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

(DS447)

RESPONSES OF THE UNITED STATES TO THE PANEL'S QUESTIONS FOLLOWING THE SECOND PANEL MEETING

October 10, 2014

TABLE OF EXHIBITS

Exhibit	Long Citation	Short Citation
USA-170	9 C.F.R. §166	9 C.F.R. §166
USA-171	79 F.R. 51534	79 F.R. 51534
USA-172	9 C.F.R. §94.22(f)	9 C.F.R. §94.22(f)
USA-173	Canadian Food Inspection Agency (CFIA) Automated Import Reference System (AIRS) Webpage	Canadian Food Inspection Agency (CFIA) Automated Import Reference System (AIRS) Webpage
USA-174	Vienna Convention on the Law of Treaties, Article 31	Vienna Convention on the Law of Treaties, Article 31
USA-175	"Provisional." The New Shorter Oxford English Dictionary (1993)	"Provisional." The New Shorter Oxford English Dictionary (1993)
USA-176	United States Department of Agriculture, Animal and Plant Health Inspection Service "Regionalization" Webpage	United States Department of Agriculture, Animal and Plant Health Inspection Service "Regionalization" Webpage
USA-177	"Determination." The New Shorter Oxford English Dictionary (1993)	"Determination." The New Shorter Oxford English Dictionary (1993)
USA-178	"Particular." The New Shorter Oxford English Dictionary (1993)	"Particular." The New Shorter Oxford English Dictionary (1993)
USA-179	"Criterion." The New Shorter Oxford English Dictionary (1993)	"Criterion." The New Shorter Oxford English Dictionary (1993)

TABLE OF REPORTS

SHORT FORM	FULL FORM
Argentina – Import Measures (Panel)	Panel Report, *Argentina – Measures Affecting the Importation of Goods*, WT/DS438/R, WT/DS444/R, WT/DS445/R, circulated 22 August 2014
Australia – Apples (AB)	Appellate Body Report, *Australia – Measures Affecting the Importation of Apples from New Zealand*, WT/DS367/AB/R, adopted 17 December 2010
EC – Approval and Marketing of Biotech Products	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 – Selected Customs Matters (AB)	Appellate Body Report, *European Communities – Selected Customs Matter*, WT/DS315/AB/R, adopted 11 December 2006
Japan – Agricultural Products II (AB)	Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R, adopted 19 March 1999
Japan – Apples (AB)	Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, adopted 10 December 2003
US – Corrosion Resistant Steel Sunset Review (AB)	Appellate Body Report, *United States – Sunset Review of Anti-Dumping Duties on Corrosion-Resistant Carbon Steel Flat Products from Japan*, WT/DS244/AB/R, adopted 9 January 2004
US – Zeroing (EC) (AB)	Appellate Body Report, *United States – Laws, Regulations and Methodology for Calculating Dumping Margins ("Zeroing")*, WT/DS294/AB/R, adopted 9 May 2006, and Corr.1

1 TRANSMISSIBILITY OF FMD AND VETERINARY PRACTICES

Question 6: We refer to Dr Cupit's response to Panel question No. 2, paragraph 18(c) and Dr Bonbon's response to Panel question No. 3, paragraph 39. Please also consider the United States' comments on the experts' response to Panel question No. 2(c), paragraph 10. Based on the above, please explain:

(a) Whether "swill feeding" is permitted in the United States, and if so, under what conditions;

ANSWER:

1. In the United States, all waste-feeder operations must be licensed and are subject to regular inspection by the United States Department of Agriculture (USDA) pursuant to 9 C.F.R. §166. Licensed entities must adequately cook all waste fed to swine according to methods designed to reduce the probability of survival of foreign animal disease agents in the waste. This requirement is clearly spelled out in the regulations: "no person shall feed or permit the feeding of garbage to swine unless it is treated to kill disease organisms…at a facility operated by a person holding a valid license for the treatment of garbage."[1] USDA's Animal and Plant Health Inspection Service (APHIS) regularly searches for non-licensed garbage feeding facilities and requires such facilities to come into compliance.[2] Depending on the state, all swine found in unlicensed facilities may be quarantined and subject to testing for foreign animal diseases. It should be noted that some U.S. states including New York, Illinois, Virginia, and Georgia prohibit the feeding of garbage to swine altogether.[3]

2. The U.S. approach recognizes that swine are highly susceptible to a variety of diseases, including foot and mouth disease (FMD). Should swine in the United States come into contact with the FMD virus, and ultimately develop FMD, these animals would act as significant amplifiers of the disease, with devastating consequences for U.S. livestock populations.

(b) What measures are in place to control or prevent illegal practices relating to swill feeding using fresh (chilled or frozen) beef;

ANSWER:

3. During routine visits by animal health inspectors, licensed waste-feeder operations are informed of the importance of proper cooking of waste, appropriate biosecurity measures, signs of foreign animal diseases, and requirements for reporting.[4] During visits to swine production systems, animal health inspectors observe animals for signs of illness. Inspectors will also verify that facilities and equipment comply with licensing requirements. These mandatory inspections are in place to reduce the incidence of illegal swill feeding and have resulted in increased confidence between animal health regulators and waste-feeder operations.

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[1] 9 C.F.R. §166.2(a). Exhibit USA-170.
[2] 79 F.R. 51534. Exhibit USA-171.
[3] 9 C.F.R. §166.15(a). Exhibit USA-170.
[4] 79 F.R. 51534. Exhibit USA-171.

(c) Whether the production or sale of ruminant-based animal feed is permitted in the United States;

ANSWER:

4. The United States understands this question to distinguish between "swill feeding," discussed above, and "ruminant-based animal feed." Whereas "swill feeding" is the feeding of garbage or plate waste to pigs, "ruminant-based animal feed" is manufactured animal feed that may contain ruminant protein. The production and sale of animal feed that contains ruminant protein is permitted in the United States, although such feed may not be fed to ruminants. Ruminant protein ingredients for manufactured animal feed is obtained from renderers (and possibly other sources), which cook animal products at temperatures between 239° F and 293° F to render the products into their constituent elements. This cooking yields, among other things, proteins that are used as an ingredient in animal feed, which is itself a processed product. The rendering process cooks ruminant proteins at high temperatures that inactivate any FMD virus that might exist in the ruminant source material.

(d) Has APHIS assessed, under current US regulations, the likelihood that FMD could be established and spread in the United States via the feeding of FMD-contaminated products to pigs? If so, what was the result?;

ANSWER:

5. The likelihood that FMD could be established and spread in the United States through the feeding of FMD-contaminated products to pigs was discussed in the "exposure assessment" sections of the draft risk analysis document for importing fresh/frozen beef from Northern Argentina[5] as well as the evaluation of the FMD status of a region of Patagonia.[6] The purpose of the exposure assessment section is to describe the biological pathway(s) necessary for exposure of FMD-susceptible animals to the hazards (here, FMD) released from a given risk source and estimate the likelihood of the exposure(s). As discussed below, after the evaluation of such pathways, APHIS concluded that the likelihood of exposure of susceptible swine to FMD virus through inadequately processed food waste is low.

6. Nonetheless, while the likelihood of exposure is low, in both exposure assessments APHIS also concluded that the feeding of contaminated food waste to swine was the most likely pathway of exposure of domestic livestock to FMD virus in beef or lamb meat. This conclusion was based on an APHIS study that estimated that 0.023 percent or less of plate and manufacturing waste would be inadequately processed prior to feeding swine.[7] (This represents

[5] Risk Analysis: Foot-and-Mouth Disease Risk from Importation of Fresh (Chilled or Frozen), Matured, Deboned Beef from Northern Argentina into the United States (April 2014), p. 87. Exhibit USA-169.
[6] Risk of Importing Foot-and-Mouth Disease in Susceptible Species and Product from a region of Patagonia, Argentina (January 2014), p. 70. Exhibit USA-133.
[7] Risk Analysis: Foot-and-Mouth Disease Risk from Importation of Fresh (Chilled or Frozen), Matured, Deboned Beef from Northern Argentina into the United States (April 2014), p. 87. Exhibit USA-169. Risk of Importing Foot-and-Mouth Disease in Susceptible Species and Product from a region of Patagonia, Argentina (January 2014), p. 70. Exhibit USA 133.

a three orders of magnitude reduction – as compared to untreated plate waste -- in the risk at the release level.) APHIS also concluded that the proportion of plate and manufacturing waste fed to swine has diminished over time due to a decrease in the number of waste-feeding premises.[8]

7. In the exposure assessments, APHIS also noted that the likelihood of feeding unprocessed waste to swine has been further reduced by prohibiting the feeding of unprocessed plate waste to swine.[9] As previously noted, waste-feeder operations must be licensed and are inspected regularly by USDA inspectors.[10]

(e) Whether any of the previous factors changed since the date of the establishment of the Panel.

ANSWER:

8. As noted, APHIS has found that due in part to the stringent licensing restrictions, both the proportion of plate and manufacturing waste fed to swine has been decreasing, and the likelihood of feeding unprocessed plate and manufacturing waste to swine has been decreasing. These findings are reflected in the final risk assessment for Patagonia and the draft risk assessment for Northern Argentina. Moreover, under the changing structure of the Swine Health Program, APHIS staff now devote more time to inspection and visits to swine farms.[11] Accordingly, it does seem likely that these factors have changed since the date of Panel establishment.

9. The key point, however, is that the draft and final APHIS risk assessments that the United States has placed on the record in this dispute reflect APHIS's evaluation of the factual situation as of the time the risk assessments were prepared, and not as of the time of Panel establishment. Accordingly, the record does not support any contention by Argentina that APHIS would have made the exact same evaluation at the time of Panel establishment.

Question 7: Is the United States aware of any cases in which deboned and matured fresh beef has been shown to be a source of an FMD infection? If so, please provide documentation.

ANSWER:

10. The United States is not aware of any cases in which deboned and matured fresh beef has been shown to be a source of FMD infection. However, as the United States has explained in its prior submissions, the United States has a high appropriate level of protection (ALOP) with

[8] Risk Analysis: Foot-and-Mouth Disease Risk from Importation of Fresh (Chilled or Frozen), Matured, Deboned Beef from Northern Argentina into the United States (April 2014), p. 87. Exhibit USA-169. Risk of Importing Foot-and-Mouth Disease in Susceptible Species and Product from a region of Patagonia, Argentina (January 2014), p. 70. Exhibit USA-133.
[9] Risk Analysis: Foot-and-Mouth Disease Risk from Importation of Fresh (Chilled or Frozen), Matured, Deboned Beef from Northern Argentina into the United States (April 2014), p. 87. Exhibit USA-169. Risk of Importing Foot-and-Mouth Disease in Susceptible Species and Product from a region of Patagonia, Argentina (January 2014), p. 70. Exhibit USA-133.
[10] 9 C.F.R. §166. Exhibit USA-170.
[11] 79 Fed. Reg. 51534. Exhibit USA-171.

respect to FMD, and as a result, has successfully prevented outbreaks of FMD since the 1920s. Although deboning and maturation, when performed properly, is an important control measure, a deboning and maturation requirement – standing alone without taking into account, for example, any other internal control structures – is not sufficient to meet the U.S. ALOP.

Question 8: Argentina states that "the US Government regularly purchases FMD vaccine for its official stockpiles from the same Argentine private sector companies that supply SENASA". Can the United States confirm this statement? If so, what is its significance to this dispute?

ANSWER:

11. The United States has not purchased FMD vaccine for its stockpiles from an Argentine supplier. Argentina's statement perhaps refers to the fact that the United States has, through the North American Foot-and-Mouth Disease Vaccine Bank (NAFMDVB), purchased three concentrated antigens corresponding to South American FMD virus strains from a company in Argentina. A local supplier, as might be expected, is best situated to provide antigens to strains endemic to the particular area.

12. In any event, the location of various suppliers of animal health materials should have no bearing on the outcome of this dispute. As noted previously, vaccination practices are but one of eight criteria that APHIS assesses pursuant to 9 C.F.R. §92.2.[12] Additionally, while vaccine quality is an important factor in evaluating vaccination practices, APHIS also considers implementation, control, and monitoring of vaccination. These latter mentioned factors are related to the activities of the regulating authority (in Argentina's case, Argentina's National Veterinary Authority, SENASA) and are not connected to the supplier of the vaccine in use.

Question 9: In its comments on the OIE's responses, the United States refers to "the risks associated with vaccination, such as those associated with meat derived from feet, head and viscera". If the protocols under 9 CFR 94.22 were applied to Argentine fresh (chilled or frozen) beef, would Argentina be permitted to import feet, head and viscera of FMD-susceptible animals into the United States?

ANSWER:

13. The regulations at 9 C.F.R. §94.22 (2013) govern restrictions on the importation of beef from Uruguay in order to mitigate the risk of FMD transmission. Under 9 C.F.R. §94.22(f), fresh (chilled or frozen) beef and ovine meat from Uruguay may be exported to the United States if "the meat consists only of bovine parts or ovine parts that are, by standard practice, part of the animal's carcass that is placed in a chiller for maturation after slaughter. The bovine and ovine parts that *may not* be imported include all parts of the head, feet, hump, hooves, and internal organs."[13] (emphasis added) Therefore, if the conditions of 9 C.F.R. §94.22 were applied to

[12] 9 C.F.R. §92.2. Exhibit USA-76.
[13] 9 C.F.R. §94.22(f). Exhibit USA-172.

Argentina, Argentine exports of feet, head, and viscera of FMD-susceptible animals would not be permitted into the United States.

Question 10: Is Argentina allowed to export fresh (chilled or frozen) beef and/or FMD-susceptible animals and animal products originating in Patagonia to Canada? If so, under what conditions?

ANSWER:

14. The U.S. understanding is that Canada does not allow exports of fresh beef (or animal products for human consumption) from Patagonia. Although Canada has recognized the Patagonia region as FMD-free without vaccination, Canada has not yet recognized Argentina's beef slaughter inspection system as equivalent and, therefore, has not yet allowed Argentina to export fresh beef (or animal products for human consumption) to Canada.

15. The specific import conditions applied to different commodities from FMD-free countries can be found in the Canadian Food Inspection Agency's Automated Import Reference System.[14]

Question 11: In case the response to Panel question No. 10 above is affirmative, what are the measures in place aimed at ensuring that FMD-susceptible products imported into Canada from Argentina do not cause an introduction of FMD into US territory?

ANSWER:

16. As noted in response to question 10, Argentina is not allowed to export fresh beef, animal products for human consumption, or live animals to Canada.

2 HARMONIZATION (ARTICLE 3 OF THE SPS AGREEMENT)

Question 13: Did APHIS ever request that Argentina provide it with a copy of any of Argentina's dossiers to the OIE? Did Argentina ever provide APHIS with a copy of any of the dossiers it submitted to the OIE?

ANSWER:

17. APHIS requests information from countries seeking import authorization under 9 C.F.R. §92.2. The factors listed include veterinary infrastructure, disease status, status of adjacent regions, disease control programs, vaccination status, physical geography, animal movements, livestock demographics, disease surveillance, laboratory capacity, policies and infrastructure of animal disease control in the region. Accordingly, APHIS seeks as much information as possible

[14] *See* Canadian Food Inspection Agency (CFIA) Automated Import Reference System (AIRS) Webpage, available at: http://www.inspection.gc.ca/animals/terrestrial-animals/imports/airs/eng/1300127512994/1326599273148. Exhibit USA-173.

from the applicant country, including dossiers from the World Animal Health Organisation (OIE), which address similar topics as those listed at 9 C.F.R. §92.2.

18. APHIS files contain certain documents submitted by Argentina to the OIE but it is not clear whether Argentina provided to APHIS a complete copy of any particular OIE dossier.

Question 14: In its comments on the OIE answers, the United States asserts that APHIS takes into consideration whether the OIE has extended official recognition as part of its own risk analysis. Please explain how OIE disease-status recognitions are taken into consideration as part of APHIS' risk assessment, and how the weight they are given compares to that given to the exporting country's compliance with Chapters 3.1 and 3.2 of the Terrestrial Code and the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

ANSWER:

19. In evaluating claims of disease-free status, APHIS follows a similar approach to that set out in the OIE Handbook on Import Risk Analysis for Animals and Animal Products, which provides guidance to OIE members on the conduct of such import risk analyses.[15] Upon receiving an application from an exporting country, APHIS conducts a risk analysis on that country to determine the conditions under which the relevant product can enter the United States. In reviewing this application, APHIS takes into consideration all relevant facts, including whether or not the OIE has extended official recognition.

20. As is the case in any complex rulemaking process, it is not possible to provide a general characterization of the weight provided to any particular factor under examination. Rather, the evaluation of all factors is a holistic process, and certain factors may take on heightened importance depending on the specific factual circumstances. Similarly, an applicant country's compliance with Chapters 3.1 and 3.2 of the OIE Code, which cover veterinary services,[16] is an indicator of its level of veterinary infrastructure and authority , which is one of eight areas reviewed pursuant to 9 C.F.R. §92.2(b). This is also a factor considered in the APHIS process, though it is not possible to provide a general characterization of the weight of one factor as compared to any other factor under examination.

Question 15: With reference to paragraph 26 of Argentina's second opening statement, assuming, arguendo, that an OIE disease-status determination is not an international standard, guideline or recommendation, can a Member applying the Terrestrial Code recommendations relating to disease-status invoke the "safe harbour" of Article 3.2?

ANSWER:

21. Yes, a Member applying the Terrestrial Code recommendations relating to disease-status can invoke the provisions of Article 3.2, even if OIE disease-status determinations are not

[15] *See* U.S. Comments on the OIE's Responses to the Panel's Questions No. 31, paras. 105-107.
[16] *See* OIE Code Chapters 3.1 and 3.2.

considered to be international standards, guidelines, or recommendations. Article 3.2 provides that SPS measures "which conform to international standards guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994."

22. For example, an importing Member's system that conforms to the Terrestrial Code recommendations would satisfy Article 3.2 and that measure's general treatment of imports in relation to the disease-status of the place of origin would be "presumed to be consistent" with the Agreement. However, when applying the Terrestrial Code recommendations in any particular case, that application would not itself be application of a measure conforming to an international standard, guideline, or recommendation (which does not exist for that exporting Member). Therefore, an exporting Member alleging the misapplication of the Terrestrial Code recommendations due to its disease-status would have the opportunity to show that the importing Member had applied the incorrect recommendation and thus overturn the presumption.

Question 16: In its comments on the OIE's answers, the United States asserts that the recommendations in Article 8.5.22 "should only be valid if the factual premises underlying the veterinary certificate are in fact true and that the veterinary control system is as represented by the regulatory authorities". Who determines whether the factual premises are "true"? When is this determination made?

ANSWER:

23. The exporting country first makes an assertion of truth in compliance with the certificate. The importing country always reserves the right to reject the certificate if it has reason to believe that the certification is not truthful. OIE Article 8.5.22 provides that veterinary authorities of the importing country should require the presentation of an international veterinary certificate attesting that the accompanying meat satisfies certain conditions.[17] The OIE Code defines an "international veterinary certificate" as one "issued in conformity with the provisions of Chapter 5.2., describing the animal health and/or public health requirements which are fulfilled by the exported commodities."[18] Article 5.2.2 states that an international veterinary certificate should be signed by a certifying veterinarian that is "authorised by the Veterinary Authority of the exporting country to sign international veterinary certificates[.]"[19] Article 5.2.3 provides that paper certificates "should bear the signature of the certifying veterinarian and the official identifier (stamp) of the issuing Veterinary Authority."[20]

24. Accordingly, the certifying veterinarian is from the exporting country and is averring to the truth of the conditions stated in the certificate. That certificate is authorized by the exporting country's Veterinary Authority. The importing country reserves the right upon inspection to reject the certificate if it has reason to believe the certificate is not truthful.

[17] OIE Code Article 8.5.22.
[18] OIE Code Glossary.
[19] OIE Code Article 5.2.2.
[20] OIE Code Article 5.2.3.

Question 17: We understand paragraphs 98-102 of the United States' second written submission as stating that since APHIS has not finished its review process, Article 3.3 of the SPS Agreement is inapplicable.

(a) Is our understanding correct? If so, can the United States please explain the basis for such a statement? In your response, please make specific reference to the text of Article 3.3, according to which measures adopted under Article 3.3 must be "in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5". Moreover, "all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement".

(b) We also understand the United States to be arguing that Article 3.3 only applies when an SPS measure has been "introduced or maintained" and not when a Member has yet to introduce or maintain an SPS measure. Is the United States saying that there is currently no measure in place with respect to ruminant and swine products from Argentina and Patagonia?

ANSWER:

25. The United States appreciates the opportunity to clarify its views on the relevance of Article 3.3 of the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement") in the circumstances of this dispute. Article 3.3 sets out circumstances in which an importing Member "may" adopt certain SPS measures; Article 3.3 is not itself an independent obligation. Rather, Article 3.3 serves to foreclose a finding of a breach of Article 3.1 in circumstances in which an importing Member chooses not to base its SPS measures on an international standard.

26. The United States has explained that the Panel need not look to Article 3.3 in this dispute because the United States' FMD measures, in accordance with Article 3.1, are based on the OIE Code. Furthermore, the mere fact that the OIE has concluded its re-assessment of Argentina following Argentina's FMD outbreaks, while APHIS had not yet done so at the time of panel establishment, does not indicate otherwise. Rather, as discussed at length in U.S. submissions, at the expert meeting, and at the second meeting of the parties, the official FMD status designations of the OIE are not "international standards, guidelines, or recommendations," and the United States is not required to conform immediately with the judgment of the OIE with respect to a specific country designation in order to satisfy Article 3.1.[21]

27. Furthermore, in the event the Panel would proceed to an examination of the U.S. measure under Article 3.3, the U.S. measure would meet the requirements of Article 3.3. Article 3.3 requires a scientific justification for the measure at issue. In this dispute, the United States has explained at length the scientific justification for maintaining an import control measure following an FMD outbreak, and during the time the importing Member is evaluating a renewed

[21] U.S. Second Written Submission, paras. 86-91.

claim of disease-free status. The United States has further explained that the most appropriate SPS provision for examining this justification is Article 5.7, which sets out in detail a Member's obligations with respect to the maintenance of measures in the face of changing conditions and uncertainty.

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.

(a) When were the measures in question adopted?

ANSWER:

28. The basic question raised in this dispute is about timing and the mutual obligations under the SPS Agreement when a claim is made that the exporting Member's territory is free of disease or of low disease prevalence. It is not disputed by Argentina that in the period from 2000 through 2002 it suffered a series of significant FMD outbreaks. It is also not disputed by Argentina that the removal of import authorization was an appropriate response. In fact, these were the exact steps taken by other WTO Members as well.

29. However, in November 2002,[22] Argentina made a claim to APHIS that the disease situation in the country had changed and that APHIS should change its measure prohibiting Argentine imports. Argentina then provided some initial information to support this claim.

30. The United States agreed to review the information and to consider Argentina's request for import authorization. At this point in time, the prohibition of Argentine beef became conditional or provisional upon U.S. review of the new information, and the United States affirmatively took action to collect and review the information.[23]

31. Accordingly, the pertinent question in this dispute is not simply "when were the measures in question adopted," but rather, "for the purpose of applying Articles 2.2. 5.1, and 5.7 in a coherent manner in the face of changing factual circumstances, when should the measures be considered to have been adopted for the purpose of applying Article 5.7?" The answer to this question, explained in U.S. submissions,[24] is that for the purpose of applying Article 5.7, the measures were provisionally adopted at the time that the United States began the evaluation of Argentina's renewed claim of disease-free status.

[22] U.S. First Written Submission, para. 132.
[23] Notice of Determination of the Foot-and-Mouth Disease and Rinderpest Status of a Region of Patagonia, Argentina. Exhibit USA-167.
[24] *See* U.S. Response to the Panel Question No. 24(b), paras. 88-95; U.S. Second Written Submission, paras. 29-34.

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

ANSWER:

32. The United States is pleased to elaborate on the interpretation previously set out in the U.S. answers to the first set of questions from the Panel and in the U.S. second written submission.[25] The customary principles of public international law, as reflected in the Vienna Convention on the Law of Treaties, require that a treaty "shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and light of its object and purpose."[26]

33. The dictionary definition of the adverb "provisionally" is "in a provisional manner; as a temporary measure."[27] In the first sentence of Article 5.7, it serves the purpose of describing that the measure adopted is done so in a provisional manner and is limited in duration (temporary). In this case, the prohibition of product from Argentina was to be time-limited by the process of the collection of information and review of data, which would result in a decision concerning the application made by Argentina for import authorization.

34. The plain meaning of the verb "adopt" is to "[c]hoose for one's own practice, take up" or to "[a]prove, accept (a report etc.)."[28] To "adopt" a measure means that the Member takes the measure as a matter of practice. It could mean that there needs to be a formal promulgation of a legal instrument. However, it is well established that in WTO dispute settlement, a measure is not limited to a formal legal document, but can encompass other forms of state action, written or unwritten.[29] A Member's temporary prohibition pending a review of new information and a final decision based on that information is clearly a measure that was adopted by APHIS. Moreover, the United States would again emphasize that on this particular interpretive issue, the context is of great importance.

35. As the United States has noted, Article 5.7 – which serves as an exception to other obligations – is linked into the SPS Agreement only through Article 2.2. Article 2.2 states that a measure may not be **maintained** without sufficient scientific evidence except as provided for in Article 5.7. It would not be a sensible reading of the SPS Agreement as a whole to conclude that a measure may only be maintained without scientific evidence if that measure is newly adopted at the time of evidentiary insufficiency. Rather, a far more plausible interpretation is that – as Article 2.2 states – the measures may be "maintained" during the period a Member is proceeding with its obligations under Article 5.7 to obtain and evaluate the full amount of evidence needed for a risk assessment under Article 5.1.[30]

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[25] *See* U.S. Response to the Panel Question No. 24(b), paras. 88-95; U.S. Second Written Submission, paras. 29-34.
[26] Vienna Convention on the Law of Treaties, Article 31. Exhibit USA-174.
[27] "Provisional." The New Shorter Oxford English Dictionary (1993), p. 2394. Exhibit USA-175.
[28] "Adopt." Exhibit USA-150.
[29] *E.g., Argentina – Import Measures (Panel)*, paras. 6.39-6.42 (citing *US – Corrosion Resistant Steel Sunset Review (AB)* and *US – Zeroing (EC) (AB)*).
[30] If APHIS had refused to take action, or had undertaken no action, not received the information or taken any steps forward with the application, then it would make sense to say that no measure was adopted provisionally. If this had

36. Furthermore, this interpretation is completely consistent with the object and purpose of the SPS Agreement. In contrast, it would be contrary with that object and purpose to interpret the terms "adopt provisionally" in a manner that constricted the terms beyond their plain textual meaning to include only formal written regulatory or legislative documents. For example, it would not make sense to conclude that Article 5.7 would have been satisfied if there had been a U.S. law that provided the United States would prohibit Argentine beef temporarily during the period that it reviewed the new information submitted and issued a final decision but that Article 5.7 would not have been satisfied if APHIS had demonstrated the same through action. Such an interpretation would frustrate the purpose of Article 5.7, which was to address precisely these moments of scientific insufficiency and provide a mechanism to resolve them.

Question 19: In its second opening statement, the United States asserts that "the US regulatory system is clear that once an application is received, the existing restrictions are provisional in pending the evaluation of the application". Where is this set forth in the US regulatory system? Can the United States provide a citation to a regulation or procedure to this effect?

ANSWER:

37. The procedure for review of an application and the final determination by APHIS in the evaluation of import authorizations is outlined and discussed in the APHIS document "Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking," which was submitted as Exhibit USA-74. That document provides that the process of reviewing an import authorization application begins when the "Chief Veterinary Officer (CVO) of a foreign government request[s] recognition of status for a particular disease or seeking authorization to export animals and/or animal products to the United States."[31] The process includes four steps: (1) Data evaluation; (2) Verification through site visits; (3) producing risk analyses; and (4) regulatory decision. The document shows that the process begins with an application and during the four steps, the requested products are not permitted entry until a decision is reached in step 4. This four-step process demonstrates the limited and bound nature of the provisional restriction. The proposed and final determinations in connection with Argentina's applications for Northern Argentina and Patagonia, respectively, confirm the process described in Exhibit USA-74.

Question 20: In its responses to Panel questions after the first substantive meeting, the United States argues that "with each change in circumstance" in the exporting Member in terms of its disease situation and regulatory regime, time is required for the importing Member to evaluate such change. Please clarify whether, by that statement, the United States means that every time the situation in an exporting Member with respect to a given risk changes, a pre-existing measure in force vis-à-vis products from that Member falls within the scope of Article 5.7.

occurred, then with respect to Argentina's application, perhaps it would have been correct to conclude that the 2001 prohibition on imports from Argentina was the final measure. However, this is not the case, and the record clearly supports this.

[31] "Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking." Exhibit USA-74, p. 2.

ANSWER:

38. The United States respectfully submits that the relevant question is not whether

> "every time the situation in an exporting Member with respect to a given risk changes, a pre-existing measure in force vis-à-vis products from that Member falls within the scope of Article 5.7."

But rather whether:

> "every time the situation in an exporting Member with respect to a given risk changes, a pre-existing measure in force vis-à-vis products from that Member may no longer meet the requirements of Article 2.2 (not to be maintained without sufficient scientific evidence) and/or Article 5.1 (to be based on a risk assessment appropriate to the circumstances), such that the importing Member may need to rely on Article 5.7 while it evaluates the changed circumstances."

39. As the United States has explained, this is a general and far-reaching issue under the SPS Agreement, and a question of first impression for the Panel to decide. The United States and Argentina agree that where the circumstances have changed, a previously-justified measure may no longer meet the requirements of Article 2.2 or 5.1. Where the parties disagree is how this problem is to be addressed under the SPS Agreement. The United States submits that in these circumstances, the rights and obligations under Article 5.7 would apply, and that the importing Member may maintain its measure while it collects additional information and makes a more objective assessment of risk. Argentina at times has agreed that this is the right result. But Argentina has not agreed that Article 5.7 should apply, and instead has posited an undefined "reasonable man" standard with no apparent basis in the text of the SPS Agreement.

40. The United States also notes that its interpretation comports with international practice and expert opinion: Dr. Cupit stated in his response to the Panel's Question 47(c): "Any change to an input or factor that is considered in a risk assessment could make a difference to the time taken to finalise the risk assessment and therefore make a decision."[32]

Question 21: We understand that the United States' interpretation of Article 5.7 (as providing the time for Members to conduct a risk assessment when circumstances change) only relates to situations where an exporting Member makes a claim as to the disease-free status of a region.

(a) Is our understanding correct?

(b) If so, what happens in case the exporting Member makes any other types of market access request (e.g. an equivalence request under Article 4) or there is a need to update the risk assessment (as was the case in *Japan – Apples*)

[32] Individual Experts' Responseto the Panel Question No. 47(c), para. 405.

ANSWER:

41. The United States appreciates the opportunity to clarify its views on this issue. The fundamental issue involving the proper relationship between Article 2.2, Article 5.1 and Article 5.7 in the face of changing circumstances or scientific uncertainty could arise in many other scenarios in addition to the one in this dispute.[33] For instance, in a situation involving SPS measures aimed at preventing the introduction of disease, the importing Member may face a situation where there is has been a change in scientific understanding, or in the availability of different types of control measures. Similarly, with respect to an equivalence regime: to the extent that the measures under the regime are subject to Article 2.2 and 5.1, the rights and obligations under Article 5.7 would apply while the importing Member is examining a claim of equivalence.

Question 22: Please address the conclusion of the Appellate Body in *Japan – Agricultural Products II* that the four requirements of Article 5.7 are cumulative. In your responses, please refer to the second sentence of Article 5.7, beginning with the words "in such circumstances…", and explain the relevance of these words for interpreting the relationship between the four requirements.

ANSWER:

42. In its discussion of Article 5.7 in *Japan – Agricultural Products II*, the Appellate Body stated that a measure falling within the scope of Article 5.7 must be:

> "[Under the first sentence] (1) imposed in respect of a situation where 'relevant scientific information is insufficient'; and (2) adopted 'on the basis of available pertinent information'."

And

> "[Under the second sentence] may not be maintained unless the Member which adopted the measure: (1) 'seek[s] to obtain the additional information necessary for a more objective assessment of risk'; and (2) 'review[s] the . . . measure accordingly within a reasonable period of time'."[34]

43. The phrase "[i]n such circumstances," in the second sentence of Article 5.7 reflects, as the Appellate Body noted, the "cumulative" nature of the four requirements that must be met for a measure to fall within the scope of Article 5.7.

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[33] The Panel refers to *Japan – Apples (AB)*, The findings in that dispute are completely consistent with the U.S. interpretation of the relationship between Article 5.7 and Articles 2.2 and 5.1. In fact. the Appellate Body did not reach the issue of risk assessments based on "subsequent information." *Japan – Apples (AB)*, para. 215. Nor does the need to update a risk assessment necessarily mean that the "relevant scientific information is insufficient" to conduct a risk assessment, a condition for application of Article 5.7.

[34] *Japan – Agricultural Products II (AB)*, para. 89.

44. In sum, the United States understands that Article 5.7, although consisting of two sentences, sets out a single, four-part set of requirements. These requirements are "cumulative," in the sense that each of the four requirements must be met in order for a measure – which otherwise would be inconsistent with SPS obligations as being maintained without sufficient scientific evidence and/or not based on a risk assessment – to be justified under the terms of Article 5.7.

Question 23: With reference to the four cumulative requirements identified by the Appellate Body in *Japan – Agricultural Products II*, please explain whether not having had the time to complete a risk assessment is the same as having insufficient scientific evidence to do so.

ANSWER:

45. These relate to separate elements of Article 5.7. Insufficient scientific evidence relates to the first element of the first sentence, and would help to inform the amount of additional information required under the first element of the second sentence. With regard to the time required to complete an assessment once additional information is obtained, the second element of the second sentence is clear that the importing Member is entitled to "review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

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?

ANSWER:

46. As the United States has explained, and as the Panel question indicates, the U.S. interpretation of Article 5.7 is based on a reading of the provision in the context of other SPS provisions, notably Article 5.1 and Article 2.2. The United States is not aware of an interpretative approach to other provisions of the SPS Agreement that would provide the needed time under Article 2.2 to obtain and review "sufficient evidence," or to complete a new assessment of risks under Article 5.1. The United States further notes that the Panel in *EC – Approval and Marketing of Biotech Products* recognized that "[I]t may be inferred from the absence of any temporal limitation that at any given time, SPS measures must be based on an

assessment of risks which is appropriate to the circumstances existing at that time[.]"[35] Accordingly, in a matter in which a complainant brings a claim based on Article 5.1, the risk assessment upon which the measure is based must be appropriate to the circumstances at that moment in time. In the view of the United States, then, a Member could assert another Member's breach of Article 5.1 by claiming changed circumstances.

47. Article 5.7 is typically invoked by the responding Member, and obligates the Member invoking it to review its SPS measure "within a reasonable period of time." If the responding Member cannot satisfy the standard for adopting a measure taken provisionally, then it cannot claim the protection of Article 5.7.

Question 26: Article 5.2 requires Members, when conducting a risk assessment under Article 5.1, to take into account the "prevalence of specific diseases" and the "existence of [] disease-free areas". In light of these specific textual references between the risk assessment-related provisions and those on disease prevalence, why would a claim of disease-freedom or low disease prevalence under Article 6.3 trigger Article 5.7, rather than a need to update an existing risk assessment? In your response, please consider the findings of the panels in *EC – Approval and Marketing of Biotech Products* and *Japan – Apples*.

ANSWER:

48. The U.S. position is not, as the question states, that "a claim of disease-freedom or low disease prevalence under Article 6.3 [would] trigger Article 5.7, rather than a need to update an existing risk assessment." Rather, the United States understands that a claim of disease-freedom or low disease prevalence would indeed require a need to update a risk assessment (or at least that part of the assessment addressed to risks particular to the exporting country). Article 5.7 would not be automatically "triggered." Rather, the rights and obligations under Article 6.3 would apply in the event the importing Member undertook an evaluation of the claim. As the United States has explained, this interpretation fits the practice of Members (as well as the OIE). And this is the only interpretation that avoids the untenable result that the importing Member must immediately change its existing measures upon receipt of a claim, even while the new risk assessment is underway.

49. As the United States has explained, the application of Article 5.7 in this dispute is informed by Article 2.2, Article 5.7, and Article 6.3.[36] Article 5.2 provides that a risk assessment should take into account factors such as "prevalence of specific diseases or pests" as well as "existence of pest- or disease-free areas." Article 6, particularly Article 6.3, also specifically addresses situations in which an exporting Member asserts a claim of disease free status. In reading the SPS Agreement as a whole and these relevant provisions together, it is clear that a claim of changed circumstances, in this case disease freedom, contemplates an interaction between importing and exporting Members to validate the claim and incorporate the conclusion into an assessment of risk.

[35] *EC – Approval and Marketing of Biotech Products*, para. 7.3031.
[36] U.S. Second Written Submission, paras. 9-15.

50. The findings of the panels in *EC – Approval and Marketing of Biotech Products* and *Japan – Apples* are not in opposition with the view of the United States in this dispute, and the scientific questions at issue were quite different.[37] Those panels addressed risk assessments under Article 5.1 and Article 2.2. *Japan – Apples* did not find that Article 5.7 was not available in a situation in which a claim of changed circumstances is made with respect to disease status. In fact, the Appellate Body in that case expressly noted that neither the Panel nor the Appellate Body itself had made findings on the issue of scientific evidence arising subsequent to the original risk assessment.[38] In *EC – Approval and Marketing of Biotech Products*, the panel found that Article 5.7 was not available because the European Communities had in fact completed risk assessments based on the new information contained in the applications for product approvals.[39]

4 THE TIMING OF APHIS' REVIEW OF ARGENTINA'S APPLICATION CONCERNING FRESH (CHILLED OR FROZEN) BEEF

Question 27: With reference to the letter sent by Dr Clifford to SENASA on 24 September 2010, stating that APHIS was "currently drafting a proposed rule that would allow the importation of fresh, chilled, or frozen Argentine beef under certain conditions", please explain:

(a) Whether, under US regulations or as a matter of practice, APHIS only starts drafting a proposed rule after the completion of a risk assessment;

ANSWER:

51. Generally, as a matter of practice, APHIS starts drafting a proposed rule after Veterinary Services (VS) staff have prepared a preliminary draft of a risk assessment. Importantly, this preliminary draft does not represent USDA's full and final scientific conclusions. Rather, it is a working paper that is subsequently subjected to internal scientific and legal reviews and potential revision (both within APHIS and USDA). After these reviews and any subsequent revisions, the finalized draft of the risk assessment is published as part of a proposed rule for public comment and possible further revision and changes.

(b) If so, whether the completed risk assessment is made available to the requesting country prior to the publication of a proposed rule;

ANSWER:

[37] In *Japan – Apples*, the issue was whether apples were a pathway for entry, establishment, or spread of fire blight. In *EC – Approval and Marketing of Biotech Products*, the issue was the risk of harm based on the science of biotechnology products.

[38] "Japan failed to establish that the Panel utilized subsequent scientific evidence in evaluating the risk assessment at issue, it is not necessary for us to express views on the question whether the conformity of a risk assessment with Article 5.1 should be evaluated solely against the scientific evidence available at the time of the risk assessment, to the exclusion of subsequent information." *Japan – Apples (AB)*, para. 215.

[39] *See, e.g., EC – Approval and Marketing of Biotech Products*, para. 7.3260.

52. The United States appreciates the opportunity to clarify that the premise of this question does not match the U.S. regulatory system. The "completed risk assessment" does not exist prior to the publication of the proposed rule. Rather, the risk assessment is completed at the same time as the final rule is completed, and both documents are published (and made available to the requesting country) at the same time.

53. APHIS also makes a draft risk assessment available to the requesting country when the proposed rule and draft risk assessment are made available for public comment. As discussed above, prior to that time, the preliminary draft is still a working paper that could change after appropriate scientific and legal reviews. Even after it is made publicly available along with the proposed rule, the draft risk assessment is subject to additional reviews and alterations as APHIS considers and addresses all relevant public comments to the proposed rule that it considers as part of the notice-and-comment process.

(c) In light of your previous answers, what is the significance of this letter? Can the Panel infer from the letter that, as of 24 September 2010, APHIS had all the required information to proceed with its determination with respect to Argentina's request?

ANSWER:

54. At the time of the September 24 letter, APHIS had not acquired all the information it needed to make a final determination with respect to Argentina's request. As discussed above, substantial scientific and legal reviews had to be completed before the risk assessment could be made publicly available, concurrent with the proposed rule. After publication, consideration of comments on the draft, including any comments from Argentina, and another round of internal reviews, had to be completed before APHIS could finalize the risk assessment.

Question 28: In its second opening statement, the United States refers to the April 2014 risk assessment for Northern Argentina as a "draft risk analysis".

(a) Where do the relevant US regulations specify that a published risk assessment is a "draft"? When does the "draft" risk assessment become "final"? Please provide references.

ANSWER:

55. U.S. regulations do not use the terms "draft" and "final" with regard to its risk assessments for FMD. The United States has used these terms as shorthand for the status of these documents under the U.S. regulatory system, and in particular, to highlight that (1) up until finalization, a risk assessment is subject to changes, and (2) that the final risk assessment and final rule are part of a single package.

56. 9 C.F.R. §92.2(e) provides that APHIS will make its risk assessments available for public review and comment.[40] This is done through a proposed rule or a proposed notice of determination. 9 C.F.R. §92.2(f) states that APHIS will provide a period of time during which the public may comment on its evaluation.[41] During the comment period, the public will have access to the information upon which APHIS based its evaluation, as well as the evaluation itself. Once APHIS has reviewed all comments received, it will make a final determination regarding the request and will publish that determination in the Federal Register. While not explicitly stated in 9 C.F.R. §92.2, the final determination includes releasing the final risk assessment.

(b) Please explain the steps that occur between the completion of a risk assessment and the issuance of a proposed rule. Are there any administrative guidelines or similar procedures regarding the usual length of time incurred at each step?

ANSWER:

57. As explained above, the risk assessment process is not complete until the draft assessment and the accompanying proposed rule have undergone multiple levels of review and a public comment period, resulting in a final risk assessment and final rule.

58. Before the issuance of a draft risk assessment and proposed rule, a variety of steps must be completed. A working draft of the risk assessment and a regulatory work plan must be prepared. A working draft of the proposed rule must also be prepared. These documents are subjected to multiple levels of scientific and legal reviews. After publication and a public comment period, APHIS must respond to comments and revise the proposed rule and draft risk assessment as appropriate. A final rule and final risk assessment must then be submitted through the entire review process before those documents are published as a final determination.

59. APHIS is not subject to guidelines or rules regarding the length of time to complete the required steps before a proposed rule can be issued. The time needed for these steps depends on the facts and circumstances involved. As would be expected, complicated scientific issues, novel approaches, and complex mitigation measures can take longer to evaluate than other simpler scenarios.

Question 29: At what point in time did APHIS obtain all the information necessary to complete the risk assessment for Northern Argentina issued in April 2014? Please explain exactly what specific information cited in the risk assessment was missing prior to that moment.

ANSWER:

60. APHIS obtained the information necessary to complete the April 2014 risk assessment for Northern Argentina after its November 2013 site visit. After the September 2006 site visit to

[40] 9 C.F.R. §92.2(e). Exhibit USA-76.
[41] 9 C.F.R. §92.2(f). Exhibit USA-76.

Northern Argentina to investigate the FMD outbreak there, APHIS proceeded with Argentina's application for Patagonia South and conducted a site visit there in February 2009. After these site visits, APHIS had to review the information obtained and assess the potential risks and mitigation measures. Specific information regarding the 11 factors that had been obtained in the September 2006 and the February 2009 site visits had to be re-confirmed and updated, a step which APHIS informed SENASA of in 2012.

Question 30: Did APHIS request new information from SENASA in connection with Argentina's application for imports of fresh (chilled or frozen) beef between 2006 and the date of the establishment of the Panel? If so, what information was requested, and when? Please provide references.

ANSWER:

61. After the FMD outbreak in Argentina in 2006, APHIS requested permission for a site visit to northern Argentina, conducted in September 2006,[42] to obtain information related to the outbreak. APHIS also requested permission for another site visit to the Patagonia region, conducted in February 2009,[43] and another site visit to northern Argentina, conducted in 2013,[44] in order to substantiate the information previously reported in the documentation and to update the risk analyses.

62. During the site visits, APHIS staff requested that SENASA provide APHIS with any information related to the veterinary and legal infrastructure of SENASA, border control procedures, disease control measures, laboratory and diagnostic capabilities, biosecurity procedures on cattle farms and in slaughter facilities, animal health recordkeeping systems, movement controls, and disease surveillance systems. APHIS was particularly interested in any updated information related to personnel and surveillance activities which may have changed since APHIS' last site visits, as well as any regulatory changes and changes in the veterinary infrastructure that might impact SENASA's FMD oversight. The site visits also incorporated an evaluation of outbreaks that had occurred in 2003 and 2006 and the effectiveness of control measures in these outbreaks. During the time period after the site visits, APHIS reviewed the new updated information obtained during the site visits as well as considered any implications of new SENASA regulations that could affect the FMD risk characterization.

Question 31: In several instances, the United States refers to SENASA's "history of intentional concealment and delayed reporting of outbreaks" as a reason why it could not rely on the information provided by SENASA. Other than the delayed reporting of the 2001 outbreak, does the United States have any other evidence of any concealment or delay on the part of SENASA?

ANSWER:

[42] U.S. First Written Submission, para. 145.
[43] U.S. First Written Submission, paras. 160-161.
[44] U.S. First Written Submission, para. 147.

63. The United States would note that the question does not precisely match the U.S. positions in this dispute. The United States has not made any sweeping statements that it cannot rely on information provided by SENASA. To the contrary, the final rule for Patagonia and the proposed rule for Northern Argentina do rely in substantial part on information provided by SENASA.

64. At the same time, the United States has explained that it needed to verify the information provided by SENASA and the ability of SENASA to maintain effective internal controls. The United States likewise verifies information and capabilities when other exporting countries make claims of disease-free status.

65. It is with respect to the verification of SENASA information and capabilities that the "history of intentional concealment and delayed reporting of outbreaks" has played a significant role. As the United States has explained, this history called for greater diligence, and for more time, to verify that a revamped and reorganized SENASA was able to ensure that beef from Argentina met the U.S. appropriate level of protection with respect to FMD.

5 THE TIMING OF APHIS' REVIEW OF ARGENTINA'S APPLICATION CONCERNING THE RECOGNITION OF PATAGONIA AS FMD-FREE

Question 32: We refer you to the letter that Dr Clifford sent to SENASA on 27 April 2009 (Exhibit ARG-79), stating that no additional information was "currently required to proceed with APHIS' rulemaking with respect to Patagonia", and establishing contact points for further "discussions if necessary". Please explain to the Panel what happened with respect to Argentina's application for Patagonia from that date to the date of establishment of the Panel. What additional information was requested of SENASA during that time-period? When was it requested? When was it provided? Please provide references.

ANSWER:

66. After April 2009, APHIS reviewed the information it had collected during its February 2009 site visit. In November 2012, APHIS discussed with SENASA the possibility of another site visit to complete its evaluation.[45] Argentina did not respond to this offer until July 2013, when it proposed the site visit occur in November 2013.

Question 33: At what point in time did APHIS obtain all the information necessary to complete the risk assessment for Patagonia issued in January 2014? Please explain exactly what specific information cited in the risk assessment was missing prior to that moment.

ANSWER:

67. APHIS obtained all the information necessary to complete the January 2014 risk assessment for Patagonia after its November 2013 site visit. After its September 2006 site visit

[45] U.S. First Written Submission, para. 162.

to Northern Argentina to investigate the FMD outbreak there, APHIS published a proposed rule for Patagonia South in 2007.[46] However, in response to comments that the risk analysis underlying the proposed rule was missing current information and improperly relied on outdated information, APHIS requested permission to conduct another site visit to Patagonia South to update the risk analysis. When SENASA finally agreed to this request, SENASA asked that Argentina's application for the Patagonia region be modified to include not only Patagonia South, but also Patagonia North B. APHIS then conducted a site visit to gather information on both areas in February 2009. After these site visits, APHIS had to review the information obtained and assess the potential risks and mitigation measures. Specific information regarding the 11 factors that had been obtained in the September 2006 and February 2009 site visits had to be re-confirmed and updated, a step which APHIS informed SENASA of in 2012.

Question 34: In its comments on the OIE's answers, the United States indicates that "during its February 2009 site visit, APHIS attempted to verify the implementation of SENASA Resolution No. 1282". Was APHIS able to satisfactorily verify the implementation of this resolution? If not, please explain why not. In your answer, please comment on Dr Cupit's response to Panel question No. 32, paragraph 261, and Drs Batho and Bonbon's responses to Panel question No. 33, paragraphs 268-269.

ANSWER:

68. At the time of APHIS's February 2009 site visit, it did not reach a final conclusion as to the full implementation of SENASA Resolution 1282 (2008), which governs the different requirements for movement of FMD-susceptible commodities. Dr. Batho's response[47] assumes that the resolution was fully implemented; however, assuming away the question is not scientific verification of implementation. Dr. Bonbon's response[48] draws a conclusion based on the condition that the measure is "well implemented." Dr. Cupit's response[49] does not address implementation of the measure.

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 36: Please fill in the missing information in the Table below in order to enable the Panel to compare the timing of APHIS' review of Argentina's applications as compared to the applications of Japan, the United Kingdom, Uruguay and Santa Catarina.

ANSWER:

[46] Change in Disease Status of the Patagonia South Region of Argentina with Regard to Rinderpest and Foot and Mouth Disease. Exhibit USA-104.
[47] Individual Experts' Responses to Panel Question No. 33, paras. 268-269.
[48] Individual Experts' Responses to Panel Question No. 33, paras. 268-269.
[49] Individual Experts' Responses to Panel Question No. 32, paras. 257-261.

Member	Latest FMD outbreak	Date of application	Completion of the risk assessment	Proposed rule	Final rule
Northern Argentina	2006	Nov. 2002	Aug. 2014	Aug. 2014	Pending
Patagonia South	1976	Aug. 2003	Jul. 2005 (updated Jan. 2014)	Jan. 2007 (updated Jan. 2014)	Aug. 2014
Patagonia North B	1994	Dec. 2008	Jan. 2014	Jan. 2014	Aug. 2014
Uruguay	2001	Dec. 5, 2001	Nov. 2002	Feb. 2003	May 2003
Santa Catarina (Brazil)	1993	Sept. 2007	Jan. 2009 (updated Aug. 2010)	Apr. 2010	Nov. 2010
Japan	2010	Oct. 6, 2010	Apr. 2011	Jul. 2011	Aug. 2012
United Kingdom	2007	End of 2007	Mar. 2008	Jul. 22, 2008	Nov. 2010

69. As stated in prior submissions, the facts and circumstances of each application are different, and it is not possible to draw any meaningful comparison or conclusions simply based on the critiera and the dates listed above. There are too many variables and Argentina has made no effort to put forward systematically in any way a basis for comparison. Factors such as geography, the regulatory authority and infrastructure, spread and number of the animals themselves, and even the response time and completeness of the answers by applicants are different. As Dr. Cupit noted in his answer to Question 59 concerning the time needed to complete risk assessments in Santa Catarina and Patagonia: "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."[50]

Question 37: In its second written submission, the United States notes that "[r]egulatory agencies such as APHIS do not have unlimited resources and staff, try as they might to adjust to changing demands and circumstances". In its second opening statement, the United States observes that the involvement of APHIS' staff in these WTO proceedings "has occupied a considerable amount of their time". What is the relevance of these statements for the timing of APHIS' review of Argentina's applications as compared to the applications of Uruguay, Brazil (Santa Catarina), Japan, and the United Kingdom?

ANSWER:

70. The purpose for underscoring to the Panel the limited nature of APHIS time and expert resources is to emphasize that the review of applications for import authorization does not exist in a vacuum. It is difficult to provide exact time and resource expenditures spent in connection with a specific application, let alone to do a comparative time, resource, and budgetary analysis across the entire APHIS regulatory docket. It is a fact, as recognized by the scientific experts,

[50] Individual Experts' Responses to Panel Question No. 59, para. 475.

that USDA review of an import authorization application for animal health and safety issues is considered to be "quite rigorous"[51] and relied upon by other Members.[52] It is worth noting that for the period following Argentina's request for panel establishment, time and resources that could have been dedicated solely to addressing Argentina's applications has, of necessity, had to have been devoted to addressing these proceedings.

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?

ANSWER:

71. Based on the text of the SPS Agreement, Article 5.7 is only an explicit exception to Article 2.2. Yet, panels and the Appellate Body have repeatedly found that Article 5.7 also serves as an exception to Article 5.1's requirement to base a measure on a risk assessment.[53] The reason for this common-sense understanding is clear – if a Member may maintain a measure without sufficient scientific evidence, it would violate common sense to say that a Member must still base a measure justified under Article 5.7 on a full, scientific assessment of risks.

72. At least under the circumstances such as present in the current dispute, the same type of logic would apply: upon a successful invocation of Article 5.7, Argentina cannot prevail on its claim that a different measure (such as the Uruguay rule) would meet the U.S. ALOP with respect to Argentina.

73. It is helpful to recall the circumstances under which Article 5.7 can be successfully invoked. A situation covered by Article 5.7 is by definition one in which "relevant scientific evidence is insufficient." Because of the insufficiency of scientific evidence, a Member cannot

[51] Transcript of the Meeting with the Experts, para.1.298 (Cupit).
[52] Transcript of the Meeting with the Experts, para.1.293 (Bonbon).
[53] *E.g., EC – Marketing and Approval of Biotech Products*.

complete its assessment of risks, including full consideration of factors listed in Article 5.2 and Article 5.3, such as "the relative cost-effectiveness of alternative approaches to limiting risks."[54] That is the reason that a provisional measure taken "on the basis of available pertinent information" is permitted.

74. At least in the circumstances of this dispute, the insufficiency of the scientific evidence that hampered the completion of a full assessment of FMD risks from Argentine beef would similarly hamper a determination under Article 5.6. Under Article 5.6, a Member is obligated to ensure that its measure is "not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility." However, in the context of Article 5.7, it is precisely the fact that a full assessment of risks is not possible that means a provisional measure can be taken. Although "the obligations in Article 5.1 and Article 5.6 are not dependent upon each other," the Appellate Body stated that "factual elements relevant to the analysis under one provision may also be relevant to the analysis under the other provision."[55] Accordingly, the insufficiency of scientific evidence presented in the case of Article 5.7 is the core factual premise that is relevant to both Article 5.1 and Article 5.6 analyses. That is, where a Member does not have sufficient scientific evidence to make an assessment of risk, it would not be able to determine whether a measure (or an alternative) achieves its appropriate level of protection, for purposes of the evaluation required under Article 5.6.

75. In this dispute, where no risk assessment has been completed (nor under Article 5.7, need it have been completed by the time of panel establishment due to insufficient evidence) with respect to whether beef from Argentina met the U.S. ALOP from FMD, there is no possible way that Argentina can meet its burden to show that at the time of panel establishment the rule applicable to Uruguay would have met the U.S. ALOP.

Question 40: In its response to Panel question No. 57, the United States asserts: In a situation based on a provisional measure such as this, the United States has not issued a fully considered and final determination on the record. Accordingly, the Panel in such a situation would not have had an opportunity to consider the full reasoning behind the decision of the United States. If the panel were to go further than Article 2.2 and Article 5.1 and reach other claims such as Article 2.3 and Article 5.6, it would be making affirmative findings on complex regulatory issues without the benefit of a full record.

(a) Is the United States arguing that a Panel can never reach conclusions with respect to claims under Articles 2.3 and 5.6 if the importing Member has not completed its own risk assessment as required by Article 5.1? In your response, please consider the Appellate Body's statement in *Australia – Apples* that "the obligations set out in Article 5.1 and Article 5.6 are distinct and legally independent of each other", and that, pursuant to Article 5.6, a panel is "required to undertake its own analysis of the question of whether the alternative measures proposed by [the complainant] would achieve [the respondent]'s appropriate level of protection"?

[54] SPS Agreement, Article 5.3.
[55] *Australia – Apples (AB)*, paras. 346, 347.

(b) What would be the implications of the United States' interpretation on the rights of other Members under the WTO covered agreements, including the right to initiate dispute settlement proceedings with a view to the "satisfactory settlement of the matter" under Article 3.4 of the DSU?

ANSWER:

76. The question posed by the Panel asks whether claims under Article 2.3 and Article 5.6 could be reached in a situation in which an importing Member had not completed its risk assessment under Article 5.1. As an initial matter, the United States notes that the theoretical question on the relationship between various provisions, such as this question, is difficult to answer in the abstract. The role of any panel in any dispute is to apply the provisions to the facts at issue in a particular dispute, and it is difficult to know all the various fact patterns that might possibly arise under the SPS Agreement.

77. That said, in a scenario as described in Question 39 above, in which scientific evidence is insufficient and Article 5.7 is invoked, it is difficult to see how a Panel could reach these claims. The insufficiency of scientific evidence, which is what prevents a completion of a risk analysis under Article 5.1, would also provide difficulties for the completion of an Article 5.6 and Article 2.3 analysis. Full analysis of those claims would draw upon the same factual core that is the basis for Article 5.1 assessments of risk. For example, an assessment of risks under Article 5.1 would draw upon the factors listed in Article 5.2 and Article 5.3, which would be relevant for an assessment of conditions under Article 2.3 and feasible alternatives under Article 5.6. Accordingly, even though the obligations under Article 5.1 and Article 5.6 are distinct, the Appellate Body stated that "factual elements relevant to the analysis under one provision may also be relevant to the analysis under the other provision."[56]

78. In other situations outside of the Article 5.7 context in which a Member did not complete the assessment of risk required under Article 5.1, it is possible that conclusions could be reached under Article 2.3 and Article 5.6.

79. This view elaborated above is consistent with Article 3.4 of the *Understanding on the Rules and Procedures Governing the Settlement of Disputes* (DSU) that recommendations and rulings "shall be aimed at achieving a satisfactory settlement of the matter" as well as supporting the "aim of the dispute settlement mechanism to secure a positive solution to a dispute" in Article 3.7 of the DSU. In fact, during the course of the proceedings in this dispute, APHIS has continued to process Argentina's applications for import authorization. APHIS issued a final determination on August 29, 2014, recognizing Patagonia as a region free of foot and mouth disease.[57] On that same day, APHIS also published a proposal to permit imports of fresh beef from Northern Argentina under certain conditions.

9 REGIONALIZATION (ARTICLE 6 OF THE SPS AGREEMENT)

[56] *Australia – Apples (AB)*, paras. 346, 347.
[57] Importation of Beef from a Region in Argentina. Exhibit USA-168.

Question 42: Is there any way to request authorization for imports of FMD-susceptible products into the United States other than claiming FMD-freedom?

ANSWER:

80. As a preliminary matter, the United States notes that not all FMD-susceptible products (*e.g.*, rendered proteins, treated hides, etc.) require authorization from APHIS in order to be imported into the United States. With respect to other FMD-susceptible products, such as live animals, fresh meat, and certain other animal products, authorization from APHIS is required.

81. Countries that are not FMD-free may request authorization to export FMD-susceptible products to the United States using the procedures set out in 9 C.F.R. §92.2. As APHIS explained in its public notice establishing the new procedures in 1997: "We… are establishing procedures by which regions may request permission to export animals and animal products to the United States under specified conditions, based on the regions' disease status. . . . Each request for approval to export a particular type of animal or animal product commodity to the United States from a foreign region must be made to the Administrator, and must include, in English, the following information about the region: . . . 2. Disease status-i.e., is the restricted disease agent known to exist in the region? If "yes," at what prevalence? If "no," when was the most recent diagnosis? . . . Once we have received from a potential exporting region the information necessary to conduct a risk assessment, and have evaluated the risk, we will determine under what conditions an importation can be safely allowed."[58]

82. APHIS' guidance document "Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking" similarly explains that the "[i]nitiation of the regionalization process . . . begins when the Office of the Deputy Administrator, VS, receives a request from the Chief Veterinary Officer (CVO) of a foreign government requesting recognition of status for a particular disease or seeking authorization to export animals and/or animal products to the United States."[59] APHIS' Regionalization Evaluation Services (RES) "evaluates the animal health status of foreign regions (zones) and the risk of disease introduction via commodities for import into the United States. . . . RES risk assessments for regions requesting APHIS recognition of disease freedom or a commodity-based evaluation (if the region cannot be considered free of the disease) typically follow an 8-factor framework defined in title 9, Code of Federal Regulations, part 92.2(b)."[60] In these risk assessments, RES determines the sanitary or phytosanitary characteristics of the specified region with respect to the specific disease or pest at issue and customizes appropriate import conditions to the particular SPS situation of each region.

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?

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[58] 62 F.R. 5600 (October 28, 1997) at 56000, 56002-56003. Exhibit USA-70. (Emphasis added)
[59] *See* "Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking." Exhibit USA-74, p. 2. (Emphasis added)
[60] *See* USDA Animal and Plant Health Inspection Service "Regionalization" Webpage (Emphasis added), available at: Exhibit USA-176.

ANSWER:

83. Article 6.2 should be read together with Article 6.1 and Article 6.3. The first sentence of Article 6.2 sets forth the obligation that Members should recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. The second sentence provides additional clarity as to the scope of the "concept." That is, those conceptual areas are to be defined on the basis of "factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls." Accordingly, the use of the word "determination" is in the sense of "[t]he process of making a notion more specific by the addition of attributes."[61]

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?

ANSWER:

84. The second sentence of Article 6.1 discusses illustratively a number of factors that Members "shall take into account" in "assessing the sanitary or phytosanitary characteristics of a region." These factors are not exhaustive, given the use of the phrase "inter alia." The assessment is part of the process of meeting the obligation to "ensure" that SPS measures are adapted to the sanitary or phytosanitary characteristics of the area.

85. As discussed in the answer to Question 44, the second sentence of Article 6.2 describes attributes that specify how the concept of areas and areas of low pest or disease prevalence is defined. The attributes listed in the second sentence of Article 6.2 are illustrative, given the use of the phrase "such as." Accordingly, the factors listed in the second sentence of Article 6.1 and in the second sentence of Article 6.2 are not contradictory or mutually exclusive. In fact, in the process of "ensur[ing]" that SPS measures are appropriately adapted, the two lists of factors could be complementary in many instances.

Question 46: What is the meaning of the words "in particular" in Article 6.2 in terms of the relationship between Article 6.2 and Article 6.1?

ANSWER:

86. Article 6.1 sets forth the obligation of the Member to "ensure" that SPS measures "are adapted" to the characteristics of an area. In following Article 6.1, Article 6.2 states that Members shall "in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence." The word "particular" or phrase "in particular," when used in this way, refers to "[a] minute or subordinate part of a thing considered apart from the rest; a

[61] "Determination." The New Shorter Oxford English Dictionary (1993), p.651. Exhibit USA-177.

detail, an item; a feature, a factor."[62] In the context of Article 6.2, it is clear that the sentence of Article 6.2 is linking back to Article 6.1, and relates to it as a subordinate. Accordingly, the "concepts of pest- or disease-free areas and areas of low pest or disease prevalence" are a particular step towards a Member's fulfillment of its obligation to ensure that SPS measures are adapted to the characteristics of an area.

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?

ANSWER:

87. Under Article 6.1, a Member must ensure that its SPS measure is adapted to the characteristics of an area. If the area is free of disease, then the SPS measure must appropriately be adapted to that fact. A Member's conclusion that an area is free of disease would necessarily be part of "ensur[ing]" that the SPS measure is appropriately adapted. The title of Article 6 suggests that this is one process – "Article 6: Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence." This title shows that pest- or disease-free areas and areas of low-pest or disease prevalence are included in "[a]daption" of SPS measures.

Question 48: Do you consider that the 2005 risk assessment constitutes recognition of Patagonia South as FMD-free within the meaning of Article 6? If not, why not?

ANSWER:

88. No. Exhibit ARG-9 is a USDA Risk Analysis document that accompanied a January 5, 2007, proposal that would have recognized Patagonia South as a region free of FMD and rinderpest. A "Risk Analysis" that is made available together with a proposed regulatory document is not a final scientific assessment by the United States of disease free status. When USDA publishes a proposed regulatory document and accompanying Risk Analysis, it seeks public comment on the risk analysis and proposed regulation before taking final action on that regulatory proposal. After gathering public comments, USDA must respond to those comments and make any revisions to the regulatory proposal and accompanying Risk Analysis before those documents can be considered a final decision of the agency.

Question 49: Assuming, *arguendo*, that an OIE disease-status designation is not an international standard, guideline or recommendation, can it nevertheless be considered as a "criterion" of the relevant international organization within the meaning of Article 6.1?

ANSWER:

[62] "Particular." The New Shorter Oxford English Dictionary (1993), p. 2110. Exhibit USA-178.

89. No. The plain text and meaning of the word "criterion" is "[a] principle, standard, or test by which a thing is judged assessed, or identified[.]"[63] As the OIE itself noted in its answers to the Panel's questions, the OIE official status designation is the output or result of the OIE's process that uses the OIE Terrestrial Code to reach a conclusion about the disease situation in a particular country or zone.[64]

10 THE APPLICABILITY OF ARTICLE 8 AND ANNEX C(1) OF THE SPS AGREEMENT

Question 50: In its second written submission, the United States argues that, since "Article 6 directly relates to a Member's request to export a <u>product</u>", there is no reason to distinguish between requests for regionalization and requests to import a commodity. What is the relevance of this statement for the US position that Article 8 and Annex C(1) are not applicable in this dispute because they only cover procedures concerning specific products, and not the determination of disease status for geographical areas?

<u>ANSWER:</u>

90. Article 6.1 obligates Members to ensure that their SPS measures "are adapted to the sanitary or phytosanitary characteristics of the area . . . from which the product originated and to which the product is destined." The obligation is on the adaptation of measures to the characteristics of the areas of the exporting and importing Members. The paragraphs in the U.S. second written submission referred to by the Panel in this question are responding to Argentina's flawed assertion that Article 6 is only concerned with regionalization requests and not "commodity requests." Article 6.1 makes no distinction between so-called "regionalization requests" and "commodity requests." Article 6.1 is only concerned with a Member's obligation to ensure that SPS measures are adapted to the sanitary or phytosanitary characteristics of the area.

91. The obligation in Article 6.1 is wholly different from the obligations under Article 8 and Annex C(1). As the United States has explained in this dispute, the context provided by the specific obligations set out in Annex C show that the "control, inspection, and approval procedures" covered by Annex C relate to the characteristics of the products themselves. In contrast, the measures taken under Article 6 – which are related to adaptation to regional conditions -- are not within the scope of Annex C.[65]

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

Question 52: Who bears the burden of identifying "special needs" of purposes of Article 10.1? Does the obligation in Article 10.1 only apply if it is the exporting developing country

[63] "Criterion." The New Shorter Oxford English Dictionary (1993), p. 551. Exhibit USA-179.
[64] Transcript of the Meeting with the Experts, paras. 1.122-1.123. OIE Response to Panel Question No. 5, p. 7.
[65] U.S. First Written Submission, paras. 177-187.

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?

ANSWER:

92. Article 10.1 states: "In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members." The definition of the term "special needs" is not provided in the SPS Agreement. In making a claim based on Article 10.1, the Member claiming a breach of that obligation bears the burden of identifying and justifying the "special need." Further, the developing country Member claiming a breach of that obligation should show how it communicated its "special needs" to the other Member. Otherwise, the Member that is the subject of the claim would have no opportunity to "take account" of the developing country Member's "special need."

93. Further, the United States notes that the scope of the obligation in Article 10.1 is clear: "[It] is for the importing Member to 'take account' of developing country Members' needs. The dictionary defines the expression 'take account of' as 'consider along with other factors before reaching a decision.' Consistent with this, Article 10.1 does not prescribe a specific result to be achieved."[66]

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?

ANSWER:

94. Generally, post-panel establishment evidence may be relevant in two circumstances; first, as the Appellate Body found in *EC – Selected Customs Matters*,[67] such may be referred to by the parties and the panel to the extent relevant to the legal situation that existed as of panel establishment (when the matter was referred by the DSB to the panel); second, such evidence may be relevant to a panel's consideration of whether to exercise judicial economy over certain claims. Exhibits USA-133, USA-167, USA-168, and USA-169 demonstrate APHIS action in processing and reaching determinations with respect to Argentina's applications for import authorization. These regulatory documents reflect the significant effort and substantial work done by APHIS to ensure that its review of Argentina's application is thorough and well

[66] *EC – Approval and Marketing of Biotech Products*, para. 7.1620.
[67] *EC – Selected Customs Matters (AB)*, para. 188.

documented. It confirms, in a clear, tangible way, the provisional nature of the prohibition of Argentina's imports pending the collection and review of the necessary scientific information.

95. Further, and contrary to Argentina's arguments, the exhibits do not illustrate that the United States should have completed a more complete assessment of the FMD risks posed by Argentina by the time of panel establishment. Indeed the exhibits reflect the information collected by APHIS during the November 2013 site visit to Argentina – which of course occurred after panel establishment.[68]

Question 54: In the Annex to your second written submission, you argue that it cannot be assumed that non-compliance with the SPS Agreement would mean that a measure could not be justified under Article XX(b) of the GATT 1994, because the SPS Agreement requires a risk assessment, while the GATT 1994 does not. If the Panel were to find, *arguendo*, that the US measures are justified under Article XX(b) of the GATT 1994, what would be the legal implications for the Panel's findings under the SPS Agreement?

ANSWER:

96. If the Panel were to find that the United States measures are justified under Article XX(b) of the GATT 1994, the Panel would still need to evaluate the claims under the SPS Agreement. Nonetheless, a a finding that the U.S. measure is justified under Article XX(b) would be quite relevant for a number of SPS claims, such as under Article 2.2, because of an overlap in core factual issues regarding whether the measures were needed to meet the U.S. level of protection with respect to FMD. On the other hand, the relevance with respect to other SPS claims, such as under Article 10.1, would not be as clear.

[68] Risk of Importing Foot-and-Mouth Disease in Susceptible Species and Product from a region of Patagonia, Argentina (January 2014), pp. 5, 8. Exhibit USA-133. Notice of Determination of the Foot-and-Mouth Disease and Rinderpest Status of a Region of Patagonia, Argentina, p. 51532. Exhibit USA-167. Importation of Beef from a Region in Argentina, pp. 51509, 51510, 51512. Exhibit USA-168. Risk Analysis: Foot-and-Mouth Disease Risk from Importation of Fresh (Chilled or Frozen), Matured, Deboned Beef from Northern Argentina into the United States (April 2014). Exhibit USA-169.