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

(DS447)

SECOND WRITTEN SUBMISSION

OF THE

UNITED STATES OF AMERICA

March 25, 2014

TABLE OF CONTENTS

TABLE OF EXHIBITS

EXHIBIT NUMBER	LONG CITATION	SHORT CITATION (IF APPLICABLE)
US-150	Oxford English Dictionary (1993), "Adopt"	Oxford English Dictionary (1993), "Adopt"
US-151	European Commission, Health & Consumer Protection Directorate-General, Final Report of a Mission Carried Out in Argentina from 20 to 29 April 2005 in Order to Evaluate Animal Health Controls in Place in Particular Over Foot and Mouth Disease, Public Health Control Systems and Certification Procedures (Jan. 25, 2006)	DG-SANCO Final Report on FMD Controls in Argentina
US-152	Oxford English Dictionary (1993), "Standard"	Oxford English Dictionary (1993), "Standard"
US-153	Oxford English Dictionary (1993), "Recommend"	Oxford English Dictionary (1993), "Recommend"
US-154	Agreement Between The World Trade Organization and The Office International Des Epizooties, WT/L/272 (July 8, 1998)	Agreement between the WTO and the OIE (1998)
US-155	9 C.F.R. § 94.22 (2013)	9 C.F.R. § 94.22
US-156	United States Department of Agriculture, Animal Health Inspection Service Change in Disease Status of the Patagonia South Region of Argentina with Regard to Rinderpest and Foot-and-Mouth Disease, *Public Comments* Comment Period Closed (March 6, 2007)	USDA, APHIS Change in Disease Status of the Patagonia South Region of Argentina with Regard to Rinderpest and Foot-and-Mouth Disease, *Public Comments*

TABLE OF REPORTS

SHORT FORM	FULL FORM
Australia – Apples (Panel)	Panel Report, *Australia – Measures Affecting the Importation of Apples from New Zealand*, WT/DS367/R, adopted 17 December 2010, as modified by Appellate Body Report, WT/DS367/AB/R
Australia – Apples (AB)	Appellate Body Report, *Australia – Measures Affecting the Importation of Apples from New Zealand*, WT/DS367/AB/R, adopted 17 December 2010
Australia – Salmon (Article 21.5 – Canada)	Panel Report, *Australia – Measures Affecting Importation of Salmon – Recourse to Article 21.5 by Canada*, WT/DS18/RW, adopted 20 March 2000
Canada – Aircraft (AB)	Appellate Body Report, *Canada – Measures Affecting the Export of Civilian Aircraft*, WT/DS70/AB/R, adopted 4 August 2000
China – GOES (AB)	Appellate Body Report, *China – Countervailing and Anti-Dumping Duties on Grain Oriented Flat-Rolled Electrical Steel from the United States*, WT/DS414/AB/R, adopted 16 November 2012
EC – Approval and Marketing of Biotech Products	Panel Reports, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R / WT/DS292/R / WT/DS293/R, Add. 1 to Add. 9*, and Corr. 1, adopted 21 November 2006
EC – Hormones (AB)	Appellate Body Report, *EC – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998
Japan – Agricultural Products II (AB)	Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R, adopted 19 March 1999
Japan – Apples (Panel)	Panel Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/R, adopted 10 December 2003, as modified by the Appellate Body Report, WT/DS245/AB/R
US – Poultry (China)	Panel Report, *United States – Certain Measures Affecting Imports of Poultry from China*, WT/DS392/R, adopted 25 October 2010

I. INTRODUCTION

1. At core, this dispute is about timing and the mutual obligations under the SPS Agreement when a claim is made that an exporting Member's territory, in whole or in part, is free of disease or of low disease prevalence in relation to disease of concern to an importing Member. The SPS Agreement addresses this through Article 5.7 and Article 6. The importing Member begins an assessment of risks and seeks 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. The importing Member collects information necessary for an objective assessment of the risk and reviews its existing SPS measure accordingly within a reasonable period of time. Pending the completion of the information collection and review process, the importing Member may maintain provisionally its measure affecting the importation of the product.

2. Argentina's view is the opposite. According to Argentina, 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 Agreement and is not reflected in the practice of other Members, which 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."[1]

3. Nor is Argentina's position consistent with the OIE system. The OIE does not take a Member's claim of disease freedom at face value. A Member seeking OIE recognition must submit scientific information so that a committee within the OIE can evaluate the claim.

4. Thus, contrary to Argentina's position, the evaluation of a claim of disease-free status is a dynamic process. That process must reflect the practical reality that the information about the disease in the exporting Member is in a territory that is difficult for the importing Member to access. The importing Member needs time to obtain the relevant information, analyze it, and determine the appropriate measures.

5. In this dispute, the U.S. measure is based on the international standard, and reflects the practice followed by other Members and the OIE. In 2002, Argentina claimed that it was free of the FMD disease and sought to export beef to the United States. The United States began a process of requesting information from Argentina, conducting site visits to the country, and analyzing the data that it collected. The FMD situation in Argentina and the country's ability to prevent outbreaks has been in question throughout this process, especially with recurring outbreaks in 2003 and 2006. Argentina also caused delays in the process by revising its requests to include more regions and then delaying responses to APHIS questions. Nevertheless, the United States continues to process Argentina's applications and is doing so within a reasonable period of time, consistent with Article 5.7.

---

[1] Argentina's Response to Panel Question No. 53, para. 202 (emphasis supplied).

6. Argentina's other claims fail because they are based on the flawed premise that the United States has completed its review process and adopted a permanent ban on beef from Argentina, and because Argentina has not met its burden of proof. For example, Argentina has asserted that the United States breached Article 5.6 and Article 2.3 because the United States did not apply the measures to Argentina that it extended to Uruguay and Brazil. However, the United States is continuing to review conditions in Argentina, and Argentina has failed to present any scientific evidence that the conditions extended to Uruguay or Brazil to meet the U.S. ALOP would meet the U.S. ALOP when extended to Argentina. With respect to Article 2.3, Argentina similarly fails to provide any evidence that comparisons with Uruguay, Brazil, Japan or the United Kingdom are relevant and appropriate.

7. Argentina also presents claims that lack foundation in the SPS Agreement and in past panel and the Appellate Body reports. Notably, Argentina provides no argument that should persuade this Panel to reject the reasoning of prior panels and the Appellate Body that Article 5.4 does not impose affirmative obligations, and that Article 10.1 does not prescribe a specific result to be achieved.

8. For these reasons, Argentina's claims should be rejected in their entirety.

II. LEGAL ARGUMENT

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

9. This dispute is about determining the obligations under the SPS Agreement in connection with an exporting Member's assertion that its products should be allowed to enter the territory of an importing Member because the exporting Member's territories are alleged to be disease-free or of low disease prevalence. The proper disposition of this scenario, as envisioned by Articles 5.7 and 6, is that the importing Member collects additional information needed to assess the risks of the imported product and reviews its measure accordingly, [2] making use of the relevant information provided by the exporting Member. While this process is underway, the importing Member can maintain provisionally its measure affecting importation of the product (and especially where the Member has previously assessed that unrestricted trade would pose an unacceptable level of risk).

10. The SPS Agreement – through Articles 2.2 and 5.7, as informed by Article 6 and Article 6.3 in particular – addresses precisely this situation. 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. When an assertion of the disease status of the exporting Member is made, the importing Member is not likely to have all the scientific

[2] In such a scenario, the importing Member may have had a previous assessment of risks posed by the exporting Member. It is also easy to conceive in such a scenario that this is the first encounter between the exporting and the importing Member. In either case, what is common is that the exporting Member is making an assertion of current circumstances to which the importing Member must respond.

information it will need to review its existing measure and determine whether changes are appropriate, as was the case here. Notably, the importing Member does not readily have access to the exporting Member's regulatory experts and the wide range of scientific technical information necessary to form a basis for an assessment.

11. 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."

12. 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 above, 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.

13. During this process of risk assessment, the importing Member is provisionally permitted to maintain and adopt 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 o a measure must change upon an assertion of disease-free status. Upon receipt of a claim, other Members[3] and the OIE itself conduct an examination of the claim and the data before reaching a conclusion on the claim.

14. This is the most consistent reading of the provisions of the 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 SPS 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 highly contagious and debilitating disease and bear the risk of substantial economic and social damage, simply on the basis of an exporting Member's assertion.

[3] Other Members maintain similar frameworks in which importation is not permitted pending an evaluation and determination by the importing Member's regulatory authority. *See, e.g.*, Canada (Sections 7, 40 and 41(b)) (Exhibit USA-135); European Union (Exhibit USA-136); Argentina, pp. 30-31 (Exhibit USA-133).

15. The United States further notes that such an interpretation of the SPS Agreement would be contrary to the core principle of the SPS Agreement, stated in Article 2.1, which is that each Member has "the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health."

1. Argentina's Arguments Fail to Address the Key Legal Issues in the Dispute

16. Argentina refuses to grapple with the fundamental question in this dispute discussed above, as well as raised by the Panel at the first meeting and in Questions Nos. 23, 24, and 29. Instead, Argentina asserts that even if the initial 2001 decision by the United States to remove import authorization was justified,[4] it is no longer maintained by a risk assessment and breaches Article 2.2 and Article 5.1 because of Argentina's assertion that its territories are free of FMD. Argentina argues that Article 5.7 is not relevant, ignoring the fact that the United States is reviewing Argentina's claim of changed status within a reasonable period of time.

17. Argentina's position is inconsistent with the text of the SPS Agreement and previous panel and Appellate Body reports. Articles 2.2 and 5.7 are directly relevant to the issues in this dispute. Article 2.2 states that SPS measures shall not be maintained "without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5." Article 5.7 is a "qualified" right and when its requirements are satisfied, Article 2.2's obligation not to maintain a measure without sufficient scientific evidence is "not applicable to the challenged measure."[5] Article 5.7 applies in cases in which "relevant scientific evidence is insufficient" to conduct a risk assessment, and in these instances, the panel in *EC – Approval and Marketing of Biotech Products* concluded "Article 5.7 permits Members to do, in certain circumstances, what they would not be permitted to do under Article 5.1."[6]

---

[4] Argentina does not dispute, nor can it dispute, that the measure taken by the United States to remove Argentina's import authorization in 2001 during the midst of an FMD outbreak, was in fact, a measure supported by a risk assessment. (An action that it itself recognized when it stopped its own exports.) The measure taken to remove Argentina's import authorization in 2001 was based on an assessment of the risk of FMD: namely, the scientific evidence of the contagiousness of the disease, together with the well-established practice (*see* OIE Code Article 8.6.26) that when an area is one affected by FMD, particularly active outbreaks, trade in fresh meat can be stopped. See the description of the science and the risk of FMD in the U.S. First Written Submission, paras. 18-49 and accompanying footnotes and exhibits. This science was recognized in the measure taken to remove authorization. *See* Exhibit ARG-29, p. 29898 ("FMD is among the infectious and destructive of all livestock diseases"; "We are taking these actions because the existence of FMD has been confirmed in that country.") The measure also recounted the scientific data showing that the FMD situation was deteriorating ("[s]ince these initial detections, the number of confirmed cases has increased steadily") and that action was need to "protect the livestock of the United States from FMD".

[5] *EC – Approval and Marketing of Biotech Products*, para. 7.2974.

[6] *EC – Approval and Marketing of Biotech Products*, para. 7.2993. The Appellate Body also stated in *EC – Hormones* that: "Articles 2.2 and 5.1 should constantly be read together. Article 2.2 informs Article 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1." *EC – Hormones (AB)*, para. 180.

18. If the Panel were to find that Article 5.7 does not apply to this case, the systemic implications for national animal health protection regulatory authorities would be significant. It would mean that any measure validly taken to stop imports because of risks raised by an animal disease could be found inconsistent with the SPS Agreement when the exporting Member merely declares that circumstances have changed. An exporting Member could simply argue that the former risk assessment was not current and thus the measure was in breach of Article 5.1, even if the importing Member had no opportunity to collect information, review it, and revise its measures.

19. The implication of Argentina's view is that each importing Member would be obligated to constantly update every risk assessment of every potential exporting Member in order to comply with its WTO obligations. This is infeasible and an inappropriate interpretation of the relevant provision – no importing Member has information about the status of disease and internal controls in every other exporting Member in the world.

2. Argentina's Article 6 Distinction between "Commodity" and "Regionalization" Is Not A Distinction Recognized in the SPS Agreement

20. Argentina attempts to discount the relevance of Article 6 in this case by creating a distinction between "regionalization" requests and "commodity" requests. It states that Article 6.3 in particular, applies only to Patagonia because Article 6.3 "is for regional requests, not for commodity requests."[7] It provides no reasoning or basis in the language of Article 6 or the Agreement for the existence of this distinction or what it means.[8]

21. Article 6 is clear. Article 6.1 states that measures are to be "adapted to the sanitary or phytosanitary characteristics of the area . . . from which the product originated and to which the product is destined" (emphasis supplied). Article 6 directly relates to a Member's request to export a product or, in the words of Argentina, a "commodity." Article 6.1 provides that the importing Member should ensure that measures relating to the import of the product are adapted to the SPS characteristics of the area in question.

22. Article 6.3 directly relates to Article 6.1 because, when a Member seeking to export a product (or commodity) bases its request on the assertion that its territory is an area of disease freedom or of low disease prevalence, it should provide the necessary evidence to the importing Member.

23. These Articles do not draw any distinction articulated by Argentina between a so-called "regionalization" request and a "commodity" request. Argentina's assertion to the United States, for all intents and purposes, is that it is free of FMD, and accordingly, seeks to export fresh beef

[7] Argentina's Response to Panel Question No. 48, para. 188 (*see also* Argentina's Response to Panel Question No. 29, para. 134).

[8] Nor do we understand Argentina, in its "commodity" request, to be claiming that it is not free of FMD. But if it is claiming that it is not free of FMD, then this would be a significant and material fact.

from the whole country.[9] Argentina itself acknowledges in its responses to the Panel that the term "region" may "include countries."[10] Argentina cannot arbitrarily limit the scope of applicability of Article 6 either by introducing categories that are not in the text of the Agreement or by stating that it is only alleging a breach of Article 6 with respect to Patagonia. [11]

24. Article 6 emphasizes the obligation of the exporting Member to work with the importing Member and recognizes that the importing Member is entitled to have time to review and decide on the basis of full information. Argentina's position requires it to disregard the relevance of Article 6, and particularly Article 6.3, which directly obligates the exporting Member to provide the necessary evidence before an importing Member makes a decision on the disease status of the exporting Member's territory.[12] As a result, Argentina relies upon distinctions between "commodity" and "regionalization," distinctions that are nowhere found in the Agreement

B. Measures Taken by the United States Are Justified Under Article 5.7

1. Data Concerning Argentina's Internal Controls Over FMD and Its Disease Status Are "Scientific Evidence" Within the Meaning of Article 5.7

25. At the outset, the United States notes that the term "scientific evidence" in Article 5.7 includes all the types of evidence involved in evaluating a claim that an area is free of disease or of low disease prevalence. The Appellate Body in *EC – Hormones* found that "scientific evidence" included "the observation, identification, description, experimental investigation, and theoretical explanation of natural phenomena, any methodological activity, discipline, or study, and knowledge attained through study or practice."[13] This type of evidence includes the various types of data relevant to this dispute, including, for example, information that pertains to presence of disease and assessment of systems and procedures to prevent and contain the FMD. Argentina appears to agree with this: it stated that "the term 'scientific evidence' is broad enough to encompass evidence associated with products originating in a specific country"[14] and can also "include information related to the situation in the country or region[.]"[15]

[9] Argentina submitted a request to the United States for "the recognition of all of Argentina as a region free of foot-and-mouth disease." Argentina's First Written Submission at para. 109. *See also* SENASA's application to APHIS, in which Argentina claimed the last FMD outbreak was in January 2002. (Exhibit ARG-31, p. 19.).

[10] Argentina's Response to Panel Question Nos. 49 and 52, paras. 192, 200.

[11] Argentina also argues that Article 6 covers "supplementary" SPS measures, but does not explain what this means or the basis for this argument in the text. Argentina's Response to Panel Question No. 49, para. 192.

[12] This view is supported by the SPS Committee's Guidelines to Further Practical Implementation of Article 6, para. 31 (Exhibit USA-128) and addressed by the United States in its response to Panel Question No. 51, paras. 215-217.

[13] *EC – Hormones (AB)*, para. 187 & fn.172 (internal quotations omitted).

[14] Argentina's Responses to Panel Question No. 21, para. 62.

[15] Argentina's Responses to First Panel Question No. 20, para. 76.

2. At the Time of Argentina's Application for Authorization, the United States Did Not Have Sufficient Scientific Evidence Concerning Argentina's FMD Internal Controls and Its Disease Status

26. In November 2002, at the time in which Argentina made its assertion of the status of FMD in its territory, there was insufficient scientific evidence as to the FMD situation in Argentina and that country's ability to impose and maintain internal controls so as to prevent FMD incidents from occurring so as to allow the United States to review the pre-existing SPS measure.

27. Argentina states that "there really is very little that can be unknown or uncertain" because "a great deal [is] known about how to handle products that are susceptible to the disease and the success of import protocols can be observed."[16] Argentina's argument is unpersuasive for two reasons. First, although much is known about the modes of transmission of FMD, the scientific, technical, and administrative issues involved in a successful control program are quite complex. This is particularly the case where – as is the case with Argentina – there is a land border with regions where FMD is endemic. The record demonstrates the complexity of the issue: even after Argentina claimed to have resolved its 2000-2002 FMD outbreaks, Argentina suffered FMD outbreaks in both 2003 and 2006. If issues involving FMD control were as simple and well-resolved as Argentina argues, then those repeated failures of control would not have occurred. The OIE itself suspended Argentina's status both times, which reflects the difficulties and complexities with the assessment of exporting Member's control systems.

28. Second, Argentina fails to recognize that at the time that Argentina sought access to the United States market in November 2002, the United States did not have information regarding Argentina's current disease situation and its regulatory system's ability to "handle products that are susceptible to the disease" and its ability to impose "import protocols." That is why the United States undertook a process of obtaining that information through information requests to Argentina. As Argentina notes, other Members and other institutions also conducted reviews and sought information. At the time that the United States began its process, even the OIE was still in the process of evaluating Argentina's renewed claim of disease-free status.[17] In short, the record is clear that the United States was justified in maintaining provisionally its measure when Argentina submitted its request for disease-free status in 2002.

3. The United States' Prohibition of Argentina's Import of Beef Pending Its Review of Argentina's Application Is Consistent with Article 5.7

29. Argentina argues that the United States "adopted" no measures in 2002, and that the "application by Argentina to APHIS was an action by Argentina."[18] If Argentina is arguing that

[16] Argentina's Responses to Panel Question No. 20, para. 77.

[17] Any information from other Members, such as the EU and Chile, was not definitive, nor has Argentina established that either country is comparable to the United States for purposes of this dispute. See discussion following this section that directly addresses this issue.

[18] Argentina's Responses to First Panel Question No. 24(c), para. 98.

the United States was required under Article 5.7 to issue some sort of legislation or statute in order for the measure to be fall within the scope of Article 5.7, this legal position is untenable from a textual and practical standpoint.

30. Most notably, Argentina ignores the plain text of Article 2.2 – which is the provision that operationally ties Article 5.7 into the rest of the SPS Agreement. The United States recalls that Article 2.2 states that "Members shall ensure that measures are not maintained without sufficient scientific evidence, except as provided in Article 5.7." The text of Article 2.2 text shows that Article 5.7 is not limited to newly "adopted" measures in the terms that Argentina is implying, but rather Article 5.7 also applies to situations where an existing measure is "maintained" without sufficient scientific evidence.

31. Furthermore, Argentina's argument – if adopted – would mean that the drafters intended the following unreasonable result: when new information comes to light with respect to an existing measure – whether it be a claim of disease-free status or indeed any scientific information relating to any type of SPS measure – the importing Member would immediately have to remove its existing measure an re-adopt the same measure, labeling it as provisional. Otherwise, the existing measures would be inconsistent with Article 2.2 because it was maintained without sufficient scientific evidence, and Article 5.7 could not apply because – according to Argentina – that article only applies to newly adopted measure. That result makes no sense from a scientific or practical standpoint. And, as the United States has noted, Members do not follow this procedure with respect to requests for a change in a country's disease-free status.

32. The United States further notes that Argentina's argument is wrong as a factual matter. Upon receipt of Argentina's 2002 claim of disease-free status, APHIS took action to choose to receive and review the application of Argentina within a reasonable period of time while maintaining provisionally its prohibition on Argentina's beef until APHIS made a decision on that application. It is the United States – not Argentina – that took these steps, upon the receipt of Argentina's request for import authorization.

33. Furthermore, to the extent that Argentina is arguing that some sort of "adoption" must be found to make Article 5.7 applicable, and leaving aside the fact that Argentina's interpretation is plainly untenable in light of the clear text of Article 2.2, the United States did adopt actions in response to Argentina's request. To "adopt" something, according to the Oxford English Dictionary, is to "[c]hoose for one's own practice, take up" or to "[a]pprove, accept (a report etc.)."[19] In this instance, the United States provisionally determined to prohibit Argentina's beef until a decision was made and took up review of the application to obtain more relevant information for our assessment.

34. Similarly, if Argentina's argument is that the United States cannot be said to have "adopted" a measure in 2002 because it prohibited Argentina's product in 2001 and maintained provisionally the measure in 2002, Argentina misunderstands the nature and effect of the action

[19] Oxford English Dictionary (1993), "Adopt." (Exhibit USA-150)

of the United States in 2002. In 2002, the United States decided to review Argentina's disease-free status and to apply a measure in the interim. In other words, as of 2002, the U.S. measure was provisional (until review is completed), and the United States can be considered to have adopted this approach upon the receipt of Argentina's 2002 application.

4. The United States Is Seeking the Necessary Information and Is Reviewing the Measure in a Reasonable Period of Time

a. The United States Is Seeking To Obtain the Additional Information Necessary Consistent with Its Article 5.7 Obligations

35. In evaluating Argentina's sanitary situation in order to reach "a more objective assessment of risk," the United States has been seeking to obtain additional information necessary, in accord with Article 5.7. It has sought information including that related to veterinary control and oversight, history of the disease in Argentina, surveillance information and others, consistent with 9 C.F.R. Section 92.2 for both Argentina and areas that comprise Patagonia.[20] Argentina initially provided some of this information to the United States. It sought further information from Argentina on other occasions on topics such as veterinarian licensing, the functions performed by the National Agrifood Inspection Service of Argentina, and additional detailed information on particular issues related to the FMD outbreaks in 2001 and 2002.[21]

36. Argentina contends that Article 5.7 requires the importing Member "to identify the specific pertinent information it is missing at the time of imposition of the provisional measure" and that the United States did not do so. However, as discussed above, it is clear that the United States was requesting information on the topics named in 9 C.F.R. Section 92.2. This was the pertinent information initially required by APHIS. Argentina provides no reason to discount that information request as not satisfying Article 5.7's requirement to seek "additional information necessary." Furthermore, to the extent that Argentina is arguing that the importing Member must identify all necessary information, without making any follow-up requests, Argentina's position is illogical and not supported by the text of the Agreement. The evaluation of complex scientific and technical issues tends to be an iterative process; that is, regulators need to examine information submitted, consider how it interacts with their review of the SPS measure, and determine whether follow-up questions or inquiries are needed.

37. Argentina also contends that Section 92.2 is not a request for information consistent with Article 5.7 because it requested Argentina to "supply all information on a *de novo* basis."[22] It is not clear how this objection is relevant or what the significance Argentina is imparting to the

[20] Exhibit USA-76.

[21] For example, in a letter to SENASA, APHIS acknowledged receipt of an initial tranche of information, and then stated: "[W]e are in need of additional information to adequately assess your country's request." (Exhibit USA-84).

[22] Argentina's Responses to Panel Question No. 24(c), para. 99.

term "de novo."[23] The United States was asking Argentina to provide it with answers concerning its FMD situation and internal structures as of the date that it was submitting the application. As Argentina asserts, its FMD system changed between 1997 (when it last submitted an application) and 2002 (the date of the application in issue). It makes the claim the situation was "radically improving."[24] Since Argentina alleges that the situation changed so "radically," then it is surely reasonable to conduct a thorough collection of information and review it. The request for information by the United States was for relevant necessary information in order to fulfill the requirements of Article 5.7.

38. Argentina then objects that Article 5.7 "puts the burden on the importing Member to seek such missing information," while the United States "put[s] the burden on the exporting Member to provide information."[25] This is a mischaracterization. Argentina came forth and made a claim of changed circumstances. The United States then requested that Argentina provide information. The text of Article 5.7 obligates the Member taking the provisional measure to "seek to obtain" the additional necessary information, and that is what the United States did upon receiving the claim of changed circumstances—it sought to obtain the information from SENASA, which has jurisdiction in Argentina for animal health issues. Of course, the United States also has other sources for some information, but requesting information from SENASA is a clear and obvious step. In short, Argentina has no basis for arguing that an information request to SENASA from APHIS would not fall within the scope of Article 5.7. In fact, as described above, this method of proceeding is fully consistent with the process envisioned under Article 5.7 and Article 6..

b. The United States Is Reviewing the Measure Within a Reasonable Period of Time

39. In its responses to the Panel's questions, the United States fully agrees that when a Member provisionally adopts a measure under Article 5.7, it must seek to obtain the necessary information and review the measure within a reasonable period of time.[26] Argentina misunderstands the position of the United States when it alleges that the "US claims unlimited amount of time without any requirement of informing the importing Member of anything."[27]

40. The Appellate Body clearly stated that a reasonable period of time "has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the

[23] Argentina makes a similar reference at para. 80 in its response to Panel Question No. 20. Argentina argues that it was "ejected . . . totally from the system" whereas 9 C.F.R. Section 92.4 provides for reinstatement based on APHIS initiated action. Argentina misinterpreted and mischaracterizes the U.S. system. 9 C.F.R. Section 92.4 does not commit APHIS to initiate its own reassessment. Rather, the country seeking re-instatement must submit a request to APHIS for consideration of such re-instatement and provide the necessary evidence for the assessment.

[24] Argentina's Opening Statement at the First Meeting of the Panel, para. 9.

[25] Argentina's Response to Panel Question No. 24(c), para. 99.

[26] U.S. Response to Panel Question No. 29(c), para. 134.

[27] Argentina's Response to Panel Question No. 24(c), para. 100.

difficulty of obtaining the additional information necessary for the review *and* the characteristics of the provisional SPS measure."[28] Argentina suggests in its responses to the Panel that a period of less than two years was "beyond what was reasonable" in *Japan – Agricultural Products II*. However, Argentina fails to reference the Appellate Body's guidance that the assessment of what is reasonable must be conducted on a "case-by-case" basis. Argentina also ignores that the Appellate Body made its finding based on the fact that "collecting the necessary additional information would be relatively easy"[29] in that set of circumstances.

41. At issue in *Japan – Agricultural Products II* was whether a testing method used by Japan was appropriate. It appears to have been an experimental science issue, where the data was accessible.[30] That is quite a different set of circumstances from this dispute, in which the data is (1) not in the United States, (2) of substantial scientific scope and breadth including geographical information, internal and cross-border animal movements, quarantine processes, and veterinary infrastructure; and (3) only accessible with the permission of or provided by Argentina's regulatory authority. In this dispute, collecting the necessary additional information is not easy.

42. As detailed in both the submissions of the United States and Argentina, APHIS and SENASA exchanged information and site visits were conducted in several areas and on a number of occasions. During this process, SENASA did not respond to APHIS follow up requests for information until an extended period of time had passed.[31] On other occasions, SENASA canceled site visits by APHIS.[32] Most recently, in response to the November 2012 request by APHIS to conduct a site visit, SENASA did not respond until July 2013, and then requested that such visit occur in November 2013.[33]

43. 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. First, Argentina 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, Patagonia North B be reviewed, and then combined together with Patagonia South.

44. 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. But as a matter of common sense, it is clear that it does. Regulatory agencies such as APHIS do not have unlimited resources and staff, try as they might to adjust to changing demands and circumstances. Even if one were to take the

[28] *Japan – Agricultural Products II (AB)*, para. 93.

[29] *Japan – Agricultural Products II (AB)*, para. 93.

[30] *Japan – Agricultural Products II (AB)*, para. 92.

[31] In one case, it took more than a year for SENASA to respond to a set of follow-up questions. *See* U.S. First Written Submission, para. 140.

[32] U.S. First Written Submission, para. 136.

[33] Exhibit USA-97.

statement that all the information was in hand in April 2009, Article 5.7 clearly recognizes that a reasonable period of time is necessary to "review the sanitary . . . measure." Given the complex nature of the review, which is not simply whether FMD exists or not in the country, but is also whether the country has the capacity to maintain and to prevent future FMD incidents, the time elapsed is reasonable. The U.S. process is working, and the APHIS proposed determination of Patagonia as FMD-free demonstrates this.

5. Actions Taken By Other Entities Such As the European Union (EU) Are Neither Determinative of Either the Sufficiency of the Scientific Evidence Nor the Reasonable Period of Time

45. Argentina argues that actions taken by the EU and documents issued with respect to the EU's own decisions on import authorization for Argentina's beef are "particularly relevant."[34] However, the documents provided by Argentina are neither determinative of either the sufficiency of the scientific evidence or the applicable reasonable period of time with respect to the United States because: (1) Argentina has not demonstrated that any conclusions reached by the EU are applicable to the United States since it has not shown that the two Members have the same appropriate level of protection; and (2) the documents themselves are reports and summaries of site visits by EU authorities, for which the comprehensiveness is not clear and for which the raw data is not available.

46. Even if the Panel were to consider the EU summary reports submitted by Argentina, it should recognize that they provide a picture of Argentina's system at the time that was enough to find that the data was not sufficient for the United States.

47. The following set of excerpts from EU audits between November 2002 through July 2006 raise questions about Argentina's internal control system with respect to surveillance, slaughterhouse controls and implementation of deboning and maturation, ability to respond quickly to outbreaks, capacity to implement its vaccination program, capacity to control potential routes of transmission such as swill feeding, and ability to control its border. In each of these categories, the EU's reports highlights problems on issues that are relevant to U.S. review of Argentina's internal controls and to which U.S. regulators would want to examine in further detail.

(1) Surveillance

a. <u>On traceability of cattle</u>: "[W]eaknesses previously identified in animal identification and movement controls undermine the reliability of the system."[35] Other weaknesses include: "[n]o official visit [by a

[34] Argentina's Responses to Panel Question No. 25(c), para. 110.

[35] Exhibit ARG-107, p. 14.

veterinarian] is required on the farm prior to the official authorization [of animals for the EU market."[36]

b. Surveillance of vaccinated animals: "[A]t farm level, no systematic, formal, system to estimate the number of animals to be vaccinated, taking into account movements, births and deaths since the last vaccination, has been put in place."[37] Problems in survey design because of a "lack of a solid scientific base for some aspects of its design and the high number of false positives . . . weaken the reliability of the results, specially with regard to the conclusion of absence of FMD virus."[38] (emphasis supplied).

(2) Slaughterhouse

a. On FMD controls at slaughter: "In one establishment, one of the two pH meters was defective and could not be calibrated."[39] "Three different pH measurements showed three different results for the same carcasses."[40] "[T]he time and the temperature are not always recorded when the first carcass enters the maturation chiller, as should be standard procedure."[41]

b. Ante-mortem (pre-slaughter) checks: "[A]nte-mortem inspection is not always carried out by the veterinarians, as a veterinary assistant was seen to sign a pen card."[42] "Pen cards were issued for a pen in which animals were not located."[43] (emphasis supplied).

(3) Response to Outbreak

a. "The reaction to the suspect Tartagal outbreak and later to the confirmed outbreak was slow. Discrepancies were detected between the dates recorded in official documents and those notified to the OIE. In addition, other information/documentation received from SENASA did not reflect the situation nor was it always consistent."[44]

---

[36] *Id.*

[37] Exhibit ARG-107, p. 11.

[38] DG-SANCO Final Report on FMD Controls in Argentina (Exhibit USA-151), p. 26.

[39] *Id.*, p. 18.

[40] *Id.*, p. 18.

[41] *Id.*, p. 18.

[42] *Id.*, p. 17.

[43] *Id.*, p. 17.

[44] Exhibit ARG-110, p. 4.

b. "The procedures in place permitted a rapid and effective response to the FMD outbreak [in 2006], although no contingency plan currently exists."[45]

(4) Vaccine and Vaccination Quality Control

a. Vaccine Banks: The EU team concluded: "Control on the FMD vaccine bank is insufficient."[46] Some entries noting problems included: "Argentina produces its own vaccines. However, potency tests were in most cases not completed before the vaccine batches were released for use."[47] Evidence showed that one vaccine batch that was beyond its expiration date was used by SENASA, however, SENASA records showed that "this batch had been completely destroyed."

b. Vaccination implementation: "Supervision of the vaccination process by SENASA officials was found to be insufficient."[48] EU team also found problems with partially used vials of vaccine, which were "routinely re-used during the following days."[49] "No instructions are in place to ensure that these [partially used] vials are maintained at the correct temperature and in acceptable condition."[50]

(5) Swill Feeding[51]

a. The EU team concluded that "[c]ontrols on holdings using swill feeding are insufficient."[52]

(6) Border Control

a. The EU team found that Argentina's newly established buffer zone between Bolivia and Paraguay had only "partly effective" controls and local offices.[53]

[45] Exhibit ARG-111, p. 20.

[46] Exhibit ARG-110, p. 5.

[47] Exhibit ARG-110, p. 5.

[48] Exhibit USA-151, p. 11.

[49] Exhibit USA-151, p. 11.

[50] Exhibit USA-151, p. 11.

[51] This is one of the potential transmission routes for FMD.

[52] Exhibit ARG-110, p. 5.

[53] Exhibit USA-151, p. 26.

48. This sampling of issues raised by the EU in a number of isolated audit trips is sufficient to raise questions as to the sufficiency of the scientific evidence, as well as the relevance and the weight to be attributed to those findings. While the EU permits the import of Argentine fresh meat, it made findings that were both positive and negative. However, Argentina's submissions do not allude to the ambiguity and the questions that these reports and decisions raise. Instead, Argentina implies that the United States ought to simply rely upon the second-hand reports of another Member, rather than gather its own data and draw its own conclusions. This is despite Argentina stating that it "acknowledges the right of each WTO Member to conduct its own sanitary evaluation."[54]

49. Similarly, with respect to the OIE, there is even less information and transparency. The OIE did reach a decision with respect to Argentina based on a dossier that is not public and on proceedings and deliberations within the Scientific Committee that are also not public.[55] With respect to Chile, there is a one-page conclusory document noted as Exhibit ARG-113, which appears to be highlighting Chile's notification to Argentina that it will allow Argentine exports. This is not a basis from which to draw any scientific conclusions concerning the situation in Argentina. The United States maintains its own appropriate level of protection, which has allowed it to prevent the outbreak of FMD within its borders for over eighty years. In this dispute, the actions and evaluations of the EU and the actions of the OIE and Chile have raised questions about the FMD status of Argentina and its ability to maintain its internal controls. The United States takes due account of relevant information with respect to Argentina from all sources, but is obligated to reach its own independent judgment on facts and issues.

C. The United States Application System Has Been Applied To Argentina In A Manner Consistent With Article 8 and Annex C Of The SPS Agreement

50. Argentina has failed to satisfy its burden in alleging that the United States has acted with undue delay in breach of Article 8 and Annex C of the SPS Agreement. First, the application system administered by APHIS does not fall within the scope of measures covered by Article 8 and Annex C. Second, even if the application system is found to fall within the scope of Article 8 and Annex C, Argentina has not shown that delays in the evaluation process have been unjustifiable.

1. APHIS' Application System For Evaluating A Request For The Recognition of A Region's FMD Status Is Not A Measure Within The Scope of Article 8 and Annex C of the SPS Agreement

51. The United States has observed that measures falling within the scope of Article 8 and Annex C do not include the determinations at issue in this dispute.[56] As previously pointed out, the text of the SPS Agreement does not provide that determinations involving disease-free areas

[54] Argentina's Response to Panel Question No. 53, para. 202.

[55] This is discussed in more detail at Part II.E.

[56] U.S. First Written Submission, paras. 177-178.

of potential exporters are covered by Article 8.[57] Argentina, however, argues that Article 8 and Annex C(1) have a broad scope of coverage, suggesting that the determinations at issue in this dispute necessarily fall within that scope.[58]

a. Procedures Falling Within the Scope of Article 8 and Annex C of the SPS Agreement Do Not Include Any and All Types of Procedures

52. Article 8 and Annex C apply specifically to "control, inspection and approval procedures." Article 8, titled "control, inspection and approval procedures", provides the following:

> Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.[59]

53. Article 8 incorporates Annex C; its text must be taken into account when interpreting the scope of measures covered by Annex C. And Article 8 is clear that the types of measures covered in Annex C do not include every type of SPS procedure, but a limited class of procedures: namely, "control, inspection and approval procedures."

54. That the drafters intended for Annex C to apply only to "control, inspection and approval procedures" is confirmed by the title of Annex C itself: the United States recalls that Annex C is entitled "Control, Inspection and Approval procedures." In light of this plain text, it is not a supportable interpretation – as Argentina proposes – that Annex C applies to measures that are not control, inspection, or approval procedures.

55. In addition, the context provided by the substantive obligations contained in Annex C shows that the types of "control, inspection, and approval procedures" covered by Annex C pertain to the administration of such procedures with respect to products (and not with respect to all other SPS matters, such as determinations of disease-free status). Subsection C(1)(a) requires the undertaking and completing such procedures without undue delay and in no less favourable manner for imported products than for like domestic products. Subsection C(1)(c) concerns the information requirements for procedures related to approving use of additives or for establishing tolerances for contaminants in food, beverages or feedstuffs. Furthermore, subsections C(1)(d) – (h) also attach express obligations to procedures as they relate to products. Thus, the plain

---

[57] U.S. First Written Submission, paras. 177-178; *See* SPS Agreement, Article 8 (Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.)

[58] Argentina's Response to Panel Question No. 58, para. 232.

[59] Article 8, SPS Agreement

language of Article 8 and Annex C illustrates that their scope has been clearly defined to cover a specific type of control, inspection and approval procedures.

56. Argentina has interpreted Article 8 and Annex C to apply to any procedure, and cited the panel report in *US – Poultry (China)* to support its construction.[60] As noted, this interpretation cannot be squared with the text of the Agreement. The panel in *US – Poultry (China)* stopped short of accepting the view that the provisions of Article 8 and Annex C apply to all types of "control, inspection, and approval procedures," deciding that it was unnecessary to define the whole universe of what falls within its scope.[61] And indeed, the panel did not explain how such an interpretation could fit with the plain meaning of the text. The United States further notes that the panel's finding here appeared to be *obiter dictum*.[62]

57. Finally, the United States notes that the panel's finding in *US – Poultry (China)* addressed a different and distinguishable legal issue. At issue in *US – Poultry (China)* was a measure that caused a delay to an equivalence-based regime;[63] however, in the present dispute, the measure at issue involves determinations of disease-free status. The evaluation does not "check and ensure the fulfillment of a sanitary and phytosanitary measure." Rather, the APHIS evaluation evaluates the FMD situation of a particular region, and the status that APHIS determines is then used to decide what kind of measure to adopt.

58. Argentina has failed to acknowledge the inherent differences between the procedures contemplated by Article 8 and Annex C(1) and the procedures at issue in this dispute. It simply argues that there are no limits to procedures falling under the scope of Article 8 and Annex C,[64] and therefore the disease-status determinations must be subject to these provisions. However, accepting Argentina's construction would be problematic, as it would ignore that plain text of the SPS Agreement's limitation to "control, inspection and approval" procedures.

2. Argentina Has Not Established That Delays It Attributes To The United States Are Undue In Violation Of Annex C(1)(a)

59. Even if the Panel finds that the disease-free status determinations fall within the scope of Article 8 and Annex C, Argentina has failed to show that the United States has engaged in undue delay. Throughout its first written submission and responses to the Panel's questions, Argentina argues that United States has engaged in *undue delay* but only supports its claims by showing that there was a delay. Argentina cannot only assert that the United States has acted inconsistent with Annex C by showing that there was a delay in the evaluation process; Argentina must show that the delay was also *undue*. Because Argentina has failed to do so, it has failed to establish that the United States has breached its obligations under Article 8 and Annex C(1)(a).

---

[60] Argentina's Response to Panel Question No. 58, para. 230.

[61] *US – Poultry (China)*, paras. 7.361-7.362.

[62] *US – Poultry (China)*, para. 7.364.

[63] *US – Poultry (China)*, paras. 7.362-7.365.

[64] Argentina's Response to Panel Question No. 58, para. 232.

60. Panels have addressed the obligation accompanying Article 8 and Annex C(1)(a) that a Member undertake and complete control, inspection and approval procedures without undue delay. In *US – Poultry (China)*, the panel found that the measure at issue "completely foreclosed the possibility for 'completion'" of the process and therefore resulted in undue delay.[65] In *EC – Approval and Marketing of Biotech Products*, the Panel made it clear that "not every delay" caused by a Member is contrary to Annex C(1)(a), and a Member is not liable for delays not attributable to it.[66] Furthermore, the need for additional information does not amount to an *undue* delay; ultimately, the determination of whether a relevant procedure has been unduly delayed requires a case-by-case analysis.[67] The Appellate Body affirmed this understanding, reiterating that these determinations cannot be made in the abstract.[68]

61. Argentina has attempted to argue that the APHIS application system, as applied to its two requests for disease-free status recognition, has been executed in a manner inconsistent with Annex C(1)(a). Argentina does not argue that there has been undue delay in initiating the procedures, but rather that there was undue delay in completing the procedure.[69] In support of its claims, Argentina points to specific dates and events, and alleges that the timeframes in between are delays in the process. For example, in response to Panel Question No. 68, Argentina states:

> "Argentina submitted its request to APHIS in August 2003 but the risk assessment did not occur until mid-2005, the U.S. acted with undue delay by taking two years after the procedure was initiated to conduct the risk assessment."[70]

62. In other words, Argentina asserts a legal conclusion – that the U.S. acted with undue delay – without making an adequate showing that the delay alleged was in fact *undue*. Argentina points out that it submitted its request in August 2003; however, Argentina fails to acknowledge that in November 2003 the United States requested requisite additional information pursuant to this application. Argentina also fails to acknowledge that the United States performed a site visit to Patagonia in December 2003 to advance the evaluation. Additionally, the United States requested additional information in March 2004 – a request Argentina did not respond to until November 2004. Notably, Argentina does not acknowledge this or any other factors that contributed to the alleged delay.

63. As the panel in *EC – Approval and Marketing of Biotech Products* explained, delays related to the need for additional information and not attributable to the Member are not undue. There may be little dispute that the period identified by Argentina between August 2003 and mid-2005 amounted in a delay; however, as reflected above by the occurrences therein that were

---

[65] *US – Poultry (China)*, para. 7.392.

[66] *EC – Approval and Marketing of Biotech Products*, paras. 7.1495, 7.1497.

[67] *EC – Approval and Marketing of Biotech Products*, paras. 7.1497-7.1498.

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

[69] Argentina's Response to Panel Question No. 68, para. 247.

[70] Argentina's Response to Panel Question No. 68, para. 249.

obscured by Argentina, the delay was not *undue*. This is merely an example of the argumentation and claims advanced by Argentina. It cannot simply identify specific dates and events and conclude that a delay amounted to a violation of Annex C(1)(a). Argentina must demonstrate that these alleged delays were undue. Here, Argentina has failed to do so.

a. The Time Periods Taken By Other Members to Evaluate A Region's FMD Status Is Not Dispositive Of The Panel's Determination of Undue Delay Under Annex C(1)(a)

64. The time taken by other Members to perform evaluations of a region's FMD situation and complete its procedure is not of special relevance to and dispositive of the Panel's determination of whether the United States engaged in undue delay in violation of Annex C(1)(a). First, the processing period itself is not indicative of whether a Member acted with undue delay. Second, the assessment of undue delay requires a consideration of the facts of the given dispute, not an abstract analysis. Third, as indicated above,[71] Argentina has merely identified the time periods associated with its applications; Argentina has failed to show that these periods have been unjustified, and, furthermore, that the U.S. review period should have been similar to those taken by Chile and the EU.

65. First, in *EC – Approval and Marketing of Biotech Products*, the panel recognized that the assessment of undue delay requires the consideration of not only the "length of a delay as such", but more importantly the reason for the delay.[72] The panel noted that proof of a particular duration is not sufficient in itself that a process was unduly delayed. A relatively short delay does not preclude a finding of undue delay; similarly, a longer period of delay would not always and necessarily be sufficient to establish that there has been undue delay.[73] In fact, as the panel suggested, the reason for the delay is what matters in determining whether a process has been unduly delayed. Thus, showing only that there was delay and failing to acknowledge the reason(s) or show that the reason was unjustified is insufficient to prove that a procedure amounted to undue delay.

66. As stated above, Argentina has simply made conclusory arguments that the APHIS evaluation has undergone undue delay. Argentina has not proven that the alleged delays were not justifiable. Argentina also fails to acknowledge that it has contributed to delays in the evaluation process. In short, Argentina has failed to establish that the United States has engaged in *undue* delay, and therefore its claims cannot be substantiated.

67. Second, the Appellate Body has interpreted the determination of undue delay as requiring a case-by-case assessment, not one performed in the abstract.[74] The Appellate Body's interpretation seems to recognize the inherent differences involved in evaluation procedures and

[71] Argentina's Response to Panel Question No. 59, paras. 245- 246.

[72] *EC – Approval and Marketing of Biotech Products*, para. 7.1496.

[73] *EC – Approval and Marketing of Biotech Products*, para. 7.1496.

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

the time periods that accompany them. The panel in *EC – Approval and Marketing of Biotech Products* shared this understanding.[75] Pursuant to this understanding, the determination of whether undue delay occurred should consider the facts and circumstances of the dispute at hand. This may be so because different Members may require different information and engage in different procedures in performing an evaluation.

68. Whether the United States engaged in undue delay depends entirely on a consideration of the facts and circumstances surrounding its evaluation of Argentina's applications. The evaluation process outlined in 9 C.F.R. Section 92.2 is designed to allow APHIS to assess whether an applicant country will meet its ALOP. The time required for APHIS to make its assessment is not tied to the time required by other Members, and the SPS Agreement does not require it to do so. Accordingly, in assessing whether the United States has engaged in undue delay, the appropriate case-by-case analysis should consider relevant factors related to the APHIS evaluation, not the unrelated time periods taken by other Members.

69. Third, Argentina has argued that the United States has engaged in undue delay because APHIS has not completed its evaluation period in a time period consistent with those of Chile and the EU.[76] However, Argentina does not establish that the evaluation process undertaken by Chile and the EU are similar to APHIS's process. Argentina does not compare the application systems, the scope and changing nature of its requests and the appropriate level of protection associated with the United States, Chile and the EU. Without addressing these fundamental matters, Argentina cannot attempt to establish a basis for comparing the time periods.

70. Ultimately, the Appellate Body has stated that a determination of undue delay requires an assessment of both the time period and the reasons for the delay. Furthermore, the assessment requires a case-by-case analysis of the relevant circumstances of the dispute at hand. The time periods of other Members, including Chile and the EU, have not been shown to be relevant to this analysis, and the Panel should not consider them in assessing whether the United States has engaged in undue delay under Annex C(1)(a).

D. The United States Has Not Acted Inconsistent With Article 3 of the SPS Agreement

71. Argentina has argued in its first written submission, at the first Panel meeting and in its responses to the Panel's questions that the APHIS application system is inconsistent with Article 3.1 of the SPS Agreement because the application system does not adopt and incorporate certain provisions of the OIE Terrestrial Code covering FMD. In advancing this position, however, Argentina reveals its misunderstanding of Article 3.1, the OIE Terrestrial Code, and the APHIS application system itself. The application system is in fact founded upon the relevant provisions of the OIE Terrestrial Code, and therefore, using the terminology of Article 3.1, is "based on" the

[75] *EC – Approval and Marketing of Biotech Products*, para. 7.1497.

[76] Argentina's Response to Panel Question No. 59, para. 246 (arguing that "The determinations by the E.U. and Chile to re-open their markets promptly, even before Argentina submitted its requests to APHIS, are indicative of the time reasonably necessary to conduct an evaluation for FMD).

international standard. Argentina has not met its prima facie burden of showing inconsistency with Article 3.1. Notwithstanding this deficiency, the United States has demonstrated that the APHIS application system is based on the relevant provisions of the OIE Code, and therefore, Argentina's claims must fail.

1. The United States Maintains A System For Evaluating The FMD Status Of A Region That Is Based On The International Standard And Thus Consistent With Article 3.1

72. As the United States explained in its prior submissions,[77] the APHIS application system is clearly based on the OIE Terrestrial Code. Argentina's argument in response is based on the conclusory allegation of "complete disharmony between the U.S. regulatory structure and the OIE."[78] Upon examination, however, Argentina cannot support this allegation. In particular, Argentina continues to conflate Article 3.1' "based on" requirement with the Article 3.2's different "conform to" concept. At most, Argentina points to some minor differences between the APHIS process and the OIE Code, and nothing that comes near to meeting Argentina's burden to show that the APHIS system is not "based on" the OIE Code.

73. Turning first to the legal issue, the United States notes that Argentina's argument is founded on an erroneous interpretation of what it means to be *based on* the international standards, recommendations and guidelines that is inconsistent with the leading guidance articulated by the Appellate Body in *EC – Hormones*. As discussed previously by the United States, the Appellate Body has provided a clear interpretation of what *based on* means within the context of Article 3.[79] In *EC – Hormones*, the Appellate Body recognized that Article 3.1 obliges Members to base SPS measures on the international standards *where they exist*.[80] The *EC – Hormones* panel mistakenly equated the term and corresponding presumptions of "based on" under Article 3.1 with "conform to" under Article 3.3; the Appellate Body found that such a construct was erroneous.[81] The Appellate Body explained that the requirement for a Member to base its SPS measure on international standards does not require it to embody the international standard completely. The Appellate Body found that "such a measure may adopt some, not necessarily all, of the elements of the international standard" (emphasis supplied). Further, an SPS measure under Article 3.1 does not benefit from the presumption of consistency with the relevant provisions of the SPS Agreement and the GATT 1994; however, the complainant still must meet its burden[82] – to show that the measure has not adopted some of the elements of the international standard.

---

[77] U.S. Opening Oral Statement at the First Meeting of the Panel, para. 53; *see also* U.S. Response to Panel Question No. 13(b), para. 32.

[78] Argentina's Response to Panel Question Nos. 13(a)-(c), para. 39.

[79] U.S. Response to Panel Question No. 14, paras. 46–52.

[80] SPS Agreement, Article 3.1

[81] *EC – Hormones (AB)*, paras. 167, 170.

[82] *EC – Hormones (AB)*, paras. 167, 171.

.

74. Argentina argues that the APHIS application system is not *based on* the international standards for FMD established by the OIE because it has not *conformed to* some relevant provisions of the Code.[83] Argentina provides a table on pages 10-11 of its responses to the Panel's questions in attempt to *expose* "how far apart" the U.S. system is from the OIE standards.[84] The table identifies 4 specific sections of the OIE Code that are not expressly incorporated into the U.S. regulations. In doing so, however, Argentina neglects to acknowledge the other relevant sections of the OIE Code that comprise the international standards, recommendations and guidelines for FMD. An analysis of the other relevant provisions shows that the U.S. system is close to and based on the relevant international standards within the OIE Code.

75. As the United States has observed, the relevant international standards, guidelines and recommendations are contained in Chapters 1.6, 2.1 and 8.6 of the OIE Code.[85] Argentina agrees with the United States that Chapter 8.6 contains relevant provisions, as it covers FMD.[86] Notably, although it acknowledges that Chapters 2.1 supplements Chapter 8.6, and points out that Chapters 4.1-4.4 are relevant provisions, Argentina suggests that the sections contained in Chapter 8.6 are the *only* provisions relevant to the panel's analysis.[87] Behind Argentina's approach, the determination of whether the APHIS application system is *based on* the OIE Terrestrial Code FMD standards, guidelines and recommendations depends entirely on whether the system conforms to Articles 8.6.3, 8.6.4, 8.6.5, 8.6.22 and 8.6.23 of Chapter 8.6 alone. However, a determination of whether the APHIS application system is "built or founded upon" some of the relevant OIE international standards for FMD must not consider select relevant provisions – the determination should consider all of the relevant provisions.

76. The United States has demonstrated that the relevant sections of the APHIS application system are based on the relevant corresponding provisions of the OIE Terrestrial Code.[88] The application process outlined at 9 C.F.R. §92.2(b) incorporates seven of the eight criteria contained in Article 1.6.5 of the OIE Code. The United States system also permits for re-instatement. This procedure is similar to the OIE process for the recovery of FMD-free status in Article 8.6.9 of the OIE Code. Under both APHIS and the OIE systems, a region loses its FMD-free status upon experiencing an FMD outbreak, until its FMD situation is reassessed and its status reinstated.

[83] Argentina's Response to Panel Question No. 13, paras. 39-40.

[84] Argentina's Response to Panel Question No. 13, para. 40.

[85] U.S. Response to Panel Question No. 13, para. 30.

[86] Argentina's Response to Panel Question No. 13, paras. 33-34.

[87] *See* Argentina's Response to Panel Question No. 13.

[88] U.S. Response to Panel Question No. 13, para. 32; U.S. First Written Submission, para. 335.

a. The APHIS Approach To FMD Status Attributions Is Based On The OIE Approach Contained In Chapter 8.6 Of The OIE Code

77. In light of Argentina's submissions, its argument under Article 3.1 of the SPS Agreement relies squarely on its proposition that the APHIS system for FMD status classification does not conform to the OIE approach in Chapter 8.6 of the OIE Code. Notwithstanding the fact that the approach advanced by Argentina is improper because an analysis under Article 3.1 should consider all of the relevant provisions of the international standard, the APHIS application system pertaining to FMD is based on Chapter 8.6.

78. At the outset, the U.S. would like to clarify the purpose for the recognition of a region's FMD status. APHIS evaluates the FMD situation in a given region to determine whether the disease is present and also to assess the region's prevention and control capabilities. Using this information, APHIS then decides what SPS measure is appropriate to match the disease status of the region. Although APHIS regulations may not adopt the exact terminology employed by the OIE to assign disease statuses, the purpose and effect of APHIS' approach is in fact consistent with that envisioned by the OIE.

79. Argentina correctly acknowledges that (some of the) relevant provisions of the OIE approach to FMD status designations are contained at Articles 8.6.2 – 8.6.5, 8.6.22 and 8.6.23.[89] However, it appears that Argentina misunderstands and/or misrepresents both the U.S. and the OIE approach to FMD status attributions. In fact, when comparing the two approaches to FMD status attribution, it becomes evident that APHIS incorporates a substantial portion of the OIE's approach.

80. The APHIS approach to recognizing a region's FMD status is contained at 9 C.F.R. §92.2 and 9 C.F.R. Part 94. As previously observed by the United States, this approach is similar to and based on the OIE approach outlined in Chapter 8.6 of the OIE Code.[90]

81. Argentina acknowledges that Chapter 8.6 of the OIE Code recognizes two categories of FMD-free status, those being FMD-free where vaccination is not practiced and FMD-where vaccination is practiced.[91] However, Argentina's position on the relevance of the OIE's FMD-free where vaccination is practiced designation is somewhat confusing. On the one hand, Argentina implies that the United States is not "based on" the relevant international standard of the OIE because APHIS regulations do not contain an express designation of FMD-free where vaccination is practiced.[92] On the other hand, Argentina "is not challenging the U.S. standards and regulatory structure as such" or "contesting here as a legal matter the U.S. standard on

[89] Argentina's Response to Panel Question Nos. 13(a)-(c), para. 40.

[90] U.S. Response to Panel Question No. 13, para. 32; U.S. First Written Submission, para. 335.

[91] *See* Argentina's Response to Panel Question Nos. 13(a)-(c), para. 38.

[92] *See* Argentina's First Integrated Executive Summary, para. 22.

vaccination."[93] The status of FMD-free where vaccination is practiced is not a legal matter before the Panel. Therefore, the FMD-free where vaccination is practiced designation is neither relevant to nor dispositive of the determination of whether the U.S approach to FMD is "based on" the OIE Code.

82. Additionally, in identifying the FMD-free statuses recognized by the OIE, Argentina does not acknowledge that Article 8.6.7 contains a status of "FMD infected". The OIE attributes this status to countries or zones that do not satisfy the requirements to qualify as either an FMD free country where vaccination is not practiced or where vaccination is practiced.[94] Thus, Chapter 8.6 explains that the OIE recognizes countries or zones that are (a) FMD-free where vaccination is not practiced; (b) FMD-free where vaccination is practiced; and (c) FMD-infected.

83. Comparing the APHIS system with the OIE Code shows that the manner in which APHIS recognizes FMD statuses is based on the Chapter 8.6 of the OIE Code. Argentina argues that the APHIS system *as applied* has the opposite meaning and effect.[95] However, this assertion is not supported. The fact that APHIS continues to evaluate the disease-free status of Argentina does not support that APHIS's determination is the "opposite" of anything coming out of the OIE system. Far from it. In fact, the record shows that with respect to Patagonia, APHIS has proposed a finding of disease-free status.

84. In sum, under APHIS' practice, which is based on the OIE's approach, APHIS evaluates a region's FMD situation and determines not only whether it is an area free of disease but also whether it is one of low disease prevalence. APHIS has applied the same approach to its evaluation of a region's FMD status to all Members, including Argentina, in the same manner.

85. At bottom, Argentina's complaint is that APHIS has yet to adopt the same disease-free status designations as the OIE. But Argentina's expectations about the duration of the evaluation period do not support a claim that the APHIS application system is substantively inconsistent with the OIE's framework for assessing a region's FMD situation. Argentina has not acknowledged this, and the mere fact that APHIS has yet to conclude its evaluation does not equate to inconsistency with Article 3.1.

2. The OIE FMD Status Attributions Are Not Standards, Guidelines or Recommendations For The Purposes Of Article 3 Of The SPS Agreement

86. Argentina contends that decisions of the OIE World Assembly of Delegates constitute standards, guidelines or recommendations, and such decisions include those on what areas are officially included in the list of FMD-free countries, zones or compartments.[96] However,

[93] Argentina's Response to Panel Question No. 21, para. 64.

[94] OIE Code, Article 8.6.7 (2013) (Exhibit USA-23)

[95] Argentina's First Written Submission, paras. 199-200.

[96] Argentina's Response to Panel Question No. 17, para. 48.

Argentina fails to recognize that while these lists may serve as decisions of the OIE for its own purposes, they do not serve as standards, guidelines or recommendations for the purposes of Article 3 of the SPS Agreement.

87. The United States has observed, and Argentina agrees, that a standard, guideline and recommendation encompass the same concept representing the international approach within the context of the SPS Agreement.[97] Notwithstanding this understanding, the Panel may derive a complete understanding of the terms "standard," "guideline," and "recommendation" within the context of the SPS Agreement through understanding the terms as defined.

88. A "standard" is "a rule, a means of judgment or estimation; a criterion. A document embodying an official statement of a rule or rules"[98] Thus, as the EU acknowledged during the first Panel meeting with the third parties, an international standard is embodied by a process and system, not a list.[99] A "guideline" is a "directing or standardizing principle laid down as a guide to procedure, policy, etc."[100] A "recommendation" is "the action or an act of recommending a person or thing; a recommended course of action."[101] These are rules or norms. They are not the conclusion of the application of country-specific facts to rules or norms. The list of designations is the application of country-specific facts to standards, guidelines, or recommendations, not the standards, guidelines or recommendations themselves.

89. Argentina's own suggested definition supports this. For example, it states that a guideline is "Information intended to advise people on how something should be done or what something should be: *The EU has issued guidelines on appropriate levels of pay for part-time manual workers.*"[102] This definition and example proves the point of the United States. In the example sentence, the EU issued guidelines on pay, for example a pay range. The EU likely did not issue a list of employees determining at a micro-firm level what Mr. Smith, one of potentially thousands of employees, who works for Company A, in Country B should specifically be paid. The guideline is the rule or general direction, and that is different in nature from the application of the rule or general direction to a specific case.

90. "Recommendation" should be read together with "standard" and "guideline." Argentina puts forth a broad definition that is "a suggestion that something is good or suitable for a particular purpose or job" and "advice telling someone what the best thing to do is."[103] But it is clear, and Argentina agrees, that the three terms "standard, guideline, and recommendation"

---

[97] U.S. Response to Panel Question No. 17, para. 57; *see also* Argentina's Response to Panel Question No. 17, para. 50

[98] Shorter Oxford Dictionary "Standard," p. 3028 (Exhibit USA-152)

[99] U.S. Response to Panel Question No. 17, para. 60.

[100] Shorter Oxford Dictionary "Guideline" (Exhibit USA-130).

[101] Shorter Oxford Dictionary "Recommendation" p. 2504. (Exhibit USA-153)

[102] Argentina's Response to Panel Question No. 17, para. 55.

[103] Argentina's Response to Panel Question No. 17, para. 56.

should be read together for consistency. The common denominator for these three terms is the sense that the United States has put forward: that standards, guidelines, and recommendations are not the conclusion of the application of country-specific facts to rules or norms. That understanding can be satisfied by all three terms. Argentina's contention cannot.

91. Based on these definitions and the understanding of the terms within the context of the SPS Agreement, it is evident that the OIE Terrestrial Animal Health Code is the system that guides and directs Members on the OIE's recommended approach to FMD, not a list of status designations.

a. The Agreement Between The World Trade Organization And The OIE Does Not Confirm Argentina's Contention That OIE FMD Status Designations Constitute Standards, Guidelines or Recommendations

92. In support of its contention that decisions of the World Assembly of Delegates constitute standards, guidelines or recommendations, Argentina cites the Agreement Between the World Trade Organization and the Office International Des Epizooties [OIE].[104] Argentina asserts that the agreement "further confirmed the OIE's mandate to recognize disease and pest-free areas for trade purposes, in the context of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures."[105] The Agreement, however, does not confirm the OIE's mandate for recognizing disease and pest-free areas. Furthermore, the Agreement does not contain anything explicitly or impliedly that recognizes the OIE's mandate as purported by Argentina; the Agreement also does not indicate that the OIE's decisions are international standards, guidelines or recommendations for the purposes of Article 3 of the SPS Agreement.

93. With respect to standards, guidelines or recommendations, the Agreement mentions solely that the OIE and the WTO may agree on the procedure to be followed when the SPS Committee submits specific questions to the OIE concerning "the standards guidelines or recommendations of the OIE within the meaning of Article 12, paragraph 6, of the SPS Agreement."[106] This language does not recognize or confirm the OIE's mandate to recognize disease and pest-free areas as international standards, recommendations or guidelines generally or for the purposes of Article 3 of the SPS Agreement specifically. It does not say that the list of OIE designations for FMD is a standard, guideline or recommendation for purposes of the SPS Agreement.

94. The United States has observed that Annex A(b) of the SPS Agreement provides the following definition of the relevant *international standards, guidelines and recommendations*: "for animal health and zoonoses, the standards, guidelines and recommendations developed

[104] Argentina's Response to Panel Question No. 17, para. 48; *see also* Agreement Between the World Trade Organization and the Office International Des Epizooties (Exhibit USA-154)

[105] Argentina's Response to Panel Question No. 17, para. 48.

[106] Agreement Between the World Trade Organization and the Office International Des Epizooties, at para 7. (Exhibit USA-154)"

under the auspices of the International Office of Epizootics."[107] The OIE codifies its standards, guidelines and recommendations for animal health in the Terrestrial Animal Health Code. The OIE itself confirms that the Terrestrial Animal Health Code sets out "standards for the improvement of animal health and welfare and veterinary public health worldwide, including through standards for safe international trade in terrestrial animals and their products."[108]

95. The OIE's FMD status designations are not embodied in the Terrestrial Animal Health Code. Therefore, contrary to Argentina's construct, the list that reflects these designations do not constitute a standard, guideline, or recommendation.

b. Article 43 Of The Basic Texts Of The OIE Does Not Recognize FMD Status Attributions As Standards, Guidelines Or Recommendations

96. To support its contention that FMD-free attributions are standards, guidelines or recommendations, Argentina cites the Basic Texts of the OIE, which contains the general rules and other texts adopted by the Assembly. Chapter 13 outlines the procedures for sessions of the assembly, and as Argentina acknowledged, Article 43 provides guidance on the provisional agenda for the sessions.[109] Argentina in particular relies on the language in Article 43 stating that, among other items, the provisional agenda is to include the consideration of draft standards, guidelines and recommendations.[110]

97. Argentina's reliance on this language is misplaced. In particular, the mere description of the types of items that may be included on the OIE Assembly agenda does not dictate the status of Argentina's OIE designations under the WTO. First, Argentina has not shown that Argentina's FMD designation was in fact labeled as a "standards, guidelines and recommendations" on the OIE Assembly agenda. Second, the mere fact that an item is on the OIE Assembly agenda does not show that the OIE considers the item to be a "standard, guideline and recommendation." In fact, the Assembly considers other items on its agenda, including a report on the animal health situation world-wide; all items approved by the Council after consultation with the Director General; and any other matters in the form of Motions, Resolutions or Recommendations arising from different items on the Agenda.[111] Third, even if an item is labeled on the agenda as a standard, guideline or recommendation, that description would not govern whether, as a matter of interpreting the SPS Agreement, Argentina's FMD designation was in fact a "standard, guideline and recommendation" under the SPS Agreement. This would be a matter to be determined according to the text of the SPS Agreement, and the particular label used by the international organization is not determinative.

---

[107] U.S. Response to Panel Question No. 17, para. 57.

[108] "OIE: Terrestrial Animal Health Code" (Exhibit USA-144).

[109] Argentina's Response to Panel Question No. 17, para. 52.

[110] Exhibit ARG-116, Article 43.

[111] Exhibit ARG-116, Article 43.

3. The United States Has Not Acted Inconsistent With Article 3.3

98. Article 3.3 authorizes Members to introduce and maintain SPS measures based on scientific justification. [112] The United States' regulatory approach to FMD is based on the relevant provisions of the OIE Code. As applied to Argentina, APHIS is currently performing its scientific evaluation to determine the FMD situation in the regions requested by Argentina. However, because the APHIS has not concluded its scientific evaluation of Argentina's requests, it has not come to a final resolution of its process. Therefore, Article 3.3 is not applicable in this matter, and consequently, Argentina has failed to demonstrate that the United States has acted inconsistent with its obligations under this provision of the SPS Agreement.

99. As explained above in Part A, Argentina's claims fundamentally concern the issue of timeliness, which rests centrally within the realm of Article 5.7. Because the United States has not concluded its regulatory process and issued a determination on Argentina's requests, the issue is whether or not the United States has acted in a reasonable period of time. Article 3.3 applies when an SPS measure has been "introduced and maintained" in a particular manner, not in the instance where a Member has yet to introduce or maintain an SPS measure. Argentina itself acknowledges that the issue is about timeliness. In its responses to the first set of questions from the Panel, Argentina agrees that the United States promptly "initiated" its relevant procedures.[113] Argentina's central concern is that the United States has not "completed" the process.[114] Argentina fashioned its concern as a separate, "undue delay" claim, it is apparent that the timeliness claim is the only claim advanced by Argentina, not a claim under Article 3.3.

100. Argentina neglects to acknowledge this fact, and grounds its claims under Article 3.3 on its interpretation of Article 3.1. In its responses to the first set of questions from the Panel, Argentina asserts that the United States has acted inconsistent with Article 3.3 because Article 3.1 contemplates a "binary" situation.[115] In other words, Argentina argues that the United States can either be consistent with Article 3.1 or Article 3.3, and implies that it must necessarily be inconsistent with one provision.[116]

101. The Appellate Body in *EC – Hormones* found that the panel was wrong in its conclusion that an SPS measure reflects the same level of protection as the international standard to be *based on* that standard under Article 3.1.[117]

102. Because APHIS has yet to conclude its process, Article 3.3 does not apply to this matter. As a result, the Panel need not make a determination on Argentina's related claims.

---

[112] Article 3.3, SPS Agreement

[113] Argentina's Response to Panel Question No. 68, para. 248.

[114] Argentina's Response to Panel Question No. 68, para. 248.

[115] Argentina's Response to Panel Question No. 14, para. 42.

[116] *See* Argentina's Response to Panel Question No. 14, paras. 42-46.

[117] *EC – Hormones (AB)*, para. 168.

Additionally, Argentina has failed to meet its burden to show that the United States has acted inconsistent with its obligations under this provision, and therefore, its claims must fail.

E. Measures by the United States Are Consistent with Article 5.6

1. The U.S. Review of Argentina's Application and Provisional Prohibition on Argentina's Product Is Not a Measure that "Achieves an Appropriate Level of Sanitary Protection"

103. The core issue in this dispute is whether or not the United States has reached a final determination on the status of Argentina's applications within a reasonable period of time. The appropriate framework for analysis in this case is under Article 5.7 of the SPS Agreement. Just as the panel found in *EC – Approval and Marketing of Biotech Products* that the European Communities' delays for approval were not "measures to achieve their appropriate level of sanitary protection," the Panel in this dispute should similarly find with respect to the provisional prohibition of Argentina's product pending a final decision within a reasonable period of time.

104. It cannot be "more trade restrictive than required" when a Member takes a provisional measure to review an assertion by another Member of its disease status in accordance with Article 5.7 and Article 6. This is not, as Argentina alleges, a "a de facto 'zero risk level.'"[118] As discussed above, Article 5.7 and Article 6 contemplate a process in which product is not imported prior to the completion of the review of the exporting Member's assertion of disease status. This is entirely consistent with the OIE's own approach to its FMD list designations, in which a designation is not attributed until the review of the applying Member's dossier. In other words, as the OIE emphasizes: "[b]efore trade in animals or their products may occur, an importing country must be satisfied that its animal health status will be appropriately protected."[119]

2. OIE Guideline for FMD-Free with Vaccination Status Are Not Applicable Because It Does Not Achieve the Appropriate Level of Protection of the United States

105. The United States has explained that animals and animal products that are vaccinated still pose an FMD threat that does not meet the appropriate level of protection of the United States.[120] Article 8.6.23 of the OIE Code addresses the export of fresh meat of cattle for "FMD free country or zones where vaccination is practiced" and essentially treats such meat the same as meat from FMD free countries without vaccination—that is, without any conditions. The United States finds that this treatment does not achieve the appropriate level of protection in which imports of FMD-susceptible animals and animal products must be safe, meaning they must not introduce into or disseminate within the United States the FMD virus.

---

[118] Argentina's Closing Oral Statement at the First Meeting of the Panel, para. 7.

[119] OIE Code Chapter 5.3.3 (Exhibit USA-19).

[120] U.S. First Written Submission, para. 299.

106. Argentina has not disputed this, nor has it argued that Article 8.6.23 in fact does meet the appropriate level of protection of the United States. In fact, Argentina in its responses to the Panel's questions, stated that it "has accepted that it would only be listed along with Uruguay . . . under §94.1(b)(4)."[121] Accordingly, OIE guidelines should not be considered as achieving the appropriate level of protection of the United States.

3. Argentina Has Provided No Evidence That Applying the Same Mitigations to Argentina as Currently Applied to Uruguay Would Achieve the United States' ALOP

107. Argentina has asserted in this litigation that the mitigation protocols that apply to Uruguay are appropriate for Argentina because the sanitary situations are "similar."[122] It makes the same argument with respect to Santa Catarina and Patagonia South. The only fact that Argentina has put into evidence is that the rest of Argentina has the same OIE designation as Uruguay[123] and that Patagonia South has the same OIE designation as Santa Catarina. Because these are the same, Argentina, contends, the conditions under which products from those non-Argentina regions enter the United States are applicable to the regions in Argentina.

108. This is flawed reasoning. Simply because two items are considered "the same" for purposes of one set of criteria does not mean that they are in fact identical, or even close. For example, two test-takers could receive a "pass" mark on an examination—however, that does not mean that the two test-takers scored exactly the same, or even answered the same questions correctly. For example, consider a situation where a test-taker had to be at or above the 60th percentile to pass a certain test. In that situation, a test-taker that scored in the 60th percentile would receive the same "pass" as the test-taker in the 90th percentile. If, however, those test-takers were to sit for an examination testing the same subjects but with a different cut-off for a passing score, one of those test-takers could pass while the other would not.

109. The OIE designation list, similarly, does not tell us in any detail how any particular Member passed. While Members that seek a designation submit a dossier to the OIE's Scientific Committee for review, the Scientific Committee does not issue a lengthy opinion to the OIE membership and does not make that opinion public. In most cases, site visits are not conducted.[124] A letter from the Director General of the OIE is sent to applicant Member Countries to inform them "of the outcome of the evaluation, with a summary record of evaluation including reasons for a positive or negative outcome."[125] Moreover, even the

[121] Argentina's Response to Panel Question No. 1, para. 5. In its applications to the United States, requested authorization to import fresh bovine meat on terms that it be "maturated and deboned." This was memorialized in a note sent from SENASA's President to APHIS in December 2002. *See* Exhibit USA-79, p. 3.

[122] Argentina's First Written Submission, para. 308.

[123] Although Argentina invokes Brazil's 14-states OIE designation in its response to Question 47, Brazil's 14-states OIE designation is not evidence for the same reason that Uruguay's OIE designation is not evidence.

[124] Exhibit USA-22, p. 8.

[125] Exhibit USA-22, p. 5.

applications of Members seeking OIE designation are not released by the OIE—if one Member is interested in the application of another Member seeking a designation, the former must request it from the latter. The latter is not obligated to disclose the application.[126]

110. Argentina further argues that the OIE status "has probative value" and that "Members can and do reasonably rely" on that status.[127] Regardless of the accuracy of these assertions, Argentina's argument does not establish that a particular OIE designation should necessarily be accepted, without any further review, by the United States or any other Member. As noted, given that the OIE designation is not useful in evaluating finer gradations of risk than that entailed by the particular OIE disease status, the OIE designation is not conclusive as to whether a measure that made use of that OIE status would meet the importing Member's appropriate level of protection. Furthermore, the OIE itself is circumspect about its own pronouncements about the on-the-ground situation in any given Member, even after it has issued a designation. The OIE caveats its conclusion with the following: "Information published by the OIE is derived from declarations made by the official Veterinary Services of Member Countries. The OIE is not responsible for inaccurate publication of country disease status based on inaccurate information or changes in epidemiological status or other significant events that were not promptly reported to the Central Bureau subsequent to the time of declaration of freedom."[128] In other words, *caveat emptor*. That is why "Argentina acknowledges the right of each WTO Member to conduct its own sanitary evaluation" (emphasis supplied).[129]

111. Argentina insists that the United States must have accepted "the underlying scientific evidence . . . each time it joined the OIE consensus" on designations.[130] The United States has been clear that it does not view OIE designations as an "international standard" nor does it view that OIE designations are binding on the United States. The United States participation in any consensus is not a statement on what the United States views the situation in Argentina to be, or whether or not Argentina can meet United States standards, particularly given the fact that the underlying data and reasons for the designation are typically never provided or tested in an open setting.[131]

4. Conditions Set Forth In Article 8.6.25 of the OIE Code Are Not Equivalent to Conditions Set Forth For Uruguay

[126] Exhibit USA-22, p. 5. ("It is recommended that the questions are first referred to the applicant Member Country concerned, which is requested to provide clarification to the Member Country soliciting information, with copy to the OIE Headquarters.").

[127] Argentina's Response to Panel Question No. 53, para. 202.

[128] Exhibit ARG-103, point 6.

[129] Argentina's Response to Panel Question No. 53, para. 202.

[130] Argentina's Response to Panel Question No. 53, para. 202.

[131] Accordingly, the fact that the United States was present at the consensus vote of the General Assembly does not imply that the United States adopted the findings of the OIE as its own.

112. Argentina also asserts that the Uruguay conditions apply to it since (1) the conditions under which product from Uruguay enters the United States is similar to the conditions in the OIE Code at Article 8.6.25 that apply to FMD-affected regions that have an official control program, and (2) that because the rest of Argentina has an FMD-free with vaccination designation, it necessarily has a better situation than FMD-affected areas with an official control program.[132]

113. Aside from the fact that this argument is flawed for the reasons stated above concerning the OIE designation system, this argument is additionally unsound because OIE Code Article 8.6.25 does not contain the same conditions under which Uruguay can export product to the United States. Key differences between the Uruguay conditions at 9 C.F.R. Section 94.22[133] and OIE Code Article 8.6.25 include the following:

- The meat imported is beef or ovine meat from animals that have been born, raised, and slaughtered in Uruguay. OIE Code Article 8.6.25 does not require this.

- Foot-and-mouth disease has not been diagnosed in Uruguay within the previous 12 months. OIE Code Article 8.6.25 does not require this.

- The meat comes from bovines or sheep that originate from premises where foot-and-mouth disease has not been present during the lifetime of any bovines and sheep slaughtered for the export of beef and ovine meat to the United States. OIE Code Article 8.6.25 does not require this.

- The meat comes from animals that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.[134] OIE Code Article 8.6.25 does not require this.

- The meat has not been in contact with any meat from regions other than those listed as FMD-free in 9 C.F.R. §94.1(a)(2). OIE Code Article 8.6.25 does not require this.

- The establishment in which the animals are slaughtered allows periodic on-site evaluation and subsequent inspection of its facilities, records, and operations by an APHIS representative. OIE Code Article 8.6.25 does not require this.

114. Accordingly, Argentina cannot simply state that because it has the OIE's designation for FMD-free with vaccination status, that it must, *a fortiori*, be able to meet the standard for a "lower" status such as OIE Code Article 8.6.25, and that therefore, it must be able to meet the

[132] Argentina's Response to Panel Question No. 44, para. 179.

[133] 9 C.F.R. §94.22 (2013) (USA-155)

[134] Moving animals directly from the premises of origin to the slaughter establishment protects the integrity of sourcing by preventing commingling with potentially infected but asymptomatic animals. This condition minimizes contact with other potentially infected animals, and therefore mitigates the risk of exposure to potentially FMDv-infected animals.

conditions extended to Uruguay, for the simple reason that the conditions extended to Uruguay are not the same conditions as OIE Code Article 8.6.25. As a result, Argentina's argument fails to support its Article 5.6 claim because the OIE actions are not applicable. The United States is undergoing a review of Argentina's FMD system to see what set of conditions would be appropriate to extend to Argentina, given its particular profile.

115. It is Argentina's burden to demonstrate that an alternative measure would meet the appropriate level of protection of the United States. As the Appellate Body stated, "we cannot conceive of how a complaining could satisfy its burden . . . without relying on evidence that is scientific in nature."[135] Argentina has failed to meet its burden to present the factual record necessary to establish a successful claim under Article 5.6.

F. Argentina Has Failed To Establish That The United States Has Acted Inconsistent With Article 2.3

116. To establish that the United States has acted inconsistent with Article 2.3, Argentina carries the burden of showing that: (1) the measure discriminates between 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 Members compared.[136] The United States has previously explained that Argentina has not met its burden of proving these elements.[137] With respect to the third element, the United States would like to address issues raised by the Panel in its questions, and elaborate on the fact that Argentina has yet to demonstrate that conditions identical or similar to Argentina and Patagonia prevail in this dispute.

1. The APHIS Application System Does Not Entail Arbitrary Or Unjustifiable Discrimination Between Members Where Identical Or Similar Conditions Prevail

117. Argentina has maintained that the United States has acted inconsistent with Article 2.3, alleging that the United States has applied its regulations in a contrary manner to Argentina as compared to other Members.[138] Specifically, Argentina argues that the conditions in Argentina are similar to Uruguay, and those present in Patagonia are similar to Santa Catarina (Brazil) because they have been attributed the same FMD status from the OIE.[139] Argentina has also asserted that the animal health conditions in Chile are equivalent to the conditions in Patagonia

[135] *Australia – Apples (AB)*, para. 364.

[136] *Australia – Salmon (Article 21.5 – Canada)*, paras. 7.110 – 7.111.

[137] U.S. First Written Submission, Part IV(H).

[138] Argentina's Opening Oral Statement at the First Meeting of the Panel, para. 50.

[139] Argentina's Response to Panel Question No. 37, paras. 156-157.

South.[140] However, beyond these broad conclusive comparisons, Argentina has failed to establish that identical or similar conditions prevail for the purposes of Article 2.3.

a. The OIE FMD-Status Attributions In Themselves Do Not Establish Identical or Similar Conditions For The Purposes of Article 2.3

118. According to Argentina, the OIE's official recognition of the FMD status of a country or area is sufficient to establish that regions have identical or similar conditions within the meaning of Article 2.3.[141] Argentina asserts that, because the process of achieving official recognition from the OIE involves an in-depth examination of the application and data, regions receiving the same FMD status have sufficiently identical or similar conditions.[142]

119. APHIS does consider the OIE's FMD status attributions in performing its own risk assessments. As Argentina pointed out, APHIS considers regional conditions in assessing the risk of introducing FMD posed by a particular region.[143] What APHIS does not do, however, is conclude that identical or similar conditions prevail in regions based on the statuses attributed by the OIE. The United States has previously demonstrated that, while it takes into account the OIE FMD-free status determinations, these attributions have circumscribed.[144]

120. The OIE's FMD status designations reflect that (1) the OIE has accepted documentary evidence of a region's record of regular and prompt animal disease reporting, FMD surveillance and regulatory measures for early detection; (2) there have been no reported FMD outbreaks, evidence of FMDV infections or vaccination against FMD in the preceding 12 month period; and (3) the OIE is comfortable with the detailed description of the region's boundaries and protection zones, if applicable.[145] While important indicators of a regions FMD situation, these factors do not lead to a conclusion that regions receiving the same status designation have identical or even similar sanitary conditions.

121. These factors do not consider additional, important regional dynamics, including whether the region accepts imports from FMD-infected regions and the veterinary services' capacity to detect, prevent and control the spread of FMD. Most notably, the OIE's FMD status designations do not indicate whether a region has identical or similar sanitary conditions for the purposes of determining which SPS measures are required to meet the United States' appropriate level of protection for those countries.[146]

---

[140] Argentina's Response to Panel Question Nos. 37-38, 40, paras. 156-157.

[141] Argentina's Response to Panel Question No. 37, para. 156.

[142] Argentina's Response to Panel Question No. 37, paras. 155-156.

[143] Argentina's Response to Panel Question No. 37, para. 157.

[144] U.S. Response to Panel Question No. 39, para. 167.

[145] U.S. Response to Panel Question No. 39, para. 168.

[146] U.S. Response to Panel Question No. 39, para. 168.

122. The United States has observed that Argentina has not shown that its situation is identical or similar to Uruguay, Japan or United Kingdom, or that Patagonia's situation is identical or similar Santa Catarina (Brazil).[147] Furthermore, Argentina relies on the description of Chile as equivalent to Patagonia South in a 2007 proposed rule to conclude that identical or similar conditions prevail between the regions for purposes of Article 2.3. As stated by the United States in response to the Panel's First Questions, this description pertained to the regions' OIE FMD status attributions.[148] To this point, the United States made the same observation in a 2005 risk analysis associated with Patagonia South: "Argentina recognizes FMD status for surrounding countries as classified by OIE. Chile is recognized as FMD-free without vaccination."[149] However, the United States has never proclaimed that such an observation, in itself, deems Chile and Patagonia identical or similar under Article 2.3.

123. APHIS takes into account the OIE FMD status attributions; however, without more, these designations do not show that any two regions are identical or similar. Argentina has failed to meet its burden in asserting this claim.

III. CONCLUSION

124. For the foregoing reasons, Argentina's claims should be rejected in their entirety.

[147] *See* U.S. First Written Submission, Part IV(H).

[148] U.S. Response to Panel Question No. 39, para. 165.

[149] Exhibit ARG-9, p. 25.

ANNEX

1. In this Annex, the United States provides comments on certain of Argentina's answers to the Panel's first set of questions. The absence of a U.S. comment on a particular answer by Argentina does not imply U.S. agreement, but rather reflects that the United States has addressed the relevant issues in this or in prior submissions in this dispute.

I. MEASURES AT ISSUE AND SCOPE OF ARGENTINA'S CLAIMS

1. (To Both Parties) *Please comment on paragraphs 43-45 and 47 of the European Union's third party submission with respect to the relationships between 9 CFR 94.1(a) and 94.1(b) and the relevance for Argentina's claims and the Panel's terms of reference..*

2. In its answer, Argentina mischaracterizes the disease free status categories for FMD that APHIS recognizes "as applied" to Argentina.

3. Argentina attempts to distinguish the OIE's approach to FMD status categorization from the United States approach.[150] Specifically, Argentina states that United States recognizes only two categories of disease status for FMD. However, the OIE's approach reflects the fundamental principle expressed in Article 6: "levels of prevalence of specific disease or pests" exist in the real world and that under certain circumstances, imports from areas of varying "low disease prevalence," not only areas of disease-freedom, may be authorized while meeting a Member's appropriate level of protection. The U.S. approach, as reflected in sections 94.1, 94.11 and 94.22 of APHIS' regulations, is based on the OIE's fundamental approach to recognizing the prevalence of FMD in regions.

4. In particular, the relevant sections of the U.S. regulations include Section 94.1(a) (a provision Argentina has not challenged), 94.1(b), 94.11 and 94.22. Under these provisions, the U.S. regulations envision the OIE's approach to recognizing FMD prevalence.

5. As explained in the U.S. response to Panel Question No. 1, the OIE also contemplates these disease status categories for FMD and applies them in determining which category is applicable to a given region, including Argentina and Patagonia. Thus, the APHIS approach to disease status for FMD is similar to the OIE both as a general matter, and as applied to Argentina.

6. Argentina's answer also presents a number of other inaccurate and inconsistent observations, which, if not clarified, could cause some confusion for the Panel. First, Argentina contends that no measure can be derived from Section 94.1(a); however, Section 94.1(a) in fact establishes the category of FMD-infected, and APHIS can adopt a measure in response to this status.

7. Second, Argentina characterizes the import protocol under Section 94.22 as "very redundant and restrictive."[151] This is simply incorrect. The protocol establishes necessary conditions that meet the appropriate level of protection of the United States. (The United States also notes that Argentina has confirmed that it is not challenging these protocols *as such*.) Under

[150] Argentina's Response to Panel Question No. 1, para. 2.

[151] Argentina's Response to Panel Question No. 1, para. 3.

this section, United States develops protocols so as to facilitate trade in fresh beef while ensuring exports may be imported safely and in accordance with the U.S. appropriate level of protection. It was under this section that APHIS authorized fresh beef exports from Uruguay.[152]

8. Third, Argentina contends that Section 94.1(a) falls within the Panel's terms of reference because Argentina's claims were expressed in relation to 9 C.F.R. §94.1 generally.[153] Argentina has no support for this proposition. In particular, Argentina cites its Panel Request and First Written Submission,[154] but neither document shows that section 94.1(a) is within the Panel's terms of reference. Section 2 of Argentina's Panel Request does not support its contention that Section 94.1(a) falls within the Panel's terms of reference. The "broad reference to the regulations"[155] is actually to the "Application of prohibitions on imports"[156], and not the list of regions free of FMD contained in Section 94.1(a). Likewise, paragraph 383 of Argentina's First Written Submission does not support Argentina's contention. As an initial matter, it is axiomatic that the terms of reference are established by the request for panel establishment; a party may not expand the scope of a dispute by addressing additional measures during the proceeding. In addition, paragraph 383 states that Argentina "challenges the application of the prohibitions contained in Part 94 Title 9 of the CFR,"[157] but Section 94.1(a) contains lists of regions declared free of FMD; the lists do not serve as prohibitions.

9. Fourth, Argentina itself says that it "bifurcated its claims regarding beef and the Patagonia region in order to track the US regulatory approach."[158] This seems to suggest that, contrary to Argentina's ongoing contentions, it is in fact concerned with the U.S. regulatory approach to FMD *as such*. Although Argentina has not directly challenged the U.S. regulatory system *as such*, the record is abundant with facts demonstrating that APHIS' approach to regulating FMD is not trade restrictive and consistent with the SPS Agreement.

2. (To Both Parties) *Can you please confirm whether you believe the US measures are taken for the purpose set forth in Annex A(1)(a) of the SPS Agreement? Is Section 737 of the 2009 Omnibus Appropriations Act an SPS measure?*

10. Argentina believes that the measures at issue are sanitary measures covered by Article 1.1 of the SPS Agreement.[159] The United States does not disagree.

---

[152] 9 C.F.R. §94.22 (USA -)

[153] Argentina's Response to Panel Question No. 1, para. 7.

[154] Argentina's Response to Panel Question No. 1, para. 7.

[155] Argentina's Response to Panel Question No. 1, para. 7.

[156] Doc. No. WT/DS447/2, Sec. 2.

[157] Argentina's First Written Submission, para. 383 (cited at Argentina's Response to Panel Question No. 1, para. 7).

[158] Argentina's Response to Panel Question No. 1, para. 8.

[159] Argentina's Response to Panel Question No. 2, para. 12.

11. Argentina also contends that Section 737 of the 2009 Omnibus Appropriations Act *is* an SPS measure (even though Argentina did not identify Section 737 in its First Written Submission).[160] Argentina is incorrect. Section 737 was an SPS measure, but ceased to exist before this dispute was initiated and is therefore not an SPS measure included with the terms of reference of this dispute.[161]

12. Additionally, Section 737 did not – as Argentina contends – illustrate political interference in APHIS' evaluation process and amount to undue delay.[162] As the United States has previously observed, Section 737 – even during the period when it was in effect – did not eliminate the United States' ability to conduct activities necessary to review the proposal to authorize Argentine fresh beef imports.[163]

13. Furthermore, China's reliance on the findings in *US – Poultry (China)* is misplaced. Section 737 is substantially different from the measure at issue in *US – Poultry (China)* for a number of reasons. For example, the measure at issue in *US – Poultry (China)* maintained legal force when that dispute was initiated in. Argentina fails to recognize that Section 737, however, did not. For this reason alone, as well as the substantive differences between the two provisions, the findings in *US – Poultry (China)* do not support Argentina's argument that Section 737 amounted to undue delay.

3. (To Argentina) ***In light of Argentina's clarification that it is challenging the US measures "as applied" Please tell us whether the 1997 APHIS Policy document which is listed in your Panel Request and provided in Exhibit ARG-63 is a measure at issue in this dispute?***

14. Argentina states that it is not challenging the policy in this dispute.[164]

5. (To Argentina) ***Has Argentina ever requested APHIS to recognize the whole Argentine territory under 9 C.F.R. 94.1(a)? If so, when and why did Argentina decide to modify its request into one for the authorization of imports of fresh (chilled or frozen) beef from its territory?***

15. Argentina has submitted multiple applications and requests for revision of its application throughout the period in question in this dispute, and this is an example of the changing and challenging nature of evaluating Argentina's FMD situation.

II. FOOT-AND-MOUTH DISEASE AND ERADICATION EFFORTS IN ARGENTINA

[160] Argentina's Response to Panel Question No. 2, para. 13.

[161] U.S. Response to Panel Question No. 2, para. 8.

[162] *Contra* Argentina's Response to Panel Question No. 2, para. 13.

[163] U.S. First Written Submission, para. 223.

[164] Argentina's Response to Panel Question No. 3, para. 16.

9. (To Argentina) ***Does Argentina have evidence to support its assertion that "there is no a single case in record of transmission of the FMD disease through trade of fresh, chilled or frozen (deboned and matured) beef"?***[165]

16. The U.S. response to Question 8 addresses the issues raised by Argentina in its response.

11. (To Both Parties) ***Please explain the relevance of APHIS' recognition of the "regional cooperation and surveillance program involving Uruguay, Brazil and Argentina", described in paragraph 330 of Argentina's first written submission and mentioned in Exhibits ARG-8 and ARG-65, to Argentina's claims.***

17. In Argentina's response to Question 11, it argues that the existence of a regional cooperation and FMD surveillance program involving Uruguay, Brazil and Argentina demonstrates that these three countries have conditions that are identical or similar for purposes of Article 2.3.[166] Argentina's argument makes no sense. A regional approach to controlling FMD does not demonstrate that the participating regions necessarily have identical or similar conditions. The regional approach establishes just that: Uruguay, Brazil and Argentina have some coordinated understanding of the need to collectively control FMD.

18. Argentina tries to draw support for its untenable proposition from the the fact that APHIS commented on regional cooperation when the United States authorized beef imports from Uruguay. The fact, however, that APHIS made note of these cooperative efforts does not lead to the conclusion that that the conditions in Uruguay, Argentina and Brazil are similar. [167] Indeed, as explained in the U.S. response to Question 11, there are many differenced in the FMD control programs among the countries that must be assessed on an individual country basis.[168]

19. In sum, the existence of a regional cooperation agreement does not negate the need for APHIS to assess each Member's internal systems. Nor does it demonstrate that Members engaged in regional cooperation have identical or similar conditions for the purposes of Article 2.3 of the SPS Agreement.

III. HARMONIZATION (ARTICLE 3 OF THE SPS AGREEMENT)

13. ***In their respective first written submissions, Argentina and the United States refer to different provisions of the OIE Terrestrial Code in support of their arguments under Article 3 of the SPS Agreement.***[169] ***Moreover, the European Union asserts that Articles***

[165] Argentina's Opening Oral Statement the First Meeting of the Panel, para. 10.

[166] Argentina's Response to Panel Question No. 11, para. 29.

[167] Argentina's Response to Panel Question No. 11, para. 31.

[168] U.S. Response to Panel Question No. 11, para. 26 (differences including veterinary infrastructures, size and allocation of human and material resources

8.5.22 and 8.5.23 of the Code, to which Argentina refers, do not support Argentina's claims.[170]

a. **(To Both Parties)** ***Please identify precisely the international standards, guidelines or recommendations that are relevant to the Panel's assessment of whether the US measures are based on the relevant standards, guidelines or recommendations. ?***

20. The United States addresses Argentina's argument at Part II.D of its second submission.

c. (To Both Parties) ***Please discuss the similarities and differences between the relevant provisions of the OIE Terrestrial Code and the US measures.***

21. The United States addresses Argentina's argument at Part II.D of its second submission.

14. (To Both Parties) ***Is it possible that a measure is both based on an international standard, guideline or recommendation (e.g. the OIE Terrestrial Code) and, at the same time, achieves a higher level of protection than such a standard, guideline or recommendation?***

22. The United States addresses Argentina's argument at Part II.D of its second submission.

15. (To Both Parties) ***Assuming arguendo that the US measures are based on an international standard, guideline, or recommendation and thus consistent with Article 3.1, what would be the consequences on the rest of Argentina's claims? In your answer, please address the relationship of such a finding to the applicability of Article 3.3 and the rest of the provisions of the SPS Agreement.***

23. In Argentina's response, Argentina alleges that it would be an "absurd result if a Member could meet the lower threshold of Article 3.1 and still have some sort of safe harbour or other release from the obligations of the remainder of the SPS Agreement."[171] But despite Argentina's resort to rhetorical excess, the United States has not argued that Article 3.1 releases Members of its other obligations of the SPS Agreement. Simply, Argentina has failed to support its positions. As the United States has explained, the obligations of Article 3.1 are subject to the express exception of Article 3.3, which even when met, nonetheless require any measure that falls within Article 3.3 not to be inconsistent with other relevant provisions of the SPS Agreement.[172] Here, the United States has explained that even if the U.S. measure is found inconsistent with Article 3.1, the measure would fall within the exception of Article 3.3; and is not inconsistent with the other relevant provisions of the SPS Agreement. Accordingly even under the scenario where

[169] *See, e.g.*, Argentina's First Written Submission, paras. 190-206, 421-428; U.S. First Written Submission, paras. 324-341.

[170] EU'S Third Party Submission, para. 34.

[171] Argentina's Response to Panel Question No. 15, para. 46.

[172] *Contra* Argentina's Response to Panel Question No. 15, para. 46.

Argentina established a *prima facie* breach of Article 3.1, the U.S measure would be covered by the exception under Article 3.3, and would not amount to a breach of the SPS Agreement. Nothing about this scenario is "absurd." To the contrary, it follows from the express text of Article 3 of the SPS Agreement.

17. (To Both Parties) ***Does the OIE's attribution of an FMD status to a specific country constitute an international standard, guideline, or recommendation for the purposes of Article 3 of the SPS Agreement? If so, is it a "standard", a "guideline" or a "recommendation"?***

24. The United States addresses Argentina's argument at Part II.D of its second submission. Argentina also argues that the OIE designation must be a standard otherwise a Member would not be able to assert an Article 3.2 "conformity" defense.[173] Argentina's hypothetical is not present in this dispute. Moreover, the SPS Agreement does not require that every sort of evaluation by an international organization must necessarily be able to be defined or framed as an international standard.

19. ***According the OIE Terrestrial Code, "[t]o qualify for inclusion in the list of FMD free zones where vaccination is not practised, a Member Country should [declare to the OIE that] there has been no outbreak of FMD during the past 12 months".[174] Further, "[t]o qualify for inclusion in the list of FMD free countries where vaccination is practised, a Member Country should [declare to the OIE that] (a) there has been no outbreak of FMD during the past two years; [and] (b) no evidence of FMDV circulation has been found during the past 12 months".[175]***

a. **(To Argentina)** ***Do the parties agree that the time-periods established under the OIE Terrestrial Code are sufficient to provide the minimum amount of epidemiological data for a country or region to be evaluated for the purposes of acquiring disease-free status? If not, why not?***

25. The United States addresses Argentina's argument at Part II.D of its second submission.

IV. WHETHER THE US MEASURES ARE MAINTAINED WITH SUFFICIENT SCIENTIFIC EVIDENCE

a. Article 5.7 of the SPS Agreement

21. ***Is Article 5.7 applicable in a situation where the insufficiency of evidence relates to the risk associated with products originating in a specific country or region rather than with respect to the science on the risks associated with a particular disease?***

---

[173] Argentina's Response to Panel Question No. 17, para. 58.

[174] 2012 OIE Terrestrial Code, Article 8.5.2.

[175] 2012 OIE Terrestrial Code, Article 8.5.3.

26. The United States addresses Argentina's argument at Part II.A and Part II.B of its second submission.

20. (To Both Parties) ***Article 5.7 has been determined to be applicable where the relevant scientific evidence is insufficient to conduct a risk assessment. What is included in "relevant scientific evidence" within the meaning of Article 5.7? In your answers, please address the references to "available pertinent information" and a "more objective assessment of risk" in Article 5.7, as well as the relevance of the definition of a risk assessment in Annex A(4) and the factors set forth in Articles 5.2 and 5.3. Please also consider the Appellate Body's statement that the "assessment of risk" referred to in Article 5.7 is that described in Article 5.1.***

27. The United States addresses Argentina's argument at Part II.A and Part II.B of its second submission.

22. (To Both Parties) ***In the context of a WTO dispute, does the complainant bear the burden of proving the sufficiency of the relevant scientific evidence and the inapplicability of Article 5.7 or does the respondent bear the burden of proving the insufficiency of the relevant scientific evidence and the applicability of Article 5.7?***

28. The United States addresses Argentina's argument at Part II.A and Part II.B of its second submission.

23. (To Both Parties) ***The United States argues that "at the time of adoption the [US measures] were based on an assessment of risks as appropriate to the circumstances, and those circumstances have not been demonstrated to have changed".[176] In light of the requirement under Article 2.2 of the SPS Agreement that a measure not be "maintained without sufficient scientific evidence", who bears the burden of proof as regards changes in circumstances?***

29. The United States addresses Argentina's argument at Part II.A and Part II.B of its second submission.

[176] U.S. First Written Submission, para. 247.

24. ***The United States argues that:***

> ***US measures relating to FMD, including as applied to Argentina at the time its import authorization was removed, are based on an assessment of the risks posed by FMD. … From the time that the regulatory authority receives a claim and evidence of disease-free status, the pre-existing measure as applied to the relevant product from that area of the exporting Member can be viewed as provisional until additional necessary information is gathered to accept or reject the application.***[177]

a. **(To Both Parties)** ***In your views, at the time the United States imposed the ban on Argentine imports by removing Argentina from the list of approved countries, was it imposing the measure based on a risk assessment pursuant to Article 5.1 or as a "provisional" measure pursuant to Article 5.7?***

b. **(To Both Parties)** ***At the time of the establishment of the Panel, were the US measures maintained as being based on a risk assessment pursuant to Article 5.1 or as a "provisional" measure pursuant to Article 5.7?***

c. **(To Argentina)** ***To the extent you disagree with the United States' argument, please explain if and how, in your view, the provisions of the SPS Agreement can and/or should take into account the time required for an importing Member to review applications from exporting Members. At what point in time is a Member reviewing an authorization request subject to the obligations under Articles 2, 5, and 6 of the SPS Agreement?***

30. The United States addresses Argentina's argument at Part II.A and Part II.B of its second submission.

25. (To Both Parties) ***What is the significance to an argument that a measure is justified under Article 5.7 of the SPS Agreement that:***

a. The measure was based on a risk assessment at the time of imposition?

b. An international standard, guideline, or recommendation exists regarding the same situation?

c. Other completed risk assessments exist on the same matter?

31. The United States addresses Argentina's argument at Part II.A and Part II.B of its second submission.

[177] U.S. Opening Oral Statement at the First Meeting of the Panel, para. 30.

29. (To Argentina) ***In reference to paragraphs 58-61 of the European Union's third party submission:***

a. Is there a line to be drawn between "definitive" and "provisional" SPS measures?

b. Can a measure originally taken pursuant to Article 5.1 eventually become one where there is insufficient scientific evidence to conduct a risk assessment such that it is now "provisional" under Article 5.7?

c. Can a provisional measure be maintained indefinitely?

d. What is the relationship between Articles 5.1, 5.7, and 6.3 of the SPS Agreement?

32. The United States addresses Argentina's argument at Part II.A and Part II.B of its second submission.

30. (To Both Parties) ***Is there a relationship between the requirement under Article 5.1 of the SPS Agreement that Members base their SPS measures on a risk assessment "as appropriate to the circumstances" and the obligations under Annex C(1)(a) and C(1)(b)?***

33. In its response, Argentina presents an argument that purports to link Article 5.1 to Annex C(1). Argentina's argument is unpersuasive. Argentina starts by citing the finding in *EC – Biotech* to that the language "appropriate to the circumstances" contained in Article 5.1 does not relieve a Member of the obligation to base its SPS measure on a risk assessment.[178] From this, Argentina jumps to the conclusion that this phrase contained in Article 5.1 also does not relieve a Member from complying with the obligations under Annex C(1)(a) and C(1)(b).[179] This argument, however, is a complete *non sequitur*, and Argentina has not demonstrated how the language "appropriate to the circumstances" in Article 5.1 establishes a relationship between the provisions.

31. (To Both Parties) ***Is there a relationship between the obligation to "maintain" SPS measures based on scientific principles and not without sufficient scientific evidence in Article 2.2 and the obligations under Annex C(1)(a) and C(1)(b)?***

34. In its response to Question 31, argues that Argentina argues that Article 2.2 could inform this Panel's analysis under Article C(1)(a) and C(1)(b). Argentina's line of reasoning is not convincing.

[178] Argentina's Response to Panel Question No. 30, para. 137.

[179] Argentina's Response to Panel Question No. 30, paras. 137-139.

35. Argentina relies on the panel findings in *US – Poultry (China).* But that panel report does not support Argentina's contentions. The panel cited the Appellate Body Report in *Japan – Agricultural Products II* in stating that Article 2.2 obliges Members to not "maintain a measure without sufficient scientific evidence."[180] The panel in *US – Poultry (China)* did not use Article 2.2 as interpretive context for its understanding of Annex C(1)(a) and C(1)(b) containing procedural obligations.

36. The *US – Poultry (China)* panel did, however, recognized that Article 5.7 serves as an exception to the obligation that Members may not maintain SPS measures without sufficient scientific evidence.[181] Under Article 5.7, an SPS measure may be maintained without sufficient scientific evidence, subject to the requirements of the provision. As explained at length in Part II.B, Article 5.7 requires Members to seek, within a reasonable period of time, additional information necessary for a more objective assessment of risk and review the measure accordingly. The United States notes that this obligation under Article 5.7 (as opposed to the obligation under Article 2.2) is indeed similar to the obligation set out in Annex C(1)(a) – providing that a Member must complete a control, inspection or approval procedure without undue delay. Thus, to the extent that Argentina is proposing a linkage between Article 5.7 and Annex C, the United States would agree.

37. Indeed, as the panel in *EC – Approval and Marketing of Biotech Products* recognized, a situation where a regulator needed to obtain additional information to process a product application would not be a case where any delay was "undue"[182] Thus, under both Article 5.7 and Annex C(1)(a), a Member seeking additional information within a given period of time may be consistent with the respective provisions of the SPS Agreement.

b. Articles 2.2, 5.1, and 5.2 of the SPS Agreement

[180] *US – Poultry (China)*, para. 7.199.

[181] *US – Poultry (China)*, para. 7.197.

[182] *EC – Approval and Marketing of Biotech Products*, para. 7.1498.

34. (To Both Parties) ***What is the meaning of the words "tak[ing] into account" as contained in Articles 5.1, 5.2, 5.3 and 6.1 of the SPS Agreement or "take account of" in Article 10.1 of the SPS Agreement? In your answer please discuss prior panel and Appellate Body decisions on these provisions as well as the relevance of the Appellate Body's reasoning in China – GOES that the word "consider" (as used in Article 3.2 of the Anti-Dumping Agreement) is synonymous to the phrase "take into account", and that a Member's "consideration" of a given fact or criterion "must be reflected in relevant documentation" so as to "allow an interested party to verify" whether the fact or criterion in question has indeed been "considered".[183] What would be "relevant documentation" in the context of an SPS measure?***

38. The United States response to Question 8 addresses the issues raised by Argentina in its response.

35. (To Argentina) ***Has Argentina ever formally requested the United States to produce copies of any risk assessments for Argentina as a whole and/or Patagonia? If so, please document Argentina's requests.***

39. Argentina never formally requested the United States to produce copies of any risk assessments for Argentina as a whole and Patagonia. In its response, Argentina argues that the requests it made for the United States to complete the evaluation process amount to an *implied formal request* for the United States to produce risk assessments.[184] Argentina cites three communications to serve as documentation in support of its assertion; however, a review of the correspondence reveals that Argentina did not formally request the risk assessments. Although Argentina attempts to conflate a request to complete a process with a formal request for the production of risk assessments, these are not the same. Argentina's request for APHIS to complete the evaluation process referred to its interest in being recognized as FMD-free and obtaining authorization to import fresh beef, not to receive any risk assessments. In short, Argentina never formally requested the United States to produce risk assessments.

V. WHETHER THE US MEASURES ENTAIL ARBITRARY OR UNJUSTIFIABLE DISCRIMINATION BETWEEN MEMBERS WHERE IDENTICAL OR SIMILAR CONDITIONS PREVAIL (ARTICLE 2.3 OF THE SPS AGREEMENT)

[183] *China – GOES (AB)*, paras. 130-131 & fn. 216.

[184] Argentina's Response to Panel Question No. 35, para. 149.

37. (To Argentina) ***Does Argentina consider that the attribution by the OIE of the same FMD status to Argentina and Uruguay, on the one hand, and Patagonia and Santa Catarina (Brazil), on the other hand, is sufficient to establish that the two pairs of regions are in "identical or similar conditions" within the meaning of Article 2.3 of the SPS Agreement? If not, please point to evidence substantiating Argentina's arguments in this respect.***

40. The United States addresses Argentina's argument at Part II.F of its second submission.

38. (To Argentina) ***Please explain the grounds of Argentina's assertion that "the animal health status of Chile and Patagonia South are equivalent", other than APHIS' statement quoted at paragraphs 512 and 555 of Argentina's first written submission.***

41. The United States addresses Argentina's argument at Part II.F of its second submission.

VI. WHETHER THE US MEASURES ARE MORE TRADE-RESTRICTIVE THAN NECESSARY TO ACHIEVE THE US ALOP (ARTICLES 2.2, 5.4, AND 5.6 OF THE SPS AGREEMENT)

40. ***Argentina urges the Panel to adopt a different interpretation of Article 5.4 of the SPS Agreement than the panel in EC – Hormones.***

a. **(To Argentina)** ***– Please explain whether there are "cogent reasons" to do so.***

42. Argentina provides no basis for this Panel to reject the DSB's interpretation of Article 5.4 in *EC – Hormones*, which concluded that Article 5.4 does not impose affirmative obligations on Members.

43. Argentina asks the Panel to ignore the same legal question at issue in *EC – Hormones* in this subsequent dispute, and instead to apply an interpretation of the word "should" that was used in another dispute (*Canada – Aircraft*) regarding a different provision in another agreement (Article 13.1 of the Dispute Settlement Understanding). Argentina, however, has provided no basis for construing a DSU provision regarding requests for information in the same manner as a substantive SPS provision regarding the factors Members should consider when adopting their appropriate level of protection.

41. (To Argentina) ***Explain the basis for your interpretation of Article 5.4 of the SPS Agreement with reference to the customary rules of interpretation of public international law. What does Argentina believe a Member must do to demonstrate compliance with Article 5.4? How is Argentina's understanding of the obligation in Article 5.4 substantively different from the obligations set forth in Article 5.5 of the SPS Agreement?***

44. Argentina did not answer the Panel's question and admits that "Article 5.4 is not specifically prescriptive." This is in accord with the conclusion of the panel in *EC – Hormones* that the language of Article 5.4 does not impose affirmative obligations. In addition, Argentina's

response to the Panel's question is not based on the text of Article 5.4. Article 5.4 references a Member "determining the appropriate level of sanitary or phytosanitary protection," it does not identify specifically any measure taken, nor does it directly state that negative trade effects must be minimized, only that the objective of minimizing negative trade effects be "take[n] into account."

44. (To Both Parties) ***Please express your views concerning the Appellate Body's reasoning in Australia – Apples with respect to the Panel's role in making an assessment under Article 5.6 of the SPS Agreement as to whether the alternative measure proposed by the complainant would achieve the importing Member's appropriate level of protection, and the relevance of that reasoning for the Panel's analysis. In your answers, please address how the Panel should evaluate any scientific evidence adduced by the parties with respect to this analysis.***

45. The United States addresses Argentina's argument at Part II.E. of its second submission.

47. (To Argentina) ***In light of your statement in para. 313 of your first written submission, what is the relevance to your arguments of the fact that "USDA included, as a priority planned for the first half of 2013, the publication of a proposed rule regarding the authorization of imports of fresh (chilled or frozen) meat, under certain conditions, from a region of Brazil (comprised of the States of Bahia, Distrito Federal, Espirito Santo, Goias, Mato Grosso, Mato Grosso do Sul, Minas Gerais, Prana, Rio Grande do Sul, Rio de Janeiro, Rondonia, São Paulo, Segipe, and Tocantins)?***

46. The United States addresses Argentina's argument at Part II.E. of its second submission.

VII. REGIONALIZATION (ARTICLE 6 OF THE SPS AGREEMENT)

48. (To Both Parties) ***The United States argues that Article 6.3 is "most directly relevant" to assess APHIS' review of "Argentina's pending applications".[185] We note that Argentina only raised claims under Article 6 in connection with its application for recognition of Patagonia. Does Article 6.3 apply to Argentina's request for authorization to imports fresh (frozen or chilled) beef from the Argentine territory as a whole into the United States? In your answers, please consider the following wording in Article 6.3: "Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence …".***

47. The United States addresses Argentina's argument at Part II.A and Part II.B of its second submission.

[185] U.S. Opening Oral Statement at the First Meeting of the Panel, para. 23.

49. (To Both Parties) ***What is the relationship between Articles 6.1, 6.2 and 6.3 of the SPS Agreement? Do the Article 6.3 requirements only apply to claims of inconsistency with Article 6.1? Is there a relationship between Articles 6.1 and 6.2 and Article 5.1?***

48. The United States addresses Argentina's argument at Part II.A and Part II.B of its second submission.

50. (To Both Parties) ***Is Article 6 of the SPS Agreement the only applicable provision with respect to "pest- or disease-free areas"? In your answer, please refer to Article 5.2.***

49. Argentina states that a "violation of Article 6 would implicitly, but necessarily, lead to a finding of a violation of Article 5." Argentina's answer does not answer the Panel's question. It is clear that Article 5.2 does refer to "pest- or disease-free areas." Argentina's answer also is overbroad and imprecise: Article 6 contains a number of provisions with different conditions, as does Article 5. It is not implicit or necessary that any breach of Article 6 would necessarily lead to a breach of Article 5, which contains eight sub-provisions.

51. (To Both Parties) What is the relevance of the SPS Committee's ***Guidelines to Further the Practical Implementation of Article 6*** **(Document G/SPS/48 of 16 May 2008) to the Panel's analysis?**

50. Argentina agrees that the *Guidelines* are a useful illustration. This is significant because the *Guidelines* reflect a framework of interaction between exporting and importing Members consistent with the process outlined in Part II.A and Part II.B of the second submission of the United States. Under the *Guidelines*, the appropriate procedure when a exporting Member seeks to export a product based on an assertion that its territory is disease free or of low disease prevalence is (1) the exporting Member submits a request to the importing Member; (2) the importing Member is not required to allow the product in until the request is reviewed; (3) the review process includes examining evidence provided by the importing Member and any site visits; and (4) past experience with the exporting Member is relevant.

51. However, Argentina contradictorily argues that the Panel should disregard the *Guidelines* in this dispute because it is an "as applied" dispute. The panel reports and Appellate Body reports do not provide any basis for Argentina to conclude that this Panel should ignore the *Guidelines* based on the "as applied" nature of Argentina's claims.

52. Argentina also contradictorily argues that the Panel should disregard the *Guidelines* in this dispute based on its allegation that the United States acted inconsistently with regard to Article 6. Again, there is no basis or reasoning for the Panel to accept this argument.

52. (To Both Parties) ***The first sentence of Article 6.1 requires Members to adapt their SPS measures to the SPS characteristics of an "area", whereas the second sentence thereof requires Members to taken into account the SPS characteristics of a "region". What is the relevance, if any, of such a difference in terminology?***

53. Argentina points out the conceivable shades of meaning that might differentiate "area" and "region," but Argentina does not indicate that any of these potential shades of meaning are relevant to any issue in this dispute.

53. (To Both Parties) ***Given the requirement in Article 6.1 of the SPS Agreement that Members "take into account … appropriate criteria or guidelines … developed by the relevant international organizations", what is the relevance of disease statuses attributed by the OIE, in particular with respect to Patagonia?***

54. The United States refers to the discussions in Part II.B.4.b, Part II.D.2, Part II.E and Part II.F with respect to the OIE disease designations. In joining the consensus with respect to any given designation, it cannot be implied that the United States necessarily accepts all "the underlying scientific evidence on which the OIE based its decisions, as well as the positive assessment of SENASA's capabilities."[186]

55. The disease designations are not "criteria" or "guidelines" as those terms are understood and as the United States elaborated upon in its answers to this question and in its prior submissions. Argentina, in its answers to this question, does not address the terms "criteria" or "guidelines."

54. (To Both Parties) ***What is the meaning, under the customary rules of interpretation of public international law, of the following terms in Article 6:***

a. "adapt to" in Article 6.1, first sentence?

b. "recognize" in Article 6.2, first sentence?

c. ***"based on" in Article 6.2, second sentence? Does the wording "based on" have the same meaning as it has, e.g., in Articles 3.1 and 5.1 of the SPS Agreement?***

56. Article 6.1, 6.2, and 6.3 should be read together, as the United States discusses in its answer to the Panel's Question 49. "Adapt to" in Article 6.1 must be seen as part of a dynamic process of adjusting an importing Member's measures to the condition of an area in the exporting Member's territory. Argentina's answer fails to take the larger context of Article 6 into account. In this dispute, the United States is following a procedure in which scientific evidence concerning the nature of Argentina's disease status is being evaluated for the purpose of adapting the measures of the United States.

[186] Argentina's Response to Panel Question No. 53, para. 203.

57. Argentina's response to Question 54(b) is to assert that the United States did not recognize Patagonia as a disease free region *as applied*, while acknowledging that the United States does recognize the concept *as such*. Argentina misreads the full text of Article 6.2. This article states that it is the "concept" that is "recognize[d]." A "concept" is "an idea of a class of objects, a general notion; a theme, a design."[187] The United States, at the time of establishment, did recognize that the concept of disease free status could apply to Patagonia. The plain terms of Article 6.2 provide that the obligation to "recognize" the concept of a disease free area is different than the obligation to "recognize" a disease free area.

58. Argentina argues that "based on" in Article 6.2 should be seen as "whether the measures . . . adequately address how the measures themselves are related to such factors."[188] It is not clear what this means. Argentina also does not show how its understanding is a definition of the term "based on" in the ordinary sense of the words. The United States believes that the ordinary meaning should be used, and that is the meaning referred to in *EC – Hormones*. The United States also observes that "based on" in Article 6.2 is followed by the phrase "such as," which connotes that the list that follows is illustrative and not exhaustive.

VIII. WHETHER THE UNITED STATES' REVIEW OF ARGENTINA'S APPLICATIONS INCURRED UNDUE DELAYS (ARTICLE 8 AND ANNEX C(1) OF THE SPS AGREEMENT)

55. (To Both Parties) *Can the obligation to transmit the results of the procedure under Annex C(1)(b) of the SPS Agreement be triggered in cases where there are no final results?*

59. In its response to Question 55, Argentina recognizes that the Panel in *EC – Approval and Marketing of Biotech Products* provided a clear answer to this question: that is, "the Panel did not find a violation of the third obligation in Annex C(1)(b) [to transmit final results] stating that there were no final results which could have been communicated."[189] Argentina attempts to distinguish the findings from this dispute, but without avail.

60. Similar to the importing Member in *EC – Approval and Marketing of Biotech Products*, the United States could not have communicated final results to Argentina because no final results existed. Argentina argues that APHIS "should have come to a decision on Argentina's applications", yet that is an argument about undue delay under Article C(1)(a), and does not in any way fit with the text of Article C(1)(b)..[190] In short, Argentina cannot overcome the the indisputable fact that the United States has not concluded its process and has not obtained results that could be communicated.

---

[187] U.S. Response to Panel Question No. 54(b), para. 227.

[188] Argentina's Response to Panel Question No. 54, para. 207.

[189] Argentina's Response to Panel Question No. 55, para. 214.

[190] Argentina's Response to Panel Question No. 55, para. 214.

56. (To Both Parties) ***Can statements in the SPS Committee in response to questions from the exporting Member satisfy the obligation to communicate the stage of the procedure under Annex C(1)(b) of the SPS Agreement?***

61. The United States addresses Argentina's argument in the United States' response to this question.[191] In addition, the United States notes that when it needed Argentina to correct or supplement its applications, it promptly communicated that need to Argentina.[192]

57. (To Both Parties) ***Assuming, arguendo, that the US measures are consistent with Article 8 and Annex C(1)(a), what would be the impact on Argentina's other claims, in particular its claims under Articles 2 and 5 of the SPS Agreement? What would be the implications of a finding that the US measures are inconsistent with Article 8 and Annex C(1)(a) and/or not justified by Article 5.7?***

62. The United States addresses Argentina's argument in the United States' response to this question.[193]

58. (To Both Parties) ***The United States' argues that determinations involving disease-free areas fall outside the scope of Article 8 and Annex C of the SPS Agreement.***[194]

a. ***Please discuss the types of measures falling within the purview of Annex C(1) and Article 8 and whether there is any difference in the scope of coverage between the two. In your answers, please consider the language in Annex C(1): "Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that …".***

63. The United States addresses Argentina's argument at Part II.C.1.a of its second submission.

b. ***Can an assessment of the risk be considered an "approval procedure" for the purposes of Annex C of the SPS Agreement?***

64. In addition to its response to this question, the United States acknowledges, as Argentina has pointed out, that the Panel and Appellate Body in *Australia – Apples* considered this question. Notably, neither made a determination on this question. The Appellate Body understood that Annex C(1)(a) and Article 8 establish obligations for specific procedures.[195] These procedures are control, inspection and approval procedures. In this dispute, the procedures associated with conducting a risk assessment associated with a claim of disease-free

[191] U.S. Response to Panel Question No. 56, paras. 232-235.

[192] Exhibit USA-102.

[193] U.S. Response to Panel Question No. 57, paras. 236 – 241.

[194] *See* U.S. First Written Submission, paras. 177-187.

[195] *Australia – Apples (AB)*, para. 438.

status. Therefore, as the United States has observed, the relevant procedures at the center of this dispute do not fall within the scope of Annex C.[196]

59. (To Both Parties) ***Are the time-periods that other Members have taken to complete a similar approval process for Argentina relevant for the purposes of the Panel's determination as to whether the time-period required for the completion of APHIS' rulemaking process is undue? What is the relevance of the fact that Chile and the European Union reopened their markets to Argentine fresh (chilled or frozen) beef, respectively, after six months since the last FMD outbreak and in 2002?***

65. The United States addresses Argentina's argument at Part II.C.2.a of its second submission.

68. (To Argentina) ***On what date(s) should the Panel centre its analysis of whether the delay in the United States' review of Argentina's applications was "undue"? For instance, should the relevant period of time be considered to start in 2002/2003 (i.e., the dates of the filing of Argentina's requests), in 2006 (i.e., the date of the last FMD outbreak in Argentina), in 2009 (i.e., the date of the extension of Argentina's request for Patagonia to Patagonia North B), or on a different date?***

66. The United States addresses Argentina's argument at Part II.C.2 of its second submission.

69. ***The United States argues that, at the time of APHIS' site visit to Patagonia in February 2009, "the revisions introduced under Resolution No. 1282 had not been completely implemented".[197]***

a. **(To Argentina) –** ***Please explain when the revisions in question were fully implemented, and what impact such revisions had on transport restrictions between Patagonia South and Patagonia North B before and after APHIS' site visit.***

67. Argentina provides a communication dated April 27, 2009 from APHIS, which stated that, at the time, APHIS did not need additional information with regard to the Patagonia request. This communication does not support Argentina's contention that Resolution No. 1282 was fully implemented when the United States conducted its site visit in February 2009. As the United States has indicated, the Resolution had not fully been implemented during its site visit,[198] and Argentina offers no proof to the contrary.

IX. SPECIAL AND DIFFERENTIAL TREATMENT (ARTICLE 10.1 OF THE SPS AGREEMENT)

[196] U.S. Response to Panel Question No. 58(b), para. 245.

[197] U.S. First Written Submission, para. 161.

[198] U.S. First Written Submission, para. 161

70. (To Argentina) ***With respect to the Article 10.1 claim, Argentina's Panel Request refers to the application of the United States' "sanitary measures" without making reference to any of the specific legal instruments listed earlier in the document. Please indicate how this claim relates to the specific measures Argentina identified in its Panel Request.***

68. The United States notes that with respect to its Article 10.1 claim, in its Panel Request, Argentina did not make *any* reference to *any* of the specific legal instruments.

71. (To Both Parties) ***Please provide the Panel with your views on the interpretation of the term "special needs" in Article 10.1 of the SPS Agreement. In your answer, make reference to the customary rules of interpretation of public international law as well as any relevant jurisprudence from other panels or the Appellate Body examining the same or similar provisions. Also, please discuss whether Article 10.2 constitutes relevant context for the interpretation of Article 10.1.***

69. The United States addresses Argentina's argument in its response to this question.[199] It is important to note that Argentina has not identified any allegedly special needs.

72. (To Both Parties) ***Is the requirement to "take account of the special needs of developing countries" a requirement to take account of developing countries' special needs as a group or take account of the special needs of each individual developing country?***

70. The United States notes that Argentina's response does not address the question.

73. (To Argentina) ***Argentina argues that "[d]eveloping country Members should be given priority and support for risk assessments and rulemakings".[200] Is this what Argentina considers to be the content of the obligation in Article 10.1? Please explain how your answer takes into account the reasoning of the panel in EC – Approval and Marketing of Biotech Products at paragraphs 7.1618-7.1626?***

71. The United States addresses the Panel's reasoning in *EC – Biotech* and Argentina's argument in response to Question 71.[201] Argentina urges the Panel to disregard the reasoning of the Panel in *EC – Biotech*, and to apply the reasoning of the Appellate Body in *China – GOES*.[202] However, Argentina neglects to acknowledge that that the Panel's reasoning in *EC – Biotech* is in fact directly applicable to the current dispute. In *China – GOES*, the Appellate Body did not interpret "special needs" or apply its reasoning to Article 10 of the SPS Agreement. Thus, contrary to Argentina's contention, the Panel's reasoning in *EC – Biotech* is not "simply

[199] U.S. Response to Panel Question No. 71, paras. 281-282.

[200] Argentina's First Written Submission, para. 359.

[201] U.S. Response to Panel Question No. 71, paras. 281-282.

[202] Argentina's Response to Panel Question No. 73, para. 261.

incorrect"[203]; the reasoning is logical, well founded in the text of the agreement, and directly applicable to the interpretation of Article 10.1 of the SPS Agreement.

74. (To Argentina) ***What "special needs" related to Argentina's developing country status did the United States not take account of?***

72. Argentina asserts that "the "special needs" in this case relate primarily to having full access and priority in the regulatory process that would allow importation of a product of interest to Argentina (*i.e.* beef), as compared to the speed and access that the U.S. granted to applications of developed country Members, as well as veterinary support."[204] This, however, is not a "special need" in the terms of Article 10.1. Rather, it is just a statement of Argentina's trade interest in obtaining a re-authorization to ship beef to the United States. Any Member that applied to APHIS would have the same interests.

73. Argentina also identifies developed countries that have been recognized by APHIS as FMD-free to imply that the United States offers preferential treatment to developed country Members. This contention does not support a claim of "special needs," nor does the record support Argentina's contentions.

74. As the United States has observed, in addition to Uruguay and Brazil, there are many other developing country Members that have obtained APHIS import authorization and/or designation as FMD-free.[205] These developed country Members, whom are at or below Argentina's GDP or GNI level, include Belize, Dominican Republic, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Namibia and Nicaragua.[206]

75. Argentina also identifies as a special need the provision of sanitary support to address compliance concerns.[207] However, throughout the regulatory process, Argentina has never identified a need for "sanitary support to . . . address any compliance concerns" or "financial assistance",[208] and Argentina points to no record evidence to the contrary. The United States does note, nonetheless, that APHIS has worked closely with SENASA throughout the evaluation process. ,[209]

X. GATT 1994

[203] Argentina's Response to Panel Question No. 73, para. 261.

[204] Argentina's Response to Panel Question No. 74, para. 264.

[205] U.S. First Written Submission, para. 363.

[206] U.S. First Written Submission, para. 363

[207] Argentina's First Written Submission, para. 269.

[208] Argentina's First Written Submission, para. 269.

[209] Exhibit USA-78.

80. (To Both Parties) ***The European Union argues that any inconsistency with the SPS Agreement should not automatically preclude the application of Article XX(b) of the GATT 1994 in relation to the claims brought against the same measures under the GATT 1994.[210] Please comment on this argument and on its systemic implications.***

76. In its response to this question, the United States noted the systematic implications of the position advanced in the European Union's Third Party Submission.[211] Article 2.4 explains that measures be found consistent with the relevant provisions of the SPS Agreement must be presumed consistent with Article XX(b) of the GATT 1994. Because the measures at issue here are consistent with the relevant provisions of the SPS Agreement[212], the measures are presumed necessary to protect animal life and health under Article XX(b) of the GATT 1994.

77. In its response, Argentina cites the panel report in *US – Poultry (China)* to assert that the interpretive relationship between the SPS Agreement and the GATT 1994 requires a logical conclusion that is simply not accurate. Argentina relies on *US – Poultry (China)* in drawing a conclusion that a finding of inconsistency with Articles 2 and 5 of the SPS Agreement automatically precludes the application of Article XX(b).[213] However, Argentina fails to recognize the inherent differences between the provisions, notably that Article 5 requires a risk assessment, and Article XX(b) has no such requirement. Nothing in the SPS Agreement or the GATT 1994 requires the "logical conclusion" Argentina has introduced.

[210] EU's Third Party Submission, para. 85.

[211] U.S. Responses to Panel Question No. 80, paras. 299- 300.

[212] Notably, Article 2 and 5 of the SPS Agreement.

[213] Argentina's Response to Panel Question No. 80, paras. 295-296.