

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

**(DS447)**

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

**October 31, 2014**

## **U.S. OPENING STATEMENT AT THE SECOND PANEL MEETING**

1. The core factual issues involve two regulatory proceedings: one involving Patagonia, one involving Northern Argentina. Argentina's basic complaint is that the failure to complete these processes "is a straightforward restriction on international trade" without scientific justification, and constitutes "arbitrary discrimination" *vis-à-vis* other WTO Members.
2. However, the factual landscape has fundamentally shifted since this dispute was initiated. First, the United States has issued a formal determination that recognizes Patagonia as a region that is FMD free. Second, the United States has issued a proposed rule to allow imports from Northern Argentina, with appropriate control measures that Argentina acknowledges would be acceptable.
3. With respect to the legal framework of Argentina's challenge, the critical issue has been and continues to be this: what obligations apply under the SPS Agreement and how do they operate when an exporting Member claims either that its territory, in whole or in part, is free of disease, or that it is of low disease prevalence in relation to a disease of concern to an importing Member?
4. The SPS Agreement addresses this through Articles 2, 5, and 6. The provisions of these three articles must be read together, in a manner that reflects the drafters' intention of providing a coherent, workable set of obligations governing claims of disease-free or low-disease-prevalence status. Under these provisions, the process starts when the Member making the claim of a certain disease status makes a request to the importing Member. The importing Member then must begin an assessment and seek to obtain necessary information from the exporting Member. At the same time, the exporting Member is obligated to provide the necessary information to validate its claim. Pending the completion of the information collection and review process, the importing Member may maintain provisionally a measure affecting the importation of the product that is based on pertinent available information. During this period, the importing Member collects information necessary for a more objective assessment of the risk and reviews its existing SPS measure accordingly within a reasonable period of time. Once the importing Member has completed its risk assessment, it adopts a measure that is based on the assessment and achieves its ALOP.
5. According to the logic of Argentina's arguments, when an exporting Member claims it is free of disease, the importing Member must either immediately produce an assessment specific to that Member or permit the product to enter. This view is not grounded in the text of the SPS Agreement, does not make sense of the inter-relationship of the relevant provisions, and is not the approach taken by any responsible regulatory authority. As was confirmed during the meeting with the individual experts and the OIE, neither is this view reflected in the practice of other Members nor the procedure and practice of the OIE.
6. The expert consultation process further confirms the need for importing Members to make careful assessments of disease-free or low-disease-prevalence status, and the complexity of this task. For example, the individual experts stated that importing Members conducting an evaluation process must assess the effectiveness of a multitude of complex systems within a country. Further, the OIE itself stated that its country designations do not constitute an import risk assessment. The OIE also confirmed that the paper dossier – that is, the factual submission of the Member seeking an official disease status – is not shared with other OIE Members. The experts also noted that the OIE's designation process does not involve the preparation of a full

risk assessment. Dr. Bonbon observed that a risk assessment is a detailed evaluation, and must take account of the particularized situation of both the exporting and importing Members.

7. On January 23, 2014, APHIS published a proposed notice to designate the region of Patagonia as free of FMD. APHIS also published its 87-page risk analysis, based on a careful examination of the scientific evidence related to the disease and region. In the intervening months, APHIS received, analyzed, and answered comments provided by the public. On August 29, APHIS published its final notice, which determines that Patagonia is a region free of FMD.

8. APHIS has also taken action on the second regulatory proceeding at issue in this dispute. On August 29, APHIS published a proposal to permit the importation of fresh beef from the Northern Argentina region under certain conditions. The 103-page draft risk analysis is based on a careful examination of the scientific evidence related to the disease and this region.

9. While it took the United States time to reach preliminary and final decisions for Northern Argentina and Patagonia, respectively, length of time is not the appropriate standard with which to reach a legal conclusion on the issue of timeliness. Rather, under SPS Article 5.7, the legal question is whether the period of time taken “to seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly” is “reasonable.”

**A. THIS DISPUTE SHOULD BE ANALYZED IN LIGHT OF THE OBLIGATIONS OF ARTICLES 2.2, 5.7 AND 6.3 OF THE SPS AGREEMENT**

10. When an assertion of the disease status of the exporting Member is made, the importing Member is not likely to have all the scientific information needed to review its existing measure and determine whether changes are appropriate, as was the case here. 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 use the additional information in reviewing the existing SPS measure. This process is not indefinite; it must be completed within “a reasonable period of time.”

11. Article 6 complements and reinforces this understanding of how Article 5.7 applies in these situations. Article 6.1 obligates the importing Member to adapt its measures to the SPS characteristics of the exporting Member, and those characteristics include the “level of prevalence of specific diseases.” In particular, when the exporting Member makes the assertion that its territories are free of disease or of low disease prevalence as described, Article 6.3 obligates it to “provide the necessary evidence.” During this process of risk assessment, the importing Member is permitted to maintain measures to restrict importation of product from the exporting Member, under Article 5.7.

**B. ARTICLE 5.7 APPLIES TO THIS FACTUAL SITUATION**

12. Article 2.2 is crucial in understanding Article 5.7, because it is only through Article 2.2 that Article 5.7 is tied to the obligations under the SPS Agreement. Notably, Article 2.2 speaks to the “maintenance” of a measure. A measure must not be “maintained” without sufficient scientific evidence. The application of the “sufficient scientific evidence” language in Article 2.2 is particularly difficult when that evidence changes over time – and this of course is the issue

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

13. Before turning to Article 5.7, the United States also recalls the text of Article 5.1. First, Article 5.1 includes no specific reference to the exception set out in Article 5.7. However, as Argentina acknowledges, and as many past panel and Appellate Body reports have found, Article 5.7 is viewed as an exception to Article 5.1. The second notable aspect of Article 5.1 is that it uses the verb “based on” – that is, a measure must be “based on” an appropriate assessment of the risks. This obligation also applies over time, so that a measure’s compliance with Article 5.1 may change over time, based on evolving scientific evidence.

14. It cannot be the case that the instant scientific evidence changes, a Member is in breach of its Article 5.1 obligations. Rather, read in context, Article 5.7 must be available – both to allow the importing Member time to evaluate the new evidence, and at the same time, to impose obligations on the importing Member to seek additional information and to complete its review within a reasonable period of time.

15. In light of the context of these provisions, and for Article 5.7 to serve its role as an exception to those provisions, it must not be read as being limited to the formal adoption – in the sense of promulgation – of completely new measures addressed to a new product from an exporting Member. Rather, Article 5.7 must be read to also apply to evolving situations where measures are maintained without sufficient scientific evidence, and/or where a measure is no longer “based” on an appropriate assessment of risks.

### **C. THE UNITED STATES MEETS THE REQUIREMENTS ESTABLISHED IN ARTICLE 5.7**

16. Contrary to Argentina’s arguments, the United States did “seek” information, as required under Article 5.7. In particular, the United States requested that Argentina provide information as to its disease status.

17. The United States also met the reasonable period of time requirement. The record shows that APHIS and SENASA exchanged information over the period in question and that site visits were conducted in several areas and on a number of occasions. These information exchanges need to be seen in context of the changing situations in Argentina and on Argentina’s own shifting requests for import authorization. Argentina first wanted one review of the country for import authorization for fresh beef. Then it submitted an application for Patagonia South, which initiated a separate, new review process. During this time, there were two outbreaks of FMD in Argentina. Shortly afterwards, Argentina asked that a third area, Patagonia North B be reviewed, and then asked that the area be combined together with Patagonia South.

### **D. APHIS’S REGULATORY APPROVAL PROCESS IS BASED ON INTERNATIONAL STANDARDS**

18. APHIS’s regulatory approval process is based on international standards and is consistent with Article 3 of the SPS Agreement.

19. First, the OIE process in evaluating FMD disease status is similar to that of the United States. Starting with a higher level of generality, the basic process is the same: the United

States recalls (1) the OIE only issues official status designations upon application of a Member; (2) the OIE immediately rescinds official status designations upon the occurrence of an FMD outbreak; (3) regaining official status after a claim by a Member of disease freedom is based on an application to the OIE; and (4) official status is only gained after review of the data submitted by the Member seeking status. As the United States has stated from the beginning of this dispute: this process is the same as that employed by APHIS.

20. Second, Argentina has contended that the United States must follow the OIE status designation because it is a “standard, guideline, or recommendation” under the SPS Agreement. It urges the Panel “not to try to parse the term ‘standards, guidelines, or recommendations’ too closely.” However, application of the term “standards, guidelines, or recommendations” to any particular OIE statement or document is a fact-specific, legal issue. Here, the designations themselves – even on their face – do not look like standards, guidelines, or recommendations. Further, the difference between the process of adopting, on the one hand, the OIE Code, and on the other, the annual status designations, is striking. Indeed, in its papers and in its remarks, the OIE showed that the process of adopting the official status designation is in actuality nothing like the process used for the standards set out in the Terrestrial Code.

21. Third, Argentina’s arguments concerning Articles 8.5.23 and 8.5.25 of the OIE Code have no merit. The OIE stated that after the loss of status, a Member “has no status” and therefore the recommendations that apply in the meantime are for infected regions—in this case, this meant no trade in fresh beef. The determination of how to treat the importing Member’s product is then subject to a review of the disease status situation in the importing Member to consider the applicability of another provision. That is precisely the process that the United States was undergoing when this dispute was brought.

#### **E. ARGENTINA HAS NOT MET ITS EVIDENTIARY BURDEN UNDER ARTICLE 5.6**

22. Argentina has not met its burden to show that the protocols applied to Uruguay could be applied to Argentina in a way so as to meet the U.S. ALOP. To do so, Argentina would have had to have prepared a document comparable to the full APHIS risk assessment now on the record in this dispute. But of course, Argentina has not done so; instead it relies on assertions that Argentina is like Uruguay. But as the OIE confirmed, OIE status designations are not intended to be comparisons between different countries.

23. Even if one examines the experts’ evaluation of the risks – which is not a proper use of experts – Argentina does not meet its burden. In fact, the individual experts were not able to agree and to assess whether relevant animal control systems in Argentina and Uruguay were similar enough to meet the appropriate level of protection of the United States. The same is true for Patagonia. Argentina has not shown that measures that were applied to Santa Catarina would be appropriate for the Patagonia region – Patagonia South and Patagonia North B – the regions relevant to this dispute. The fact that APHIS proposed to extend FMD-free status to Patagonia in January 2014 based on a risk assessment that accompanied the regulatory notice cannot help Argentina make its case now. Argentina must meet its burden with the evidence as of panel establishment, and it has not done so.

24. Animals and animal products that are vaccinated pose an FMD threat. The individual experts confirmed that the risk of FMD transmission still exists even with the use of vaccination.

Argentina does not and cannot dispute the fact that vaccination poses a risk that, without the use of certain control measures, some Members cannot accept.

**F. EVIDENCE ON THE RECORD DOES NOT SUPPORT ARGENTINA’S CLAIM UNDER ARTICLE 2.3 OF THE SPS AGREEMENT**

25. Argentina has not met its burden and established that the United States has acted inconsistently with Article 2.3 of the SPS Agreement. With respect to Argentina, Uruguay, and Japan, the individual experts were not able to conclude unanimously that the systems were similar with respect to surveillance, animal identification and census, movement controls, or sanitary situations. With respect to Patagonia and Santa Catarina, although the individual experts made some statements as to comparability, it must be made clear that they made those statements using the APHIS risk assessment published in January 2014, which was after the date of panel establishment. As such, they are relying on APHIS’s own findings and proposal to determine that Patagonia (the whole region) is free of FMD. In fact, APHIS made that determination final on August 29, 2014.

26. The OIE’s official recognition of the FMD status of a country or area is not sufficient to establish that regions have identical or similar conditions within the meaning of Article 2.3. As the OIE and the individual experts agree: the OIE official status designation is not an import risk assessment. Accordingly, it cannot be used to conclude that the risk from two Members with the same status designation is the same or similar. Its only use is to confirm that a Member meets the OIE’s minimum standard.

27. Neither is Argentina’s complaint that the United States has not completed the APHIS regulatory process in the same time that other countries have completed it a claim recognizable under Article 2.3.

**G. ARGENTINA’S ANNEX C(1)(B) CLAIM FAILS**

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

29. The United States also does not agree that Argentina has shown a breach of any obligation under Annex C(1)(b). The only Annex C(1)(b) claim mentioned in Argentina’s panel request is a reference to the fifth clause, involving the explanations for delay. This is a jurisdictional matter, and it is Argentina’s responsibility to ensure that each one of its dozens of claims was actually set out in its own panel request.

30. Further, the record does not support Argentina’s arguments. With respect to Argentina’s applications, APHIS (1) promptly examined Argentina’s applications for completeness upon receipt, and notified SENASA of deficiencies on multiple occasions; and (2) proceeded as far as practicable with its evaluation even when SENASA’s applications had deficiencies. Argentina has also asserted that APHIS failed to transmit final results of the evaluation process; however, this claim fails for a simple and clear reason: there were no “results” to transmit to Argentina.

## U.S. SECOND WRITTEN SUBMISSION

31. 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 in Articles 5.7 and 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.

32. 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. 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. 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.

33. 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.

34. 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.

35. 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.

**A. THIS DISPUTE SHOULD BE ANALYZED IN LIGHT OF THE OBLIGATIONS OF ARTICLES 2.2, 5.7 AND 6.3**

36. 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, 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.

37. The SPS Agreement – through Articles 2.2 and 5.7, as informed by Articles 6 and 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 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.

38. 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.”

39. 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.”

40. 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. 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.”

## **B. ARGENTINA’S ARGUMENTS FAIL TO ADDRESS THE KEY LEGAL ISSUES IN THE DISPUTE**

41. 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.” 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.”

42. 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.

**C. ARGENTINA’S ARTICLE 6 DISTINCTION BETWEEN “COMMODITY” AND “REGIONALIZATION” IS NOT A DISTINCTION RECOGNIZED IN THE SPS AGREEMENT**

43. 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. 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. 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 from the whole country.

44. Argentina cannot arbitrarily limit the scope of applicability of Article 6. 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.

**D. MEASURES TAKEN BY THE UNITED STATES ARE JUSTIFIED UNDER ARTICLE 5.7**

45. 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.

46. 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. 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. 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.

47. Argentina argues that the United States “adopted” no measures in 2002, and that the “application by Argentina to APHIS was an action by Argentina.” If Argentina is arguing that 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.

48. 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.

49. 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 and 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.

50. 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. APHIS took action 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. 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. 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.

51. 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.

52. 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.” 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.

**E. THE UNITED STATES IS REVIEWING THE MEASURE WITHIN A REASONABLE PERIOD OF TIME**

53. 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.

54. 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. 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. 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.

55. In this dispute, collecting the necessary additional information is not easy. Exchanges of information between APHIS and SENASA need to be seen in context of the changing situations 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.

56. Even if one were to take the 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.

57. 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.” 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.

**F. THE UNITED STATES APPLICATION SYSTEM HAS BEEN APPLIED TO ARGENTINA IN A MANNER CONSISTENT WITH ARTICLE 8 AND ANNEX C OF THE SPS AGREEMENT**

58. Measures falling within the scope of Article 8 and Annex C do not include the determinations at issue in this dispute. The text of the SPS Agreement does not provide that determinations involving disease-free areas of potential exporters are covered by Article 8.

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.

59. Article 8 and Annex C apply specifically to “control, inspection and approval procedures.” 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.” 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).

60. 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. And indeed, the panel did not explain how such an interpretation could fit with the plain meaning of the text.

61. 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, 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.

62. 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. 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, 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.

### **G. THE UNITED STATES HAS NOT ACTED INCONSISTENT WITH SPS ARTICLE 3**

63. 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.” Argentina cannot support this allegation. Argentina continues to conflate Article 3.1’s “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.

64. 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 guidance of the Appellate Body in *EC – Hormones*. 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.

65. 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 – to show that the measure has not adopted some of the elements of the international standard.

66. 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. 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. 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.

67. In light of Argentina’s submissions, its argument under SPS Article 3.1 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.

68. 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. 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 vaccination.” 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.

#### **H. THE OIE FMD STATUS ATTRIBUTIONS ARE NOT STANDARDS, GUIDELINES OR RECOMMENDATIONS FOR THE PURPOSES OF ARTICLE 3 OF THE SPS AGREEMENT**

69. 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. 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.

70. 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.

71. 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.

**I. THE UNITED STATES HAS NOT ACTED INCONSISTENT WITH ARTICLE 3.3**

72. Article 3.3 authorizes Members to introduce and maintain SPS measures based on scientific justification. 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 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.

**J. MEASURES BY THE UNITED STATES ARE CONSISTENT WITH ARTICLE 5.6**

73. 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 Articles 5.7 and 6. This is not, as Argentina alleges, a “a de facto ‘zero risk level.’” 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.”

74. 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. 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.

75. Accordingly, OIE guidelines should not be considered as achieving the appropriate level of protection of the United States.

76. Argentina has asserted in this litigation that the mitigation protocols that apply to Uruguay are appropriate for Argentina because the sanitary situations are “similar.” It makes the same argument with respect to Santa Catarina and Patagonia South.

77. 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.

78. Argentina further argues that the OIE status “has probative value” and that “Members can and do reasonably rely” on that status. 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.

79. 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.

80. 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.

81. 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 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.

**K. ARGENTINA HAS FAILED TO ESTABLISH THAT THE UNITED STATES HAS ACTED INCONSISTENT WITH ARTICLE 2.3**

82. 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. Argentina has not met its burden of proving these elements.

83. 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. However, Argentina has failed to establish that identical or similar conditions prevail. 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. 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.