment of a claim of disease-free status, the exporting Member will need to initiate data requests and collect information from the most relevant party – the exporting Member – and will use the additional information in reviewing the

existing SPS measure. This process is not indefinite, but must be completed within "a reasonable period of time."

24. Article 6 complements and reinforces this understanding of how Article 5.7 applies in these situations. Article 6.1 obligates the importing Member to adapt its measures to the SPS characteristics of the exporting Member, and those characteristics include the "level of prevalence of specific diseases." In particular, when the exporting Member makes the assertion that its territories are free of disease or of low disease prevalence as described, Article 6.3 obligates it to "provide the necessary evidence." This obligation on the exporting Member complements the obligation on the importing Member to "seek to obtain" the scientific information necessary to complete the assessment of risk.

25. During this process of risk assessment, the importing Member is permitted to maintain measures to restrict importation of product from the exporting Member, under Article 5.7. And there is no basis to accept – as Argentina appears to argue – that importing Members must modify their measures immediately upon an exporting Member's assertion that disease freedom or low disease prevalence is sufficient to meet the importing Member's appropriate level of protection. Indeed, Argentina itself asks the Panel to look at actions of other Members, such as the EU, and the practices of the OIE. But neither the actions of other Members or the OIE support the concept that a measure must change upon an assertion of disease-free status. Upon receipt of a claim, other Members and the OIE itself conduct an examination of the claim and the data before reaching a conclusion on the claim.

26. This is the most consistent reading of the provisions of the SPS Agreement relevant to this dispute that best understands those texts on their face, in their context, and in light of the

object and purpose of the Agreement. To not allow the maintenance of a provisional measure in this scenario would be to compel the importing Member to bear the risk of disease transmission pending the completion of the risk assessment. In the case of FMD, it would mean that an importing Member would have to risk infection by a disease with social and economic effects that are known to be severe, simply on the basis of an exporting Member's assertion.

27. Argentina's primary response to this framework is to dismiss the application of Article 6 because Argentina is not raising it in connection with its claim regarding the Northern Argentina application and states that there is a jurisdictional bar to considering Article 6.

28. This response should be rejected – it is well established that the SPS Agreement should be read as a whole, and that the relationship between relevant articles are relevant to the interpretation of any given Article. Argentina, however, would ask the panel to read provisions in isolation, an invalid interpretive process that cannot result in a correct, or workable, understanding of Articles 2.2, 5.7, and 6.3. Further, Argentina's assertion regarding a jurisdictional bar is baseless; to the contrary; under Article 7.1 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* ("DSU"), the Panel's terms of reference are to consider the "matter" raised by Argentina in the light of the relevant provisions of the covered agreements raised by *both* parties.

III. The United States Meets the Requirements Established in Article 5.7

A. Article 5.7 Applies to this Factual Situation

29. Before turning to the text of Article 5.7 itself, it is important to recall the text of Article 2.2. Article 2.2 is crucial in understanding Article 5.7, because it is only through Article 2.2 that Article 5.7 is tied to the obligations under the SPS Agreement. Article 2.2 provides:

> 2. 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. (Emphasis added)

30. Notably, Article 2.2 speaks to the "maintenance" of a measure. A measure must not be "maintained" without sufficient scientific evidence.

31. The application of the "sufficient scientific evidence" language in Article 2.2 is particularly difficult when that evidence changes over time – and this of course is the issue presented in this dispute. The issue is this: when the evidence changes, so that past evidence (in this dispute, a regulatory failure and an ongoing FMD outbreak) may no longer support an SPS control measure, is the importing Member immediately in breach? This is not a tenable reading of the Agreement. And indeed, Article 5.7 provides both an exception, and additional disciplines on the importing Member.

32. Before turning to Article 5.7, the United States also recalls the text of Article 5.1, which states:

> 1. 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.

33. For this purpose, two aspects of Article 5.1 are particularly notable. First, Article 5.1 includes no specific reference to the exception set out in Article 5.7. However, as Argentina acknowledges, and as many past panel and Appellate Body reports have found, Article 5.7 is viewed as an exception to Article 5.1. And, why is that? Because, as the United States has repeatedly stated, the various provisions of the SPS Agreement have to be interpreted in their context. And, if one does not read Article 5.7 so as to serve as an exception to Article 5.1, then it

is difficult to see how the provisions, when operating together, would meet the drafters' intent of providing a workable, comprehensive set of rights and obligations governing SPS measures.

34. The second notable aspect of Article 5.1 is that it uses the verb "based on" – that is, a measure must be "based on" an appropriate assessment of the risks. This obligation also applies over time, so that a measure's compliance with Article 5.1 may change over time, based on evolving scientific evidence.

35. Indeed, Argentina itself highlights this in its second written submission, citing the discussion in the panel report in *Japan – Apples*.[6] It cannot be the case that the instant scientific evidence changes, a Member is in breach of its Article 5.1 obligations. Rather, read in context, Article 5.7 must be available – both to allow the importing Member time to evaluate the new evidence, and at the same time, to impose obligations on the importing Member to seek additional information and to complete its review within a reasonable period of time.

36. With this context in mind, the United States recalls the text of Article 5.7:

> In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations, as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, 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.

37. Argentina, of course, focuses on one word within this provision – "adopt." But Argentina ignores the larger context provided by Article 2.2, which involves the maintenance of

[6] Argentina's Second Written Submission, para. 127 (referring to *Japan – Apples (Panel)*, para. 7.12).

a measure, and Article 5.1, which involves the issue of whether a measure is "based on" an assessment of risks.

38. Neither of these provisions – which are the obligations to which Article 5.7 serves as an exception – uses the word "adopt". In light of the context of these provisions, and for Article 5.7 to serve its role as an exception to those provisions, it must not be read as being limited to the formal adoption – in the sense of promulgation—of completely new measures addressed to a new product from an exporting Member. Rather, Article 5.7 must be read to also apply to evolving situations where measures are maintained without sufficient scientific evidence, and/or where a measure is no longer "based" on an appropriate assessment of risks.

39. Furthermore, Argentina's interpretation would have the formalistic and rather pointless result that a Member may only validly invoke Article 5.7 if it somehow took a formal step to withdraw one measure and immediately adopt an identical measure provisionally, even where – as is the case here – the Member's actions showed that it viewed the ongoing application of the conditions in the original measure as provisional. In this dispute, at the time Argentina renewed its claims of FMD-free status in 2002, the United States accepted the application and began the review process. Further, the U.S. regulatory system is clear that once an application is received, the existing restrictions are provisional pending the evaluation of the application. In other words, the record shows that the U.S. measure was provisional until review is completed.

40. The United States further notes that to the extent a functional Article 5.7 measure must be tied to the word "adopt", the United States did adopt a measure when it agreed to review Argentina's claim that circumstances had changed in its disease status. And under that measure, the existing restrictions remained in place. But the United States would again note that under a

proper reading of the relevant articles in context, Article 5.7 cannot be limited to situations where there is a formal "adoption" of a new measure.

B. The U.S. Measures Meet the Requirements of Article 5.7 of the SPS Agreement

41. Contrary to Argentina's arguments, the United States did "seek" information, as required under Article 5.7. In particular, the United States requested that Argentina provide information as to its disease status. The United States clearly sought the relevant information, since 9 C.F.R. 92.2 states that applications to APHIS "must include" information about the region in question including scope of the evaluation, veterinary systems, disease history, vaccination practices, geography, livestock demographics, surveillance, diagnostic capabilities, and emergency preparedness.[7] That is a request to seek information. To say that the United States did not "seek" information is to ignore the evidentiary record in this dispute.

42. With respect to the reasonable period of time requirement, the United States met this requirement as well. The record shows that APHIS and SENASA exchanged information over the period in question and that site visits were conducted in several areas and on a number of occasions. These exchanges of information between APHIS and SENASA need to be seen in context of the changing situations on the ground in Argentina and on Argentina's own shifting requests for import authorization. As noted in prior submissions, Argentina first wanted one review of the country for import authorization for fresh beef. Then it submitted an application for Patagonia South, which initiated a separate, new review process. During this time, there were two outbreaks of FMD in Argentina. Shortly afterwards, Argentina asked that a third area,

[7] 9 C.F.R. § 92.2(b) (Exhibit USA-76).

Patagonia North B be reviewed, and then asked that the area be combined together with Patagonia South.

43. Argentina takes note of these changes, but does not recognize that these facts have any impact on information needs and on the pace of review. The nature of the review is complex. It includes not simply whether FMD exists or not in the country, but also whether the country has the capacity to maintain and to prevent future FMD incidents. In this light, the time elapsed is reasonable. Further, the record shows that the APHIS process is working, as demonstrated by the APHIS final determination on Patagonia and the proposal to permit imports of fresh beef from Northern Argentina.

44. The Panel has specifically asked about certain correspondence by Dr. Clifford in this dispute. As confirmed in the expert session, the U.S. risk assessment process is acknowledged worldwide as extremely thorough and reliable. As part of the APHIS process, the United States attempts to be transparent with its trading partners, and communicates as best it can during the risk assessment process.

45. In an attempt to support its argument that the time APHIS took to process its applications in this case was not reasonable, Argentina claims that correspondence from Deputy Administrator Clifford of APHIS's Veterinary Services division in response to requests for updates from SENASA confirm that the United States had finished a favorable risk assessment for Northern Argentina in 2010.[8] That, however, is not correct. In the (September 2010) letter cited by Argentina, Dr. Clifford simply stated that, with respect to Northern Argentina, APHIS

[8] Argentina's Second Written Submission, para. 261.

was "currently drafting a proposed rule that would allow the importation of fresh, chilled, or frozen Argentine beef under certain conditions . . ."[9] Dr. Clifford also noted in the same letter that "[w]hile we recognize that [SENASA] would like to see this matter resolved as expeditiously as possible, it is important that APHIS follow the rulemaking process to ensure that our decision making is thorough and transparent."[10]

46. Elsewhere, Argentina claims with respect to Patagonia that statements made by APHIS's Veterinary Services division that "[APHIS did] not currently require additional information to proceed with the FMD risk assessment"[11] and that "APHIS has made significant progress toward recognizing the FMD-free status of southern Patagonia"[12] somehow demonstrates that the subsequent time USDA took to finalize and publish the notice for the Patagonia region was not reasonable. Finally, in its prior submissions and at the first Panel meeting, Argentina also pointed to statements made by the U.S. representative at the June 2011 and October 2011 WTO SPS Committee meetings to allege that the United States should have completed its risk analysis procedures earlier.

47. As the United States has previously explained, during this time period, APHIS in fact had done substantial work both in updating its risk analysis for Patagonia and finalizing the preliminary risk assessment for Northern Argentina. The United States recalls that it proposed in November 2012 another site visit but received no answer from Argentina until July 2013. At

[9] Exhibit ARG-47.

[10] *Id.*

[11] Argentina's Second Written Submission, para. 270; Exhibit ARG-79.

[12] Exhibit ARG-62.

Argentina's suggestion, that site visit was made in November 2013. That work has resulted in the final determination of FMD-freedom for the Patagonia region and the proposal to permit imports of fresh beef under certain conditions from Northern Argentina that was published last week.

48. The U.S. rulemaking and risk assessment process, however, because it is so thorough and deliberate, does take time. The beginning of the drafting of a proposed regulation by the Veterinary Services division does not by any means mean a risk assessment for northern Argentina had been completed in its entirety by APHIS. That results only when a final rule and risk assessment have been published, after a period of public comment. Further, the drafting of a risk assessment and its accompanying proposed rule by Veterinary Services is simply the starting point. As discussed earlier, these working papers are still subject to internal scientific, legal and policy reviews and revision (both within APHIS and USDA) as a whole and must include other information disclosures required by law (for example, environmental assessments) before they can be finalized and subsequently published in the Federal Register as a proposed rule or determination.

49. The United States would finally note that in the time between these correspondences and statements (in 2009, 2010, and 2011) to publication of the final determination for Patagonia and the proposed rule for northern Argentina (in 2014), the same APHIS staff who have completed the 87-page risk assessment for Patagonia and the 103-page risk assessment for northern Argentina (and their administrative notices and accompanying environmental assessments) have been extensively involved in this WTO litigation which has occupied a considerable amount of their time. And they have had to continue their work on numerous other FMD and other animal

disease applications, as well as carry out other substantive duties. The United States is one of the largest export markets for animal products, and our transparent application processes result in numerous Member requests for access. All of these requests must be managed by APHIS staff.

50. In sum, Argentina's complaints about the length of time it has taken since Dr. Clifford's letters to obtain access to the U.S. market cannot be viewed in a vacuum. Rather, the SPS Agreement provides national regulators a "reasonable" period of time to review and adjust their sanitary measures. In evaluating what is "reasonable," one must take account of all the case-specific circumstances, including the complexities of the scientific inquiries involved and the competing demands on regulators.

IV. APHIS's Regulatory Approval Process Is Based on International Standards

51. APHIS's regulatory approval process is based on international standards and is consistent with Article 3 of the SPS Agreement. There are three key points critical for the Panel's consideration. Each point supports a finding that the measures of the United States are based on international standards.

52. First, the OIE process in evaluating FMD disease status is similar to that of the United States. Starting with a higher level of generality, the basic process is the same: the United States recalls (1) the OIE only issues official status designations upon application of a Member; (2) the OIE immediately rescinds official status designations upon the occurrence of an FMD outbreak; (3) regaining official status after a claim by a Member of disease freedom is based on an application to the OIE; and (4) official status is only gained after review of the data submitted by the Member seeking status. As the United States has stated from the beginning of this dispute: this process is the same as that employed by APHIS. Moreover, as the United States has laid out

in detail in its written submissions, APHIS and OIE substantive standards are similar at base: APHIS regulations and OIE standards permit trade in fresh meat from FMD-free countries without vaccination; they permit trade in fresh meat for countries that vaccinate, albeit with some differences in conditions, and they permit trade in cooked beef for infected countries.

53. Second, Argentina has contended that the United States must follow the OIE status designation because it is a "standard, guideline, or recommendation" under the SPS Agreement. It urges the Panel "not to try to parse the term 'standards, guidelines, or recommendations' too closely."[13] However, as the United States has stated, application of the term "standards, guidelines, or recommendations" to any particular OIE statement or document is a fact-specific, legal issue. And, the issue has to be examined "closely." Not every document issued by an international organization can properly be referred to as a standard. Rather, one must look at all available information, including the text of a document and the manner in which it is adopted.

54. Here, the designations themselves – even on their face – do not look like standards, guidelines, or recommendations. No standard is set, no guideline is provided, and no recommendation is made.

55. Further, the difference between the process of adopting, on the one hand, the OIE Code, and on the other, the annual status designations, is striking. Indeed, in its papers and in its

[13] Argentina's Second Written Submission, para. 96.

remarks, the OIE showed that the process of adopting the official status designation is in actuality nothing like the process used for the standards set out in the Terrestrial Code.[14]

56. First, the OIE committee responsible for the Terrestrial Code does not review the official status designation.

57. Second, unlike the Terrestrial Code, OIE Members are not invited to participate in the process of official status designations. Indeed, an OIE Member has no meaningful role in the process**.** In fact, the OIE Membership does not even know which OIE Members have applied for official status designation, which ones have been denied official status designation, nor the reason for the denial.

58. Third, OIE Members do not have any opportunity to review the candidate's file or the underlying working papers: these are not disclosed. As the OIE noted, the *ad hoc* group's report and Scientific Committee's recommendations are summary documents that do not reference specific underlying data or sources.

59. Fourth, OIE Members do not have a meaningful opportunity to comment or question the Scientific Committee's recommendation to the World Assembly: OIE Members are given a mere 60 days to provide comment or raise questions, based on a very scanty evidentiary record.

60. Fifth, the OIE confirmed that a committee – without consultation with the OIE membership – is empowered to modify a disease status designation in response to changing circumstances. In contrast, the only way to change an OIE standard in the Terrestrial Code is

[14] *See, e.g.*, OIE Responses to Panel Questions Nos. 5 and 13, and the OIE's remarks at the expert meeting regarding confidentiality, access to work papers, and the limited participation of OIE Members in the official designation process.

through the same formal process, allowing full OIE member input, as used to adopt a new standard.

61. Finally, the status designation comes with a disclaimer: the OIE does not stand by the designation if the judgment turns out to be incorrect, and that judgment is typically based on a simple paper review of the dossier. A main reason that international standards have legitimacy, and are given legal force in the SPS Agreement, is that they are adopted in a transparent manner that allows full participation by all members of the standards-setting organization. The process for adopting OIE status designations does not result in similar legitimacy.

62. Further, the individual experts confirmed that Member states treat the OIE designations as the United States does: as a relevant fact to be considered when assessing the disease status of an importing Member. Indeed, the United States has done just this, as can be seen in its recently published risk assessments for Patagonia and Northern Argentina.

63. Third, Argentina's arguments concerning Articles 8.5.23 and 8.5.25 of the OIE Code has no merit. This was further confirmed by the OIE statements at the expert meeting. In particular, the OIE stated that after the loss of status, a Member "has no status" and therefore the recommendations that apply in the meantime are for infected regions—in this case, this meant no trade in fresh beef. The determination of how to treat the importing Member's product is then subject to a review of the disease status situation in the importing Member to consider the applicability of another provision. That is precisely the process that the United States was undergoing when this dispute was brought.

V. The U.S. Measures Are Consistent with Article 5.6 of the SPS Agreement

64. Argentina has not met its burden under Article 5.6 of the SPS Agreement of establishing that another measure is reasonably available that can meet the U.S. ALOP.

A. Argentina Has Not Met Its Evidentiary Burden Under Article 5.6

65. Argentina has not met its burden to show that the protocols applied to Uruguay could be applied to Argentina in a way so as to meet the ALOP of the United States. To do so, Argentina would have had to have prepared a document comparable to the full APHIS risk assessment now on the record in this dispute. But of course, Argentina has not done so; instead it relies on assertions that Argentina is like Uruguay. But as the OIE confirmed, OIE status designations are not intended to be comparisons between different countries. Moreover, this void in Argentina's claim cannot be filled through the use of experts during panel proceedings. The Appellate Body has made clear that "[t]he purpose of a panel consulting with experts is not to perform its own risk assessment."[15]

66. Even if one examines the experts' evaluation of the risks – which is not a proper use of experts – Argentina does not meet its burden. In fact, the individual experts were not able to agree and to assess whether relevant animal control systems in Argentina and Uruguay were similar enough to meet the appropriate level of protection of the United States. Such animal

[15] *United States – Continued Suspension (AB)*, para. 592.

control systems included, for example, surveillance,[16] animal identification and census,[17] movement controls,[18] and sanitary situations[19].

67. The same is true for Patagonia. Argentina has not shown that measures that were applied to Santa Catarina would be appropriate for the Patagonia region – Patagonia South and Patagonia North B – the regions relevant to this dispute. The fact that APHIS proposed to extend FMD-free status to Patagonia in January 2014 based on a risk assessment that accompanied the regulatory notice cannot help Argentina make its case now. Argentina must meet its burden with the evidence as of panel establishment, and it has not done so.

68. Although it has emphasized that the Uruguay and Santa Catarina protocols as reasonably available and less restrictive alternatives, Argentina has also offered, in passing, that the United States could "easily apply" the available OIE recommendations.[20] Argentina has made no real attempt to provide persuasive evidence that such recommendations meet the United States' appropriate level of protection. The United States has explained that animals and animal products that are vaccinated pose an FMD threat. The individual experts confirmed that the risk of transmission of FMD still exists even with the use of vaccination. Argentina does not and cannot dispute the fact that vaccination poses a risk that, without the use of certain control measures, some Members cannot accept. In fact, Argentina's rules for Patagonia do not permit

[16] Individual Experts' Responses to Panel Questions Nos. 34 and 54.

[17] Individual Experts' Responses to Panel Question No. 35.

[18] Individual Experts' Responses to Panel Question No. 36.

[19] Individual Experts' Responses to Panel Question No. 58(a).

[20] Argentina's Comments on Individual Experts' Responses to Panel Questions, para. 6; *see also* Argentina's First Written Submission, paras. 307, 507.

the importation of FMD-susceptible animals from Northern Argentina, where vaccination occurs, into Patagonia. Moreover, Argentina only allows deboned and matured beef from Northern Argentina to enter Patagonia.[21]

VI. Evidence on the Record Does Not Support Argentina's Claim Under Article 2.3 of the SPS Agreement

69. Argentina has not met its burden and established that the United States has acted inconsistently with Article 2.3 of the SPS Agreement.

70. With respect to Argentina, Uruguay, and Japan, the individual experts were not able to conclude unanimously that the systems were similar with respect to surveillance,[22] animal identification and census,[23] movement controls,[24] or sanitary situations.[25]

71. With respect to Patagonia and Santa Catarina, although the individual experts made some statements as to comparability, it must be made clear that they made those statements using the APHIS risk assessment published in January 2014, which was after the date of panel establishment. As such, they are relying on APHIS's own findings and proposal to determine that Patagonia (the whole region) is free of FMD. In fact, APHIS made that determination final on August 29, 2014.

72. The fact is that short of using APHIS's own risk assessment of 2014, Argentina cannot demonstrate facts in evidence to meet its burden under SPS Article 2.3.

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[21] Exhibit ARG-110, p. 22.

[22] Individual Experts' Responses to Panel Questions Nos. 34 and 54.

[23] Individual Experts' Responses to Panel Question No. 35.

[24] Individual Experts' Responses to Panel Question No. 36.

[25] Individual Experts' Responses to Panel Question No. 58.

73. The OIE's official recognition of the FMD status of a country or area is not sufficient to establish that regions have identical or similar conditions within the meaning of Article 2.3. As the OIE acknowledged and the individual experts stated: the fact gathering by the OIE is typically limited to "desk review." The OIE and the individual experts agree: the OIE official status designation is not an import risk assessment. Because the designation is not a risk assessment, it cannot be used to conclude that the risk from two Members with the same status designation is the same or similar. Its only use is to confirm that a Member meets the OIE's minimum standard. Accordingly, Argentina's Article 2.3 claim fails.

74. Neither is Argentina's complaint that the United States has not completed the APHIS regulatory process in the same time that other countries have completed it a claim recognizable under Article 2.3. The review by the United States of Argentina's requests is not a "sanitary or phytosanitary measure" subject to Article 2.3. Nor is it clear what constitutes the "discrimination." Argentina does not point to any facts in the record to show that its review process, including the interactions between the importing and exporting authority, was comparable. It can only point to the time to decision, but that alone is simply a difference with no context.

VII. Argentina's Annex C(1)(b) Claim Fails

75. Contrary to Argentina's contention, the United States does not accept Argentina's claims under Annex C(1)(b). As an initial matter, as the United States has explained, Annex C does not apply to determinations of disease-free status.

76. The United States also does not agree, as Argentina contends in its second written submission, that Argentina has shown a breach of any obligation under Annex C(1)(b). Annex

C(1)(b) consists of five clauses, each with one or more different obligations. Of those obligations, only one is within terms of the reference of this dispute. In particular, the only Annex C(1)(b) claim mentioned in Argentina's panel requests is a reference to the fifth clause of Annex C(1)(b), involving the explanations for delay. The United States makes no apologies for pointing this out at this time; this is a jurisdictional matter, and it is Argentina's responsibility to ensure that each one of its dozens of claims was actually set out in its own panel request.

77. Further, the record does not support Argentina's arguments. With respect to Argentina's applications, APHIS (1) promptly examined Argentina's applications for completeness upon receipt, and notified SENASA of deficiencies on multiple occasions; and (2) proceeded as far as practicable with its evaluation even when SENASA's applications had deficiencies. And, when the process was delayed by insufficiencies in SENASA's applications, APHIS explained that it needed SENASA to provide such necessary information.

78. Argentina has also asserted that APHIS failed to transmit final results of the evaluation process; however, this claim fails for a simple and clear reason: there were no "results" to transmit to Argentina.[26] For all these reasons, Argentina has not presented valid claims under Annex C(1)(b).

VIII. Conclusion

79. The core issue of this dispute is that the SPS Agreement contemplates and provides a framework for analyzing a dispute such as this one. It is this: when an exporting Member makes a claim about its disease status, it is consistent with the SPS Agreement under Articles 2, 5, and 6

[26] *EC –Approval and Marketing of Biotech Products*, para. 7.1595.

for the importing Member to take a reasonable period of time to collect and review the necessary scientific information to make an assessment of risk. This understanding is well understood by the practice and the procedures of other Members, by the OIE, and the United States. It is in the written reports and you heard it on Tuesday multiple times, the collection and review process of the United States is thorough and well respected, as the Panel's experts have all stated. And Argentina has failed to show that the United States, in conducting this thorough review process, did not meet its obligations to collect and review the evidence in a reasonable period of time. Accordingly, Argentina's claims must fail.

80. Mr. Chairman, members of the Panel, this concludes our opening statement. We would be pleased to respond to any questions you may have.