UNITED STATES – MEASURES AFFECTING THE IMPORTATION

OF ANIMALS, MEAT AND OTHER ANIMAL PRODUCTS

FROM ARGENTINA

(DS447)

COMMENTS OF THE UNITED STATES ON THE RESPONSES OF ARGENTINA TO THE PANEL'S QUESTIONS AND U.S. QUESTIONS FOLLOWING THE SECOND PANEL MEETING

October 24, 2014

TABLE OF REPORTS

SHORT FORM	FULL FORM
EC – Approval and Marketing of Biotech Products (Panel)	Panel Report, *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, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998
EC – IT Products (Panel)	Panel Report, *European Communities and Its Member States – Tariff Treatment of Certain Information Technology Products*, WT/DS375/R, WT/DS376/R, WT/DS377/R, adopted 21 September 2010
EC – Selected Customs Matters (AB)	Appellate Body Report, *European Communities – Selected Customs Matter*, WT/DS315/AB/R, adopted 11 December 2006
EC and certain member States – Large Civil Aircraft (AB)	Appellate Body Report, *European Communities and Certain Member States – Measures Affecting Trade in Large Civil Aircraft*, WT/DS316/AB/R, adopted 1 June 2011
US – Cotton Yarn (AB)	Appellate Body Report, *United States – Transitional Safeguard Measure on Combed Cotton Yarn from Pakistan*, WT/DS192/AB/R, adopted 5 November 2001

GENERAL:

1. The United States appreciates the opportunity to comment on the responses of Argentina to the questions of the Panel and the United States following the second meeting of the Panel. Many of the points that Argentina raises have been addressed by the United States in its prior written and oral submissions, or are not relevant to the Panel's resolution of this dispute. Accordingly, in the comments below, the United States focuses principally on points or statements that have not been addressed in prior U.S. submissions. The absence of a U.S. comment on any aspect of Argentina's response to any particular question should not be understood as agreement with Argentina's response.

2. Two key issues in this dispute were made clear through the questions and answers at and following the second Panel meeting.

3. First, Argentina now appears to agree with the United States in part on how the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement") should operate when claims of disease-freedom (or low disease prevalence) are raised by an exporting Member. In particular, Argentina states: "[W]hen an exporting Member applies for import authorization, a process begins during which the exporting Member provides information, including permitting reasonable access to the exporting Member's territory. Only after all these initiatives on the part of the exporting Member, is the importing Member obligated to move forward and prepare a risk assessment."[1]

4. Argentina's agreement with the United States makes sense: an importing Member must have a reasonable period of time and access to the exporting Member in order to make an assessment of the internal controls and the disease status of the exporting Member. This is precisely the process that the United States has articulated in its submissions and at the meetings with the Panel. Although Argentina now agrees with the process, it presents no viable, text based interpretation that leads to this result. In contrast, the United States has provided a clear framework based on the text of Articles 2.2, 5.1, 5.7 and 6.3 of the SPS Agreement.

5. Second, disease status designations by the World Organisation for Animal Health ("OIE") are not "standards, guidelines and recommendations" for purposes of Article 3 of the SPS Agreement. As the OIE and the scientific experts themselves described, the OIE disease status designations are the product of a review of a paper application by the OIE. Members do not know when an application for disease free status is made, and they cannot review the underlying work papers. The OIE typically does not conduct any on-site verification of the application. OIE disease status designations are not risk assessments, nor do they take into account any country-specific factors related to the importing Member.

6. Despite this, Argentina persists, for purposes of this dispute, in claiming that OIE designations are "standards, guidelines and recommendations" for the purpose of Article 3 of the SPS Agreement. Argentina maintains its non-viable and unworkable position, even when it does not itself treat OIE designations as standards, as highlighted by Argentina's decision not to

[1] Argentina's Response to Panel Question No. 25 Following the Second Substantive Meeting of the Panel, para. 78.

answer the U.S. question whether Argentina treats as international standards the OIE's Bovine Spongiform Encephalopathy ("BSE") designations.

3 WHETHER THE US MEASURES ARE MAINTAINED WITH SUFFICIENT EVIDENCE (ARTICLES 2.2, 5.1, 5.2, AND 5.7 OF THE SPS AGREEMENT)

Question 18: In its first opening statement, the United States argues that from the moment Argentina filed its applications for approval of imports of FMD-susceptible products, the pre-existing ban on such products "can be viewed as provisional until additional necessary information is gathered to accept or reject the application[s]", thereby falling within the purview of Article 5.7.

(b) Please provide your interpretation of the terms "provisionally" and "adopt" according to the customary rules of interpretation of public international law.

U.S. COMMENT ON ARGENTINA'S RESPONSE:

7. Throughout this dispute, the United States has presented a proper analysis of Article 5.7 of the SPS Agreement, including the word "adopt," under the applicable rules of interpretation of public international law, as reflected in Article 31 of the Vienna Convention on the Law of Treaties. The United States recalls that under those rules, the SPS Agreement is to be interpreted in good faith, in accordance with the ordinary meaning to be given to the terms of the SPS Agreement **in their context**, and **in the light of the object and purpose of the SPS Agreement**. The United States has explained that under these rules of interpretation, Article 5.7 is properly interpreted to apply to the maintenance of a pre-existing measure where changing circumstances call for a re-evaluation of the measure, and where the Member undertakes the process of re-evaluation.

8. In contrast, Argentina has not conducted the analysis called for under the Vienna Convention. Instead, Argentina has relied only on dictionary definitions of "adopt." In this regard, Argentina's answer to Question 18 is interesting. Argentina first (as it has done before) cites a dictionary definition of "adopt." But – perhaps in reaction to the uncontroverted fact that the U.S. Animal and Plant Health Inspection Service ("APHIS") did in fact undertake actions in response to Argentina's 2002 re-application – Argentina then asks the Panel **not** to apply Argentina's own definition in a formalistic way. In particular, Argentina states that "adopt" means "some decision-making beyond merely a mechanical filing confirmation or date-stamp."[2] The United States, of course, agrees with Argentina that a proper interpretive approach cannot stop with formalistic application of dictionary definitions. However, once one does engage in the full interpretative analysis, one cannot reach the result proposed by Argentina.

9. With these introductory comments in mind, the United States will address each of the sub-arguments in Argentina's response to Question 18.

[2] Argentina's Response to Panel Question No.18 Following the Second Substantive Meeting of the Panel, para. 38 (emphasis supplied).

10. First, with regard to facts, the evidentiary record demonstrates that APHIS took the position that the prohibition on Argentina's product would be provisional pending the review of its application. In fact, APHIS actions to this date, including the multiple site visits to Argentina, significant correspondence with SENASA, and issuance of risk analyses for Patagonia and Northern Argentina, go far beyond merely "filing confirmation" or "date stamp" upon receipt of Argentina's application.

11. APHIS followed the well-established procedures laid out in the document "Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking."[3] This process begins with the submission of the exporting Member's application, together with the collection and review of data by APHIS. The prohibition on the exporting Member's product is deemed provisional pending the final determination by APHIS.[4]

12. Second, with regard to Argentina's citations to findings in other disputes, those findings do not support Argentina's interpretation. First, it refers to the panel report in *EC – IT Products*. That dispute concerned an interpretation of the term "made effective" and not the word "adopt," which is not contained in the provision of Article X:1 of the *General Agreement on Tariffs and Trade 1994* ("GATT 1994"). It is not clear what Argentina's point is in referring to this dispute nor its relevance for understanding the function of the term "adopt" in Article 5.7 of the SPS Agreement.

13. Third, Argentina refers to the use of the word "adopt" by APHIS in a final rule concerning mangoes from Jamaica. This reference does not support Argentina's position. Rather, Argentina appears to be randomly searching for the term "adopt," out of context and without reasonably considering how its definition is consonant with the SPS Agreement.

14. To be clear, the United States is not taking the position that "adoption" could not include formal promulgation of a law or regulation. However, the definition of the word "adopt" is not necessarily confined to the formal promulgation of a law or regulation. This interpretation, as discussed in the U.S. answer to this question, is consonant with the relationship between Article 5.7 and Article 2.2's language regarding "maintained" measures.

15. Finally, with respect to the definition of the word "provisionally," the United States and Argentina for the most part agree. The United States has maintained from the beginning of this dispute that its prohibition on imports from Argentina is provisional, pending the completion of the APHIS process. Argentina is not correct in its assertion that the length of time that a measure is maintained in this dispute is *prima facie* evidence that a measure is "no longer 'provisional.'"[5] With respect to this dispute, the issue is whether the time taken to collect and review information to conduct a risk assessment was done "within a reasonable period of time." What is considered to be a "reasonable period of time" depends on the specific facts of each case.

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[3] Exhibit USA-74.

[4] For example, Dr. Clifford's letter to Dr. Amaya, dated September 24, 2010, communicates this message. APHIS informed SENASA that it is currently working on the application and that access cannot be allowed until the decisionmaking process is complete. (Exhibit ARG-47).

[5] Argentina's Response to Panel Question No. 18 Following the Second Substantive Meeting of the Panel, para. 40.

Question 24: In its second written submission, the United States argues for its interpretation of Article 5.7 because, otherwise, all Members would be in breach of Article 5.1 as soon as a change in the relevant science occurs, even if they did not have an opportunity to collect information, review it, and revise their measures accordingly.

(a) Do you consider that Article 5.1 provides time for a Member to conduct a risk assessment and, therefore, every Member would be in breach as soon as new science which requires updating a risk assessment comes to light? If so, where in the text of the provision does such flexibility reside?

(b) Are there any other provisions of the SPS Agreement that might cover this time-period needed to conduct a risk assessment?

U.S. COMMENT ON ARGENTINA'S RESPONSE:

16. Argentina's answer to Question 24 (as well as Question 25) confirms that Argentina now agrees with one of the fundamental U.S. positions in this dispute: Under a proper interpretation of the SPS Agreement, it is not inconsistent with the SPS Agreement for an importing Member to conduct a collection and review of information with respect to an exporting Member's application to export, and for the importing Member to prohibit importation pending that collection, review, and final decision on the application.

17. In this regard, Argentina states that:

(a) "[i]f the importing Member considers that the facts underlying its initial risk assessment remain valid, then it is not under an obligation to change them until it is presented with facts reasonably construed to the contrary";[6]

(b) the "issue of timing in regard to conducting risk assessments" should be evaluated under a framework of "reasonableness";[7]

(c) the "requirement for a risk assessment to be 'appropriate to the circumstances' provides for a certain degree of flexibility."[8]

(d) it is the burden of initiative of the exporting Member to bring this new information to the attention of the importing Member;[9] and

[6] Argentina's Response to Panel Question No. 24 Following the Second Substantive Meeting of the Panel, para. 47.
[7] Argentina's Response to Panel Question No. 24 Following the Second Substantive Meeting of the Panel, paras. 60-61.
[8] Argentina's Response to Panel Question No. 24 Following the Second Substantive Meeting of the Panel, para. 61.
[9] Argentina's Response to Panel Question No. 25 Following the Second Substantive Meeting of the Panel, para. 76.

(e) this approach regarding the burden of initiative is consistent with the "risk assessment techniques" of the OIE, particularly the fact that "the OIE only conducts a disease status review upon a request from a Member."[10]

18. These conclusions in (a)-(e) are consistent with the U.S. interpretation of Articles 2.2, 5.1, 5.7, and 6.3 of the SPS Agreement. With respect to import restrictions related to FMD, the United States has explained that it is the burden of the exporting Member to provide information as to its disease status, and then the importing Member is allowed a reasonable period of time within which to conduct an assessment of the risk. And with respect to Argentina's point (e) above, the United States stated in its first written submission exactly this point: the U.S. system is fundamentally based on the same approach as the OIE.[11] Where the disputing parties do disagree, of course, is how these conclusions can be supported under the text of the SPS Agreement.

19. The U.S. view is grounded in the text of Articles 2.2, 5.1, 5.7, and 6.3 of the SPS Agreement. Article 2.2 states that a measure shall "not [be] maintained without sufficient scientific evidence, except as provided for in [Article 5.7]." Accordingly, when an exporting Member says that circumstances have changed and that it is now disease free, it is making a claim that the scientific evidence is not sufficient to maintain the existing measure. The importing Member, in reviewing this claim, needs to validate the new claim based on scientific evidence that it does not fully have. Under Article 5.7, the importing Member "provisionally adopts" a measure to prohibit the importation pending the completion of a risk assessment based on the new data in accordance with Article 5.1. Under Article 5.7, the importing Member "seek[s] to obtain the additional information and review the [SPS] measure accordingly within a reasonable period of time." Article 6.3 supports this interpretation because it recognizes that when an exporting Member claims it is disease free, the exporting Member shall provide "reasonable access . . . to the importing Member for inspection, testing and other relevant procedures."

20. Argentina's view does not integrate the different relevant provisions of the SPS Agreement as a whole. Instead, Argentina pins its entire interpretation on five words in Article 5.1: "as appropriate to the circumstances."[12] From these five words arises "flexibility" and "reasonableness."[13] Argentina's argument is flawed for at least two reasons.

21. First, the phrase "as appropriate to the circumstances" modifies "assessment". That is, the phrase suggests that the nature of the "assessment" upon which the SPS measure is based may vary depending on the circumstances. It does not, as Argentina appears to consider, suggest that the measure would *not* need to be based on an assessment of some sort whenever circumstances make that "appropriate."

22. Second, Argentina does not put forward any standard based in the text that might apply to demarcate the boundaries of flexibility and reasonableness. Instead, Argentina asks the Panel to

[10] Argentina's Response to Panel Question No. 24 Following the Second Substantive Meeting of the Panel, para. 64.
[11] U.S. First Written Submission, paras. 321-337.
[12] Argentina's Response to Panel Question No. 24 Following the Second Substantive Meeting of the Panel, para. 70.
[13] Argentina's Response to Panel Question No. 24 Following the Second Substantive Meeting of the Panel, para. 71.

look outside the Agreement and to follow the OIE. Argentina's structure is standardless: according to Argentina, the importing Member's actions should be judged flexibly and reasonably. The U.S. view is founded on several provisions of the Agreement that already have established standards and limits. In the U.S. view, an important limit to the application of the provisional measure is the need for the importing Member to conduct the data collection and review "within a reasonable period of time" of Article 5.7.

23. Further, the United States does not agree with Argentina's assertions regarding the appropriate time frames for the risk assessment. Argentina argues that the baseline timeframe should be derived from the OIE designation process. First, contrary to Argentina's response, the OIE's review of disease status is not a risk assessment. The OIE said: "[T]he [OIE's] FMD assessment is not so much an import risk analysis[.]"[14] Dr. Bonbon specifically stated: "[W]e cannot compare the analysis and evaluation of the status by the OIE and the risk assessment – these are two different things."[15] Second, the OIE does not have any specific guidance or timeframe within which it issues its decisions on disease status designation.[16] Moreover, because the OIE does not conduct a risk assessment, its time frames are not a relevant standard for comparison.

24. With respect to the amount of time that APHIS spent reviewing the import applications of other Members, Argentina has not shown how these other countries are comparable to Argentina. Neither the OIE nor the scientific experts stated that there was any standard time period for which a risk assessment with respect to FMD should be completed.[17] With respect to applications of the United Kingdom and Japan, the United States refers to its comments on Argentina's answer to Question 35.

25. With respect to Uruguay and Santa Catarina, the scientific experts did not reach any conclusion as to whether the APHIS time for review of Patagonia and Northern Argentina should have been the same as that for Santa Catarina and Uruguay. First, the experts were not asked that question and so there is no answer. Second, the question they were asked, namely, "is there any evidence on the record explaining the difference in the time it took APHIS to conclude the risk assessments for Patagonia and for Santa Catarina (Brazil)?" resulted in inconclusive answers. For example, Dr. Cupit stated: "There is no specific information in the exhibits that indicates the time needed to undertake the risk assessments conducted by the United States in either circumstance."[18] Dr. Bonbon recounted the history of the Patagonia application process

[14] Transcript of the meeting with the Experts, para. 1.107.
[15] Transcript of the meeting with the Experts, para. 1.327.
[16] OIE's Response to Panel Question No. 13g.
[17] Panel Question No. 47 to the individual experts asked about waiting periods before which an assessment could occur. The experts did not agree that there was any typical period. In response, Dr. Cupit said: "In practice these minimum periods are difficult to meet because of the number and complexity of tasks that need to be undertaken." (para. 391). Dr. Batho said: "I am not aware of a scientifically recommended waiting period following an FMD outbreak sufficient to provide the minimum amount of epidemiological information." (para. 395). Dr. Bonbon stated: "This depends on the type of emergency control measures applied . . . ." (para. 396).
[18] Individual Experts' Responses to Panel Question No. 59, para. 475.

and that of Santa Catarina, but provided no analysis or conclusion.[19] Dr. Batho recounted the Patagonia application and made an unsupported conclusory observation about the time period.[20]

26. In sum, Argentina has moved substantially from its original position and now agrees in principle with the U.S. position that in reviewing an exporting Member's application for import authorization with respect to FMD, it is consistent with the SPS Agreement for that importing Member to maintain a prohibition on the product pending collection, review, and analysis of the relevant scientific data provided by the exporting Member. As the United States has explained, that period for collection, review, and analysis is subject to the reasonable period of time requirement under Article 5.7.

Question 25: In its second written submission, Argentina argues that Article 6.3 cannot be relevant to the interpretation of Article 5.7 because Article 5.7 places the burden of seeking additional information on the importing Member, whereas Article 6.3 places the burden of objectively demonstrating disease-freedom or low disease prevalence on the exporting Member. Argentina adds that Article 6.3 is only legally relevant to the interpretation of Article 5.1. Please explain why the issue of the shifting of the burden of proof from the importing to the exporting Member would not arise in the context of Article 5.1.

U.S. COMMENT ON ARGENTINA'S RESPONSE:

27. As noted in the U.S. comment on Argentina's answer to Question 24, Argentina now agrees with the view of the United States in connection with the process by which an importing Member and exporting Member would handle a situation of changed circumstances in a claim of disease free status.

28. Argentina states:

(a) "[It] bore 'the burden of initiative' in connection with a Member's request for market access[.]"[21]

(b) "[I]t makes sense that the Member applying for import authorization supplies the information [regarding its application] and then the measure follows the supplying and analyzing of such scientific evidence."[22]

(c) "[W]hen an exporting Member applies for import authorization, a process begins during which the exporting Member provides information, including permitting reasonable access to the exporting Member's territory. Only after all these initiatives on the part of the exporting Member, is the importing Member obligated to move forward and prepare a risk assessment."[23]

[19] Individual Experts' Responses to Panel Question No. 59, paras. 478-481.
[20] Individual Experts' Responses to Panel Question No. 59, paras. 476-477.
[21] Argentina's Response to Panel Question No. 25 Following the Second Substantive Meeting of the Panel, para. 79.
[22] Argentina's Response to Panel Question No. 25 Following the Second Substantive Meeting of the Panel, para. 76.
[23] Argentina's Response to Panel Question No. 25 Following the Second Substantive Meeting of the Panel, para. 78.

29. *A fortiori*, in Argentina's own view, the importing Member could prohibit the entry of the exporting Member's product pending the conclusion of the review process.

30. Argentina also allows the importing Member reasonable time for the importing Member's review of the exporting Member's information: "[R]easonableness applies generally to the risk assessment process and, *while it implicitly encompasses the time frames*, it extends further than that."[24] In sum, Argentina's complaint is one of *timeliness*, which the United States has pointed out from the beginning of this dispute.

31. As noted, it appears that Argentina now only disputes which articles of the SPS Agreement are the basis for this view. The United States has described at length in its many submissions why the appropriate legal basis for its view is under Article 5.7. In the end, Argentina's theory would require the Panel to reach beyond the text of the Agreement to principles such as "reasonableness." There is no need to do so when Article 5.7 already provides a clear standard and rationale.

6 WHETHER THE US MEASURES ARBITRARILY OR UNJUSTIFIABLY DISCRIMINATE BETWEEN COUNTRIES WHERE IDENTICAL OR SIMILAR CONDITIONS PREVAIL (ARTICLE 2.3 OF THE SPS AGREEMENT)

Question 35: As part of your claims of under Article 2.3, you indicate that the substantive FMD situations of Argentina, on the one hand, and the United Kingdom and Japan, on the other, are not identical. Please explain what the "identical or similar conditions" prevailing in Argentina, the United Kingdom, and Japan are for the purposes of your claims.

U.S. COMMENT ON ARGENTINA'S RESPONSE:

32. Argentina's arguments with respect to Article 2.3 should be rejected. First, Argentina has not – as Argentina alleges – been denied "regulatory access." APHIS and SENASA have had substantial interaction and exchange in the course of review and examination of Argentina's applications for import authorization. Thus, this characterization of "lack of regulatory access" should be rejected.

33. Second, Argentina argues that each and every element of the APHIS re-evaluation – including overall time periods – must be exactly the same as the APHIS re-evaluation of Japan and the United Kingdom – just because all three Members at one time had a certain FMD status, and then experienced an FMD outbreak.

34. This reasoning is incomplete and flawed. The basic problem with Argentina's response to Question 35 can be illustrated by this simple example: Two different automobiles have mechanical difficulties and are broken down. One is repaired in two weeks, while the other is repaired in two months. Is the difference in repair times a product of discrimination? In this analogy, Argentina has simply said the repair times are different, even though both cars are

[24] Argentina's Response to Panel Question No. 24 Following the Second Substantive Meeting of the Panel, para. 61.

broken down, and therefore there is discrimination. But it has not shown at a minimum whether the cars are the same or similar, whether they were broken for the same or similar reason, and whether the appropriate repair process was the same or similar. It simply points to time and the broken car and conclude discrimination has occurred. This simplistic, misleading approach cannot sustain a finding under Article 2.3.

35. Furthermore, even the factual predicate of Argentina's flawed approach – that Argentina's situation is the same as that of Japan and the United Kingdom – cannot be established. Argentina admits that its "substantive situation" is not identical to that of Japan or the United Kingdom.[25] It recognizes that "[n]either of these countries currently practices vaccination[.]"[26] The problem with Argentina's argument is that the substantive differences between the countries matter for purposes of reviewing the FMD disease status of a country or region. For example, differences and changes in sanitary regulations and laws; changing scope of applications for import authorization; veterinary response structure; and ongoing vaccination practices (as opposed to vaccination for outbreak control) are all relevant for assessing the presence and likelihood of FMD. The scientific experts agreed.[27] Argentina has not analyzed, let alone put in the record, enough evidence to show that these differences are irrelevant for purposes of "procedural" or "substantive" discrimination under Article 2.3.

36. For these reasons, Argentina's claim should be rejected.

7 THE DETERMINATION OF THE US ALOP (ARTICLE 5.4 OF THE SPS AGREEMENT)

Question 38: In its second written submission, Argentina asserts that a Member is required to have a "properly enunciated and non-trade restricting ALOP", and that the United States "should have adopted an ALOP which minimizes negative trade effects". Is Argentina arguing that this is the content of the obligation in Article 5.4? If so, please explain how you find this obligation through an interpretation of the text of Article 5.4 (speaking to the obligation to "take into account the objective of minimizing negative trade effects") under the customary rules of interpretation of public international law.

U.S. COMMENT ON ARGENTINA'S RESPONSE:

37. Argentina's answer to the Panel's question is, in essence, "no." It says: "The plain language of Article 5.4 is not explicit as to how the objective of minimizing trade effects is to be taken into account or what ALOP determination must be made by a Member."

38. Argentina nonetheless maintains its position that the U.S. measures are somehow inconsistent with Article 5.4. As the United States has consistently stated in this dispute, the text

[25] Argentina's First Written Submission, para. 344.
[26] Argentina's First Written Submission, para. 343.
[27] *See, e.g.*, Individual Experts' Responses to Panel Questions, paras. 402-406 (regarding legislative or regulatory changes); paras. 124-135 (egarding risks related to vaccination); paras. 216-225, 441-445 (regarding elements of FMD surveillance).

of Article 5.4 provides that a Member "should . . . take into account" the objective of minimizing negative trade effects. It agrees with the finding in *EC – Hormones* that the use of the verb "should" expresses exhortation and not obligation. Argentina continues to fail to explain any flaw in the approach of that panel.[28]

39. Argentina then states that the prohibition on Argentina's beef is "*as if* the United States has created a unique ALOP of zero risk for FMD," which Argentina claims is inconsistent with Article 5.4. This position is directly contrary to its position in its answer to Question 24 and Question 25. In those responses, Argentina accepts that in this dispute an importing Member can take a reasonable period of time to conduct a risk assessment before deciding upon an exporting Member's application for import authorization. In fact, Argentina's complaint is not about the appropriate level of protection ("ALOP") of the United States, but that it thinks that the time taken to review and decide upon its applications is not reasonable. These are two distinct concepts, and it is inappropriate to turn a complaint about timeliness into one about an importing Member's ALOP.

40. In fact, the United States has consistently expressed its appropriate level of protection with respect to the importation of FMD-susceptible products into the United States: Imports of FMD-susceptible animals and animal products into the United States must be safe, meaning they must not introduce into or disseminate within the United States the FMD virus. The United States has taken into account the objective of minimizing negative trade effects in determining this ALOP, for example, as demonstrated in its approach to regionalization and in permitting imports with certain mitigating conditions from a number of other Members.[29]

8 WHETHER THE US MEASURES ARE MORE RESTRICTIVE THAN REQUIRED TO ACHIEVE THE US ALOP (ARTICLE 5.6 OF THE SPS AGREEMENT)

Question 39: In *Japan – Agricultural Products II*, the Appellate Body interpreted Article 5.7 to be a qualified exemption from the obligation under Article 2.2 "not to maintain SPS measures without sufficient scientific evidence", and therefore from the obligations under Article 5.1. Further, in *Australia – Apples*, the Appellate Body has interpreted Article 5.6 as a specification of the obligation in Article 2.2 to apply SPS measures "only to the extent necessary to protect human, animal or plant life or health".

(a) In your views, does the "qualified exemption" of Article 5.7 extend to a Member's obligations under Article 5.6?

(b) Assuming, *arguendo*, that Article 5.7 does not apply to the US measures, does Article 5.6 provide for some flexibility in assessing the "necessity" of such measures in the situation where APHIS had not yet completed its risk assessments?

[28] U.S. Second Written Submission, Annex, paras. 42-43.
[29] APHIS has finalized a determination that Patagonia is FMD-free, and has issued a proposal to permit imports of beef from Northern Argentina under certain mitigating conditions.

U.S. COMMENT ON ARGENTINA'S RESPONSE:

41. Argentina's lengthy response concerning the term "measure" misses the forest for the trees. That is, Argentina fails to recognize how its theoretical discussion applies in the type of factual situation such as that presented in the current dispute. In a situation (such as present in the current dispute) in which there is insufficient scientific facts to conduct a risk assessment, the same factual insufficiency would hamper a Member from conducting the kind of assessment necessary to fulfill its Article 5.6 obligation. As the United States stated in its response to this question, it is the insufficiency of scientific facts that is central to the analysis. This would be the case regardless of whether Article 5.7 were to apply for any given reason.

9 REGIONALIZATION (ARTICLE 6 OF THE SPS AGREEMENT)

Question 41: In light of the definition of "area" in Annex A(6) and A(7) of the SPS Agreement, can Argentina's application for imports of fresh (chilled or frozen) beef be understood as a claim of FMD-freedom in Northern Argentina? If not, can it be understood as a claim of low FMD prevalence in Northern Argentina?

U.S. COMMENT ON ARGENTINA'S RESPONSE:

42. Argentina does not answer the Panel's question. Throughout this proceeding, Argentina has stated that Northern Argentina has been designated as a region that is "free of FMD."[30] It is basing this dispute, in part, on the significance of that designation. It has stated throughout its submissions that FMD is not present in Northern Argentina.[31] In its November 2002 application form to APHIS for import authorization, Argentina answered that it did not have FMD and that its last outbreak was January 23, 2002.[32] In its recent answer to Question 2, Argentina stated: "Argentina understands that [options to reduce transmission of FMDV] are applicable where there are infected animals. This is certainly not the case in Argentina, as it has been recognized as FMD free without vaccination in the Patagonia Region and FMD free with vaccination in Northern Argentina."[33]

43. Argentina incorrectly resorts to U.S. law, and in a misleading way, to state that APHIS has never treated its application as a claim of disease freedom or low disease prevalence. Regardless of Argentina's misrepresentation of U.S. law, the key point is that the relevant law here is the SPS Agreement and it is those definitions that control the application of Article 6 of the SPS Agreement. It is clear that for purposes of the SPS Agreement, Argentina is stating to the United States that Northern Argentina is either a pest- or disease-free area "in which a specific pest or disease does not occur" or an area of low pest or disease prevalence "in which a specific pest or disease occurs at low levels . . . ."

[30] Argentina's Opening Statement at the Second Substantive Meeting of the Panel, para. 53.
[31] Argentina's First Written Submission, para. 247. Argentina's Second Written Submission, paras. 25-26.
[32] Exhibit USA-32, at 14.
[33] Argentina's Response to Panel Question No. 2 Following the Second Substantive Meeting of the Panel, para. 9.

44. In short, it is quite surprising (and unsustainable) that Argentina now appears to argue that this dispute does not involve a claim by Argentina that Argentina is free of FMD or that FMD is of low prevalence in Northern Argentina.[34]

Question 44: Please provide your views as to the relationship between the first and second sentences of Article 6.2. Do the two sentences establish different obligations?

U.S. COMMENT ON ARGENTINA'S RESPONSE:

45. It appears that Argentina's answer largely agrees with that of the United States with respect to this question. The two sentences of Article 6.2 of the SPS Agreement are to be read together and do not establish different obligations. It is not clear what Argentina means when it says that the Article 6.2 obligation must be "built into" a Member's "regulatory structure." In any case, although Argentina has brought an as applied challenge and does not challenge the U.S. regulatory system, the record is clear that the U.S. system does recognize the concepts of disease freedom and low-disease prevalence.

Question 45: Please provide your views as to the relationship between the second sentence of Article 6.1 and the second sentence of Article 6.2. What is the difference, if any, between "assessing the [SPS] characteristics of a region" and "determin[ing]" pest- or disease-free areas or areas of low pest or disease prevalence"? What is the relationship between the factors listed in the two provisions?

U.S. COMMENT ON ARGENTINA'S RESPONSE:

46. It appears that Argentina's answer largely agrees with that of the United States with respect to this question. The second sentence of Article 6.1 of the SPS Agreement contains a non-exhaustive list of factors to be taken into account by a Member. The second sentence of Article 6.2 provides additional information on the attributes that would inform the concept of disease free areas.

Question 47: Does Article 6.1 relate only to the adaptation of an SPS measure to the characteristics of an area that has already been determined to be disease-free or of low disease prevalence, or does it also address the determination itself?

U.S. COMMENT ON ARGENTINA'S RESPONSE:

47. Argentina's answer largely agrees with the answer given by the United States to this question. Article 6.1 of the SPS Agreement obligates Members to ensure that their SPS measures are adapted to the characteristics of an area and this would include any determinations.

[34] 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, para. 109. *See also* SENASA's application to APHIS, in which Argentina claimed that the last FMD outbreak was in January 2002. Exhibit ARG-31, p. 19.

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

Question 51: In its second written submission, Argentina argues that the United States should have "provided assistance on any and all issues where it claimed a shortfall in capability". Please explain where Argentina finds support for this interpretation in the text of Article 10.1. Please also explain the relationship between Article 10.1 and Article 9 in terms of the obligation to provide technical assistance.

U.S. COMMENT ON ARGENTINA'S RESPONSE:

48. The Panel asks Argentina to identify which text in Article 10.1 of the SPS Agreement supports its interpretation that an importing Member must "provide[] assistance on any and all issues where it claimed a shortfall in capability." Argentina points to no text whatsoever, and none in fact exits. In short, there is no support for Argentina's position.

49. Furthermore, as discussed at the second meeting with the parties, it is Article 9 of the SPS Agreement that addresses matters related to technical assistance. Argentina does not respond to the Panel's invitation to explain the relationship between Article 10.1 and Article 9. Instead, it simply states that Article 9 "deals with technical assistance generally."

Question 52: Who bears the burden of identifying "special needs" for purposes of Article 10.1? Does the obligation in Article 10.1 only apply if it is the exporting developing country that identifies its own special needs? What should happen if it is the importing developed country that identifies the exporting developing country's special needs?

U.S. COMMENT ON ARGENTINA'S RESPONSE:

50. It is the burden of the Member claiming special needs under Article 10.1 of the SPS Agreement to show that it identified them as such. The panel reached a similar conclusion when faced with this issue in *EC – Approval and Marketing of Biotech Products*: "[T]here is no evidence on record to show that Argentina ever approached the European Communities and sought information on how the European Communities complied with its obligation under Article 10.1 when applying its approval legislation to applications concerning biotech products of export interest to Argentina."[35] Argentina did not do this: the expression of a desire to have APHIS issue a decision quickly is not the expression of a "special need." Most applicants in any process likely prefer a quick decision. Nor does a decision not made within Argentina's preferred timeframe show a breach of Article 10.1, since the language only requires a Member to "take account" of a special need. As the panel stated in *EC – Approval and Marketing of Biotech Products*, "[t]here is nothing in Article 10.1 to suggest that in weighing and balancing the various interests at stake, the European Communities must necessarily give priority to the needs of Argentina as a developing country."[36]

[35] *EC – Approval and Marketing of Biotech Products*, para. 7.1625.
[36] *EC – Approval and Marketing of Biotech Products*, para. 7.1621.

12 FINAL QUESTIONS

Question 53: During the course of these proceedings, the Panel has been presented with two risk assessments (one for Patagonia (Exhibit USA-133) and one for Northern Argentina (Exhibit USA-169)) that were concluded after its establishment, as well as a Final Rule allowing imports of FMD-susceptible animals and animal products from Patagonia (Exhibit USA-167) and a Proposed Rule allowing imports under certain conditions of fresh (chilled or frozen) beef from Northern Argentina (Exhibit USA-168). How should the Panel utilize these risk assessments and Proposed and Final Rules when evaluating Argentina's claims and the United States' defences?

U.S. COMMENT ON ARGENTINA'S RESPONSE:

51. In its answer, Argentina asks the Panel to use this evidence improperly and, in short, to find that because APHIS was able to make certain preliminary assessments (for Northern Argentina) or final assessments (for Patagonia) **after** panel establishment, then the Panel should find, as a matter of law, that APHIS should have made the same assessments **prior** to panel establishment. Argentina has no basis in law, logic, or the facts of this dispute to support this position.

52. First, with respect to the legal framework and prior DSB findings, the United States recalls the Appellate Body's findings in *EC – Selected Customs Matters*. In that dispute, the Appellate Body was sensitive to the issue of what evidence could be considered. While it found that a panel is not "precluded from assessing a piece of evidence for the mere reason that it pre-dates or post-dates its establishment," the Appellate Body stated "that a Member cannot be expected to examine 'evidence that did not exist and that, therefore, could not possibly have been taken into account when the Member made its determination. . . . ."[37] Similarly, in *US – Cotton Yarn*, which was referred to in *EC – Selected Customs Matters*, the Appellate Body, in considering the review of evidence post panel-establishment, stated: "If a panel were to examine such evidence, the panel would, in effect, be conducting a *de novo* review and it would be doing so without having had the benefit of the views of the interested parties. The panel would be assessing the due diligence of a Member in reaching its conclusions and making its projections with the benefit of hindsight and would, in effect, be reinvestigating the market situation and substituting its own judgment for that of the Member. In our view, this would be inconsistent with the standard of a panel's review under Article 11 of the DSU."[38]

53. Turning to the record in this dispute, the risk analyses and proposed and final regulatory determinations for Patagonia and Northern Argentina are evidence that post-dates panel establishment. Those documents are the product of the judgment of APHIS based on the collection and analysis of all the pertinent data, including data obtained **after panel-establishment**. The conclusions drawn from APHIS are dependent on the record before it, **as a whole**. The measures recommended and later affirmed by APHIS ensure that product from Argentina will be able to meet the appropriate level of protection of the United States. These

[37] *EC – Selected Customs Matters* (AB), para. 188, fn. 452.
[38] *US – Cotton Yarn* (AB), para. 78.

analyses and determinations show the APHIS process moving forward, and would inform the panel's consideration of whether to exercise judicial economy. However, it would not be correct to conclude, on the basis of APHIS' post-panel-establishment judgment, that the United States should have concluded before the time of panel establishment that data (including data generated or collected after panel establishment) on any particular issue was sufficient to reach that judgment.

U.S. COMMENT ON ARGENTINA'S RESPONSE TO U.S. QUESTIONS:

54. Rather than addressing the U.S. questions, Argentina resorts to purported shock and surprise that the United States would ask how Argentina – in contexts other than its submissions in this single dispute – interprets and applies the SPS Agreement. Argentina's protestations seem particularly out of place since it lists a number of SENASA resolutions that describe various restrictions and prohibitions on movement of animals related to FMD at "Chart Nr. 1 to its Second Written Submission," and that Argentina itself in its Second Written Submission raised issues regarding OIE designations concerning BSE status.[39]

55. In any event, where (as here) a complaining Member asserts far-reaching interpretations of the SPS Agreement, it is reasonable to ask that Member to explain how those interpretations square with its interpretations as reflected in that Member's actual application of the SPS Agreement. Indeed, the Panel has posed questions to the scientific experts about Argentina's measures governing the control of FMD.

56. The questions the United States posed with respect to BSE and the OIE designation is directly pertinent to Argentina's assertions regarding Article 3 of the SPS Agreement. Argentina does not dispute that it bans U.S. beef despite the fact that the OIE has designated the United States as a country with negligible risk for BSE. Argentina's own actions with regard to an OIE designation undermines its own assertion that OIE designations are international standards, guidelines, or recommendations within the meaning of Article 3.1 of the SPS Agreement.

[39] Argentina's references to *EEC – Oilseeds* and *EC and certain member States – Large Civil Aircraft* are misplaced. First, the paragraph referenced in *EEC – Oilseeds* discusses the EC statement that the subsidies in question are related to concerns over security of supplies of soybeans due to a 1973 export embargo. That the EC pointed to a soybean embargo 17 years prior to the dispute is not in any way analogous to asking Argentina to clarify its Argentina's FMD controls, which are directly relevant to this dispute. Second, the reference to *EC and certain member States – Large Civil Aircraft* is irrelevant because the United States is not asserting that Argentina cannot bring a claim because it has "unclean hands".