

***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 FIRST PANEL MEETING**

February 25, 2014

TABLE OF EXHIBITS

Exhibit	Long Citation	Short Citation
USA-134	9 C.F.R. §94.1 (2013)	9 C.F.R. § 94.1
USA-135	Canada: Animal Health Regulations	Canada: Animal Health Regulations
USA-136	EU: Description of Importation Law and Regulation	EU: Description of Importation Law and Regulation
USA-137	9 C.F.R. §92.2 (1998)	9 C.F.R. § 92.2 (1998)
USA-138	Origin of the UK Foot and Mouth Disease epidemic in 2001, <i>Report of the Department of Environment, Food and Rural Affairs</i> (June 2002)	Origin of the UK Foot and Mouth Disease epidemic in 2001 (2002)
USA-139	Lasta, et al., Combined Treatments of Heat, Irradiation, and pH Effects on Infectivity of Foot-and-Mouth Disease Virus in Bovine Tissues (1992)	Lasta, et al., Combined Treatments of Heat, Irradiation, and pH Effects on Infectivity of Foot-and-Mouth Disease Virus in Bovine Tissues (1992)
USA-140	Cottral, Persistence of Foot-and-Mouth Disease Virus Animals, their Products and the Environment (1969)	Cottral, Persistence of Foot-and-Mouth Disease Virus Animals, their Products and the Environment (1969)
USA-141	Cottral, et al., The Survival of Foot-and-Mouth Disease Virus in Cured and Uncured Meat (1960)	Cottral, et al., The Survival of Foot-and-Mouth Disease Virus in Cured and Uncured Meat (1960)
USA-142	Henderson, et al., The Survival of Foot-and-Mouth Disease Virus in Meat and Offal (1948)	Henderson, et al., The Survival of Foot-and-Mouth Disease Virus in Meat and Offal (1948)
USA-143	Garland, et al., Cattle, sheep and pigs vaccinated against foot and mouth disease, (2011)	Garland, et al., Cattle, sheep and pigs vaccinated against foot and mouth disease, (2011)
USA-144	“OIE Terrestrial Animal Health Code” Description Webpage http://www.oie.int/international-	“Terrestrial Animal Health Code” http://www.oie.int/international-

	standard-setting/terrestrial-code/)	standard-setting/terrestrial-code/)
USA-145	Oxford English Dictionary (1993), “Reasonable”	Oxford English Dictionary (1993), “Reasonable”
USA-146	Oxford English Dictionary (1993), “Claim”	Oxford English Dictionary (1993), “Claim”
USA-147	Oxford English Dictionary (1993), “Recognize”	Oxford English Dictionary (1993), “Recognize”
USA-148	Oxford English Dictionary (1993), “Concept”	Oxford English Dictionary (1993), “Concept”
USA-149	Dr. Alberto E. Pecker, SENASA, Fiebra Aftosa: Su Paso Por La Argentina (October, 2007)	Pecker, Fiebre Aftosa: Su Paso Por La Argentina

TABLE OF REPORTS

SHORT FORM	FULL FORM
<i>Australia – Apples (AB)</i>	Appellate Body Report, <i>Australia – Measures Affecting the Importation of Apples from New Zealand</i> , WT/DS367/ABR, adopted 17 December 2010
<i>Brazil – Retreaded Tyres (AB)</i>	Appellate Body Report, <i>Brazil – Measures Affecting Imports of Retreaded Tyres</i> , WT/DS332/AB/R, adopted 17 December 2007
<i>China – GOES (AB)</i>	Appellate Body Report, <i>China – Countervailing and Anti-Dumping Duties on Grain Oriented Flat-Rolled Electrical Steel from the United States</i> , WT/DS414/AB/R, adopted 16 November 2012
<i>EC – Marketing and Approval of Biotech Products</i>	Panel Reports, <i>European Communities – Measures Affecting the Approval and Marketing of Biotech Products</i> , WT/DS291/R / WT/DS292/R / WT/DS293/R, Add.1 to Add. 9, and Corr.1, adopted 21 November 2006
<i>EC – Asbestos (Panel)</i>	Panel Report, <i>European Communities – Measures Affecting Asbestos and Asbestos-Containing Products</i> , WT/DS135/R and Add. 1, adopted 5 April 2001, as modified by Appellate Body Report WT/DS135/AB/R
<i>EC – Hormones (AB)</i>	Appellate Body Report, <i>EC Measures Concerning Meat and Meat Products (Hormones)</i> , WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998
<i>EC – Hormones (US)</i>	Panel Report, <i>EC Measures Concerning Meat and Meat Products (Hormones)</i> , Complaint by the United States, WT/DS26/R/USA, adopted 13 February 1998, as modified by Appellate Body Report WT/DS26/AB/R, WT/DS48/AB/R
<i>Japan – Apples (AB)</i>	Appellate Body Report, <i>Japan – Measures Affecting the Importation of Apples</i> , WT/DS245/R, adopted 10 December 2003
<i>Japan – Agricultural Products II (AB)</i>	Appellate Body Report, <i>Japan – Measures Affecting Agricultural Products</i> , WT/DS76/AB/R, adopted 19 March 1999
<i>US – Continued Suspension (Panel)</i>	Panel Report, <i>United States – Continued Suspension of Obligations in the EC – Hormones Dispute</i> , WT/DS320/R, adopted 14 November 2008, as modified by Appellate Body Report WT/DS320/AB/R

1 MEASURES AT ISSUE AND SCOPE OF ARGENTINA'S CLAIMS

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

ANSWER:

1. In its third party submission, the European Union ("EU") notes that Argentina has not challenged 9 CFR 94.1(a), the provision which sets forth the framework used by the U.S. Animal and Plant Health Inspection Service ("APHIS") to protect the United States from foot and mouth ("FMD") disease. This is correct, as can be seen on the face of Argentina's request for the establishment of a panel.¹ Accordingly, section 94.1(a) is not a measure within the Panel's terms of reference.

2. This has important implications for this dispute. Because Argentina has not challenged section 94.1(a),² Argentina has not challenged APHIS' determination that all regions not yet analyzed by APHIS are FMD-infected regions. Argentina has also not challenged APHIS' requirement that APHIS must first evaluate a region to determine its FMD disease status before allowing importations of animals and animal products from that region.³ Instead, with respect to its application to allow imports of beef under certain conditions from the entire country, Argentina challenges only "the application of the prohibition that has been maintained by the United States . . . on imports of fresh . . . bovine meat from Argentina, as contained in the 9 C.F.R. 94.1(b)⁴" and as effectuated through the "2001 Regulations."⁵ Thus, Argentina challenges APHIS' initial decision to revoke Argentina's prior import authorization for animal products and thereby prohibit (via section 94.1(b)) Argentina's exports of animals and animal products to the United States. That initial decision to revoke Argentina's import authorization, as the United States has explained previously, is consistent with Article 5.1 of the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement").

3. Argentina also challenges the continued application of that decision to prohibit FMD-susceptible imports from Argentina pending APHIS' determination in response to Argentina's application for authorization to imports fresh (frozen or chilled) beef from the Argentine territory

¹ Request for Establishment of a Panel, *United States - Measures Affecting the Importation of Animals, Meat and Other Animal Products from Argentina*, WT/DS447/2.

² Section 94.1(a) provides: "APHIS considers rinderpest or foot-and-mouth disease to exist in all regions of the world except those declared free of one or both of these diseases by APHIS." (emphasis added) (Exhibit USA-134).

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

⁴ Section 94.1(b) provides: "The importation of any ruminant or swine or any fresh (chilled or frozen) meat of any ruminant or swine that originates in any region where rinderpest or foot-and-mouth disease exists, as designated in paragraph (a) of this section, or that enters a port in or otherwise transits a region in which rinderpest or foot-and-mouth disease exists, is prohibited." (Exhibit USA-137).

⁵ Argentina's First Written Submission, at para. 162.

as a whole into the United States. Similarly, with respect to its application to recognize Patagonia South (and subsequently North B as well) as free of FMD, Argentina challenges “the application of the prohibitions continued in Part 94 Title 9 of the U.S. Code of Federal Regulations (“CFR”)⁶ that have been maintained by the United States . . . on imports of animals, meat and other animal products from the Patagonia region”⁷, again pending APHIS’ determination of Patagonia’s disease status. Given that Argentina has not challenged APHIS’ right under section 94.1(a) to first evaluate a region before allowing imports from that region, the continued application of the import prohibition in section 94.1(b) while Argentina’s two applications are pending with APHIS are not properly presented under Article 5.1, but rather must be evaluated under Article 5.7, as the United States explains in its response to Panel Question 24.

4. Because Argentina is challenging the application of section 94.1(b) to Argentina specifically, and not the import prohibition in general (“*i.e.*, the general ban on the importation of ruminants and ruminant meat that ‘originates in any region where foot-and-mouth disease exists’”) ⁸ Argentina’s claims do not involve inquiry into whether section 94.1(b) as such is consistent with Article 5 of the SPS Agreement.

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

Can you please confirm whether you believe the US measures are taken for the purpose set forth in Annex A(1)(a) of the SPS Agreement?

ANSWER:

5. The United States confirms that the U.S. measures at issue are taken for a purpose set forth in Annex A(1)(a) of the SPS Agreement.

6. Annex A(1)(a) states:

1. *Sanitary or phytosanitary measure* – Any measure applied:

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms[.]⁹

⁶ The “prohibitions” in Part 94 Title 9 of the CFR are contained in Section 94.1(b), not Section 94.1(a).

⁷ Argentina’s First Written Submission, at para. 389.

⁸ EU’s Third Party Submission, at para. 44.

⁹ SPS Agreement, Annex A(1)(a).

7. The process by which the United States renders decisions on applications for import authorization and for the designation of FMD-free status is set forth in 9 C.F.R. §92.2. The purpose of this process is to protect the health and safety of animals within the United States against the risk of entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms. Thus, the purpose of the process by which the U.S. renders its decisions falls within the scope of Annex A(1)(a).

Is Section 737 of the 2009 Omnibus Appropriations Act an SPS measure?

ANSWER:

8. Section 737 *was* an SPS measure, but the measure ceased to exist prior to the time that this dispute was initiated. Accordingly, the Panel need not make findings on Section 737. Since Section 737 ceased to exist prior to the time that this dispute was initiated, it is not within the Panel’s term of reference.

9. To be a measure subject to the Panel’s terms of reference, the measure must be in force when the Dispute Settlement Body (“DSB”) established the panel. Here, Section 737 expired on September 30, 2009, well before this dispute was referred to the DSB in Argentina’s December 7, 2012, request for a panel.

Question 4: What is the current status of the document in Exhibit ARG-63 under the United States domestic system? Is this still APHIS’ policy or has it been superseded by another document?

ANSWER:

10. The document contained in Exhibit ARG-63 (or 62 Fed. Reg. 56027 (October 28, 1997)) is an APHIS notice published nearly 17 years ago. It set forth guidance that provided background on APHIS’ view at the time as to how the Agency intended to apply the concepts of regionalization and risk analysis to regulating the importation of animals and animal products into the United States. As guidance, the document was not legally binding. The policy document “set forth the factors [APHIS took] into account when considering future requests to export animals or animal products into the United States” from regions.¹⁰ This document was to be read in conjunction with Title 9 of the CFR – specifically Section 92.2, which codified these factors. At that time, Section 92.2 required applications for the recognition of the animal health status of a region to contain information regarding 11 factors about the region.¹¹

11. Although it has not been superseded by another document, the 1997 document no longer precisely reflects APHIS policy. For example, APHIS never utilized the six risk categories

¹⁰ 62 Fed. Reg. 56027 (October 28, 1997) (Exhibit ARG-63).

¹¹ 9 C.F.R. 92.2(b)(1)-(11) (1998) (listing the information about the region to accompany the application) (Exhibit USA-137).

framework set out in the policy.¹² However, APHIS still considers that it is following the main intent of the 1997 policy. The policy document set out the APHIS approach (new at the time) to evaluating animal disease status, which is, at core, a holistic evaluation of the combination of a region’s disease risk and the available product mitigations to determine overall risk level. This broad approach is what APHIS continues to follow today, moving away from a binary categorization. In 2012, APHIS amended Section 92.2 to consolidate the 11 factors into eight factors to clarify the information it needed to perform the evaluations.¹³

Question 6: In paragraph 42 of its first opening statement, the United States asserts that Section 737 expired in September 2009 and after that time had no legal effect. Please explain the US statements to the SPS Committee and to Argentina after 30 September 2009 referring to obligations under Section 737.

ANSWER:

12. Section 737 did not have legal force after September 30, 2009. To the extent a statement made by a U.S. delegate to the SPS Committee suggested or could be understood to suggest otherwise, that statement was incorrect. As is clear on the face of the U.S. law, Section 737 expired on September 30, 2009.

Question 7: With respect to the second proviso of Section 737, please indicate whether the Secretary of Agriculture ever conducted the required review and issued a report to the Committee with his findings.

ANSWER:

13. The U.S. Department of Agriculture (“USDA”) did not finalize its review of the domestic animal health aspects of Argentina while Section 737 was in force. Therefore, the Secretary of Agriculture did not issue a report to the congressional committees because there were no final results during that time period.

14. Prior to the first panel meeting in this dispute, USDA completed its risk analysis supporting the proposal to recognize the FMD status of Patagonia. With respect to the rest of Argentina, USDA is finalizing its review. As discussed above in response to Panel Question 6, Section 737 has expired. Accordingly, U.S. law no longer requires USDA to submit a report of its findings to the U.S. Congress.

¹² The six categories identified were described as “benchmarks” or “targets.” APHIS further noted in the policy that the “risk characterizations themselves do not determine whether an animal or its products may be safely imported . . .” 62 Fed. Reg. at 56031. The 6 categories were a theoretical framework that APHIS thought might be useful at the time, but had since discovered through experience did not work in practice.

¹³ 77 Fed. Reg. 44107 (July 27, 2012) (Exhibit USA-73).

2 FOOT-AND-MOUTH DISEASE AND ERADICATION EFFORTS IN ARGENTINA

Question 8: In light of the explanation concerning the transmission of FMD contained in paragraphs 21 and 27-30 of the United States' first written submission, please explain the potential chain of transmission of FMD from Argentine fresh (chilled or frozen) beef to susceptible animals in the US territory. In your answer, please respond to Argentina's statement that "there is no a single case in record of transmission of the FMD disease through trade of fresh, chilled or frozen (deboned and matured) beef".

ANSWER:

15. As described in paragraphs 21 and 27-30 of the U.S. first written submission, FMD is a highly contagious and easily transmitted disease. FMD virus could be transmitted from Argentina to the United States through many scenarios. The most likely potential chain of transmission of FMD is through FMD-infected food waste derived from the use in the United States of Argentine fresh (chilled or frozen) beef. Such food waste, when fed to other animals such as swine, can transmit FMD.

16. APHIS has conducted studies analyzing the likelihood of exposure of FMD-susceptible species to FMD-infected beef. Infected food waste could come from legal imports from Argentina. Waste-feeder operations take plate and manufacturing waste (primarily waste from institutions and restaurants) and process the waste into feed for swine. These operations must adequately cook the waste to reduce the probability of survival of foreign animal disease agents in the waste. However, if such feed waste is inadequately processed, FMD-susceptible species such as swine in the United States could be exposed to the FMD virus should the feed waste contain FMD-infected beef from Argentina.

17. For example, the 2001 FMD outbreak in the United Kingdom was caused by pigs that had been fed FMD-infected garbage that had not been properly heat-sterilized. The FMD-infected garbage is believed to have contained remains of imported FMD-infected meat.¹⁴ In September 2000, FMD was introduced into a free area of South Africa by the feeding of pigs with untreated swill from a ship. The last outbreak in the United States, in 1929, was also triggered by the transmission of FMD-infected waste.¹⁵

18. As the United States noted in paragraph 109 of its first written submission, the United States has adopted a general prohibition on fresh, chilled, or frozen meat from countries that are not recognized by APHIS as free of FMD, in addition to protocols for the safe removal, transport, and disposal of waste from international carriers, as the United States considers these to be among the key potential pathways through which FMD could enter the country.

¹⁴ Origin of the UK Foot and Mouth Disease epidemic in 2001, Report of the Department of Environment, Food and Rural Affairs, at para. 7 (June 2002) (Exhibit USA-138).

¹⁵ Exhibit USA-26.

19. One technique to mitigate some of the risk of transmission of FMD in fresh, chilled or frozen meat is by properly maturing and deboning the meat. Maturing the meat decreases the presence of FMD virus. FMD viral titers decline rapidly in skeletal muscle of ruminants exposed to the acid environment resulting from rigor mortis during maturation of the carcass. Inactivation of FMD virus has been shown to occur rapidly at a pH of <6.0.¹⁶

20. Deboning the meat after maturation also reduces presence of the FMD virus. Certain tissues closely associated with muscle, such as lymph nodes, bone marrow, and blood do not undergo acidification to the same degree as muscle tissue during maturation, even when exposed to the acidic environment of skeletal muscle in rigor, and therefore fail to reach pH levels sufficient to inactivate the virus. Similarly, other tissues known to harbor the FMD virus do not undergo maturation (for example, head and feet). FMD virus has been shown to survive for up to 120 days in lymph nodes and 210 days in bone marrow at 1-7 degrees Celsius.¹⁷ Several studies have demonstrated the ability of FMD virus to survive for an extended period of time in cured, uncured, and frozen meat if these tissues are not removed.¹⁸

21. However, if meat is not properly deboned and matured, and visible clots and lymph nodes are not removed, FMD virus will remain in the meat and increase the risk of transmission.¹⁹ Accordingly, APHIS must validate that a country's infrastructure (including oversight and management of slaughterhouses) can implement any mitigation in a credible and consistent manner.

22. The OIE recognizes this potential risk of FMD transmission from deboned and matured beef because it is not an available option for export when a country or zone is FMD infected. In those instances, beef can only be exported as a cooked, canned, or dried product²⁰ as provided for in Article 8.6.26.

¹⁶ Lasta, et al., Combined Treatments of Heat, Irradiation, and pH Effects on Infectivity of Foot-and-Mouth Disease Virus in Bovine Tissues, at p. 36 (1992) (Exhibit USA-139).

¹⁷ Cottral, Persistence of Foot-and-Mouth Disease Virus Animals, their Products and the Environment, at 551 (1969) (Exhibit USA-140).

¹⁸ See Lasta, et al., Combined Treatments of Heat, Irradiation, and pH Effects on Infectivity of Foot-and-Mouth Disease Virus in Bovine Tissues, at 36 (1992) (Exhibit USA-139); Cottral, Persistence of Foot-and-Mouth Disease Virus Animals, their Products and the Environment, (1969) (Exhibit USA-140); Cottral, et al., The Survival of Foot-and-Mouth Disease Virus in Cured and Uncured Meat, (1960) (Exhibit USA-141); Henderson, et al., The Survival of Foot-and-Mouth Disease Virus in Meat and Offal, (1948) (Exhibit USA-142).

¹⁹ Exhibit USA-27, at p. 7 notes transmission through imported bones, meat, offal, and meat wrappers. See also Origin of the UK Foot and Mouth Disease epidemic in 2001, *Report of the Department of Environment, Food and Rural Affairs* (June 2002) (Exhibit USA -138); Garland, et al., Cattle, sheep and pigs vaccinated against foot and mouth disease, (2011) (Exhibit USA-143)

²⁰ OIE Terrestrial Code at Article 8.6.26 (Exhibit USA-144).

Question 11: Please explain the relevance of APHIS’ recognition of the regional cooperation and surveillance program involving Uruguay, Brazil and Argentina”, described in paragraph 330 of Argentina’s first written submission and mentioned in Exhibits ARG-8 and ARG-65, to Argentina’s claims.

ANSWER:

23. APHIS’ mention in its risk assessment of Uruguay and the Cuenca del Plata Agreement for the Eradication of FMD is not of particular relevance to the proper disposition of this dispute, which involves SPS obligations as applied to the U.S. regulatory consideration of Argentina’s two pending applications.

24. The Cuenca del Plata Agreement of 1987, encapsulating the regional cooperation program between Argentina, Brazil, and Uruguay, is aimed at harmonizing FMD-related strategies at a regional level, particularly for common border areas. For example, it addresses technical issues such as coordination of cattle vaccination in certain areas; controls on the movement of animals; identification by countries of susceptible species; and the frequency of meetings between national veterinary authorities. The signatories agree to provide immediate notification of any reportable disease detected in a country that could represent a potential sanitary risk for a neighboring country. (This notification provision appears not to have been honored by Argentina with respect to the 2000-2002 FMD outbreaks in Argentina.)

25. The FMD status of adjacent regions and regional cooperation to control the spread of the disease is one of many factors that APHIS considers in its assessment of the disease status of a country as well as in its assessment of the risk that meat exported from that country may be infected with the FMD virus. Because FMD in South America presents a regional challenge, an effective regional approach is necessary to reduce the risk of disease spread within and from the region. Thus, the United States took note of the Cuenca del Plata Agreement both in its risk assessment for Uruguay, as well as its recent risk assessment for Patagonia.

26. However, that Argentina is a member of the Cuenca del Plata Agreement is just one of many relevant facts that APHIS must consider in assessing the risk posed by imports from Argentina. There are still many differences in the FMD control programs among the countries, including their veterinary infrastructures, size and allocation of human and material resources, and regulatory governance. These differences can only be assessed on an individual country basis. The fact that Argentina participates in the Agreement does not negate the need for APHIS to evaluate Argentina’s own internal systems to determine the risk of FMD transmission posed by Argentine imports.

Question 12: In light of the description of the effectiveness of FMD vaccination in paragraph 31 of the United States’ first written submission, please indicate what is the likelihood of FMD being spread in the US territory by products derived from vaccinated animals.

ANSWER:

27. The United States notes that it is not possible to estimate in a vacuum the likelihood of FMD being spread in the United States by products derived from a region where vaccination is practiced. The risk posed by such products depends on many factors that may or may not present themselves in a particular case. For example, any time there is a vaccination program, the question of vaccination practices is raised. This includes considerations of whether vaccinations are conducted correctly and consistently on a regular and comprehensive basis, whether the type and quality of vaccines being administered are appropriate to the situation, whether best practices of the past will be continued indefinitely into the future.²¹ A program that nominally conforms may still err and result in compliance failures, which create the possibility that a susceptible animal will not be vaccinated and become infected.

28. In addition to the risk noted above – namely, that internal controls may fail in any given instance – other risks are posed from animals that have been successfully vaccinated. As the United States has explained in paragraphs 31 and 299 of its first written submission, after an animal is administered the vaccine, immunity to FMD may not develop for several weeks, during which time the animal could become infected and subsequently exported.²² Moreover, vaccinated (as well as recovered) animals can carry a strain of FMD virus not covered by the administered vaccine, potentially with no visible symptoms. In addition, while a large percentage of individual animals in the herd may fully respond to FMD vaccination, some individual animals in the herd may have a limited response, resulting in partial or no immunity. The end result is that FMD could be present in certain animals even in a fully vaccinated population and such presence could go undetected. In contrast, in a country that is FMD-free without vaccination, the presence of FMD would not go undetected. Any time an animal in an unvaccinated herd is infected with FMD, an outbreak in the herd is almost certain to occur due to the highly virulent nature of FMD. Techniques like stamping out then eliminate the virus by removing the affected animals.

29. These risks, individually or combined, mean it is possible that products imported from regions that vaccinate for FMD could be derived from FMD-infected animals. As discussed in the U.S. response to Panel Question 8, meat derived from FMD-infected animals could cause FMD infections in animals ingesting feed waste containing such meat. Consequently, importation of meat from areas that are designated as FMD-free with vaccination, without further mitigations, does not meet the U.S. appropriate level of protection (“ALOP”). The United States

²¹ See Parida, S Vaccination against foot-and-mouth disease virus: strategies and effectiveness, at pp. 347-365 (2009) (Exhibit USA-117).

²² Exhibit USA-117, at pp. 347-365.

must be assured that imports of products are safe and will not introduce or disseminate FMD within the United States.

3 HARMONIZATION (ARTICLE 3 OF THE SPS AGREEMENT)

Question 13: In their respective first written submissions, Argentina and the United States refer to different provisions of the OIE Terrestrial Code in support of their arguments under Article 3 of the SPS Agreement.²³ Moreover, the European Union asserts that Articles 8.5.22 and 8.5.23 of the Code, to which Argentina refers, do not support Argentina's claims.²⁴

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

ANSWER:

30. The OIE Terrestrial Code establishes the standards, recommendations and guidelines for Member countries to consider in fighting animal diseases globally, and developing their animal health control regimes domestically. This dispute concerns FMD, and thus, the relevant international standards, guidelines and recommendations are contained in Articles 1.6.5, Chapter 2.1, Chapter 8.6 of the OIE Terrestrial Code.

31. The articles articulate international standards, guidelines and recommendations related to the process of conducting risk assessments, evaluating an exporting Member’s systems, applying for an FMD status designation, as well as the process by which an applicant may recover its status.

- (b) Please identify the precise provisions of the OIE Terrestrial Code the United States maintains its measures are based on.**

ANSWER:

32. At paras. 332 – 337, the U.S. First Written Submission identifies and matches OIE Terrestrial Code provisions upon which APHIS’ application system is based. The table at pages 93-94 of the U.S. submission, which the United States provided again with some additional amendments, identifies the comparable provisions, and reflects this “based on” relationship in a clear manner.

²³ See, e.g. Argentina's First Written Submission, at paras. 190-206, 421-428; See also U.S. First Written Submission, at paras. 324-341.

²⁴ EU's Third Party Submission, at para. 34.

U.S. Standard (APHIS Regulations)	International Standard (OIE Code)
<p><i>Application Process (9 C.F.R. § 92.2(b))</i></p> <p>1. A request for APHIS recognition of the FMD status of a foreign region (country, zone or other configuration) must include information pertaining to:</p> <ul style="list-style-type: none"> • A. The scope of the evaluation being requested. • B. Veterinary control and oversight. • C. Disease history and vaccination practices. • D. Livestock demographics and traceability. • E. Epidemiological separation from potential sources of infection. • F. Surveillance. • G. Diagnostic laboratory capabilities. • H. Emergency preparedness. 	<p><i>Application Process (Article 1.6.5)</i></p> <p>1. A request for OIE recognition of the FMD status of a country or zone²⁵ must include information pertaining to:</p> <ul style="list-style-type: none"> • A. Introductory information. • B. The veterinary system. • C. FMD eradication. • D. FMD diagnosis. • E. FMD surveillance. • F. FMD prevention. • G. Control measures and contingency planning. • H. Compliance with the Terrestrial Code.
<p><i>FMD Status Designations (9 C.F.R. § 92.2 and 9 C.F.R. Part 94)</i></p> <p>1. The outcome of the application evaluation process is the granting of one of two FMD statuses:</p> <ul style="list-style-type: none"> • A. Foreign region (country, zone or other configuration) free of FMD. <ul style="list-style-type: none"> ➔ Imports permitted • B. Animal commodity approval with conditions to protect United States animal health status. <ul style="list-style-type: none"> ➔ Imports permitted 	<p><i>FMD Status Designations (Articles 8.6.2 – 8.6.5, 8.6.7)</i></p> <p>1. The outcome of the application evaluation process is the granting of one of several FMD statuses:</p> <ul style="list-style-type: none"> • A. FMD free country/zone where vaccination is not practiced. <ul style="list-style-type: none"> ➔ Import terms (Article 8.6.22). • B. FMD free country/zone where vaccination is practiced. <ul style="list-style-type: none"> ➔ Import terms (Article 8.6.23).

²⁵ For countries/zones where vaccination is not practiced *and* where vaccination is practiced.

<ul style="list-style-type: none"> • C. Foreign region not free of FMD. <p style="margin-left: 40px;">➔ No fresh, chilled, or frozen meat.</p> <hr/> <p><i>Recovery of FMD Free Status (9 C.F.R. 92.4)</i></p> <ol style="list-style-type: none"> 1. If a foreign region free of FMD experiences an outbreak, it will lose its status as a foreign region free of FMD (9 C.F.R. 92.4(a)). This results in halting imports. 2. APHIS may later reassess the situation to determine whether interim prohibitions are still necessary. APHIS will consider OIE procedures and other relevant information received (9 C.F.R. 92.4(b)). 3. APHIS decides on reinstatement. (9 C.F.R. 92.4(c)). 	<ul style="list-style-type: none"> • C. FMD infected country or zone. <p style="margin-left: 40px;">➔ No fresh, chilled, or frozen meat (Article 8.6.26 and Article 8.6.34) (mitigation).</p> <hr/> <p><i>Recovery of FMD Free Status (Article 8.6.9)</i></p> <ol style="list-style-type: none"> 1. If a FMD free country or zone (with or without vaccination) experiences an outbreak, it will lose its FMD free status. This results in the suspension of corresponding import recommendations. 2. Following a reinstatement application, OIE may reassess the situation according to the relevant OIE criteria. 3. The OIE decides on reinstatement.
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(c) Please discuss the similarities and differences between the relevant provisions of the OIE Terrestrial Code and the US measures.

ANSWER:

33. The similarities of the aforementioned relevant provisions of the OIE Terrestrial Code and the U.S. measures are best depicted by the table above in the answer to Panel Question 13(b). As the table indicates, the U.S. application system incorporates a substantial portion of the OIE’s standards, guidelines and recommendations into its FMD application system. There are notable differences, however, due to the U.S.’ heightened commitment to ensure its FMD status determination accurately reflect a region’s disease status, and its ability to effectively prevent and control the devastating disease.

34. The U.S. application system is based on but varies, to some extent, from the relevant provisions of the OIE Terrestrial Code in (1) the application process and (2) the FMD status determinations.

35. The U.S. application process: The U.S. application process at Section 92.2 of the CFR incorporates a significant portion of the OIE standards, guidelines and recommendations reflects the process outlined in Article 5 of the OIE Code, and pertaining to an FMD application system under Article 1.6.5. The primary difference between the US process and the OIE system can be found in the risk assessment procedure.

36. In implementing its evaluation process pursuant to Section 92.2, APHIS performs a site visit after receiving an applicant’s region-specific information. This site visit is a routine practice APHIS applies to nearly every request in furtherance of the evaluation.²⁶ The site visit is a critical step in the risk assessment procedure because it allows APHIS to supplement an applicant’s paper application with an in-person, visual evaluation. In contrast, the OIE does not perform site visits systematically pursuant to each request it receives for recognition of FMD status.

37. The OIE’s evaluation often relies entirely on the information requesting Members submit (dossiers) in an FMD questionnaire, pursuant to Article 1.6.5 of the OIE Terrestrial Code. An ad hoc group of the FMD Scientific Commission is the OIE entity initially responsible for assessing the requests. This group evaluates the requesting Members’ dossiers and may engage in written and telecommunication if the ad hoc group deems it necessary; however, the ad hoc group does not systematically perform site visits.

38. Upon concluding its evaluation of a request, the ad hoc group formulates recommendations to the Scientific Commission. Ordinarily, these recommendations are based entirely on a review of the dossiers alone. The Scientific Commission then performs its own assessment, taking into consideration the ad hoc group’s report. During this assessment, the Scientific Commission may engage the requesting Member with questions and even a meeting at OIE headquarters; however, similar to the ad hoc group’s assessment, the Scientific Commission does not conduct site visits.

39. The United States considers the site visit to be a very critical step in the evaluation process, which has contributed to its ability to accurately assess applicants’ FMD status and to ensure that FMD has not entered the country in more than 80 years.

40. The FMD status determinations: The U.S. approach to designating a region’s FMD status is based on the model set forth in Chapter 8.6 of the OIE Terrestrial Code. Under Section 94 of the CFR, the U.S. incorporates a substantial portion of the OIE’s approach to designating an applicant’s FMD status, while departing in one respect to maintain its level of protection against the disease.

41. Chapter 8.6 defines the FMD status designations the OIE assigns to applicant countries and zones. Specifically, Articles 8.6.2 – 8.6.5 articulate the definitions for FMD-free countries/zones where vaccination is practiced and not practiced. Article 8.6.7 contains the definition for an FMD infected country or zone. Thus, pursuant to the OIE FMD status designation approach, a country or zone may be designated as either FMD-free where vaccination practiced, FMD-free where vaccination is not practiced, or FMD-infected.

42. The U.S. approach to designating a region’s FMD status provides for similar categorization. Under Section 94.1, a region may be either FMD free where vaccination is not

²⁶ Exhibit USA-74, at p. 3.

practiced, a region not free of FMD, or a region not free of FMD but authorized to export a particular product subject to enumerated conditions. The U.S. diverges slightly from the OIE’s approach under Articles 8.6.3 and 8.6.5 by not designating regions as “FMD-free” if the region vaccinates because of the risk that vaccinated animals pose. However, as evidenced by Section 94.22, the U.S. has authorized imports from regions that it does not consider FMD-free, but apply vaccination and meet certain conditions.²⁷ This provision demonstrates that the U.S. has authorized imports from countries that are characterized by the OIE as “FMD-free where vaccination is practiced.”

43. Based on the evaluation process described above, APHIS conducts a risk assessment, which incorporates the principles and elements discussed at OIE Code Chapter 2.1, including hazard identification, risk assessment, risk management, and risk communication.

44. In particular, the United States process for publishing a proposed determination for notice and comment, for receiving comment, and revising its decisions after consideration of relevant issues raised, is squarely contemplated by OIE Code Article 2.1.7: “The principal participants in risk communication include the authorities in the exporting country and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups” (emphasis supplied). The purpose of such communication is in part to gather “information and opinions regarding hazards and risks . . . from potentially affected and interested parties during risk analysis[.]”

45. Accordingly, the U.S. approach, as reflected in its regulations and practice, for recognizing the FMD status of regions is drawn from and consistent with the OIE Terrestrial Code. That the U.S. subjects the authorization of vaccinated imports to the satisfaction of enumerated conditions ensures that its system can be both based on the OIE Terrestrial Code while not jeopardizing its level of protection – a level that has successfully prevented FMD for a long-standing, uninterrupted period.

Question 14: Is it possible that a measure is both based on an international standard, guideline or recommendation (e.g. the OIE Terrestrial Code) and, at the same time, achieves a higher level of protection than such a standard, guideline or recommendation?²⁸

ANSWER:

46. Yes. Consistent with Article 3 of the SPS Agreement, it is possible for an SPS measure to be (1) based on the OIE Terrestrial Code while (2) achieving a higher level of protection than that international standard. During the third-party session, the EU and Australia also expressed an understanding of Article 3 that allows for a measure to be based on the relevant international standard, yet achieve an ALOP higher than that international standard.

²⁷ See Exhibit ARG–71.

²⁸ EU’s Third Party Submission, at para. 34.

47. The SPS Agreement does not preclude a situation where a Member adopts a measure that builds upon an international standard, but then achieves a different, higher level of protection than the international standard. The Appellate Body has spoken to and provided guidance on the appropriate understanding of Article 3 – an understanding that leaves open this possibility.

48. In *EC – Hormones*, the Appellate Body found that, under Article 3.1, an SPS measure may be based on an international standard by adopting some, but not all of the standard’s elements.²⁹ The Appellate Body explained that the standards do not have an obligatory effect and are not binding norms.³⁰ Furthermore, the Appellate Body acknowledged that the obligation set forth in Article 3.1 were distinct from those contained in Article 3.2, and therefore need not conform to the international standard, guidelines or recommendations.

49. Following the Appellate Body’s interpretation, it is possible for an SPS measure to be based on the international standard by adopting some of that standard. If, for example, an international standard contains elements, such as a directive on factors to be considered in an assessment, a scientific calculation, definitions of criteria or a recommended result, a measure may be based on *some* of these elements and therefore be consistent with Article 3.1.

50. The Appellate Body’s findings in *EC – Hormones* also support the proposition that a measure based on international standards may achieve a higher level of protection than that standard. This is illustrated by the manner by which the Appellate Body corrected the Panel’s interpretation of Article 3.1 and 3.3 in that dispute, which has important implications for the relationship between the international standard and an ALOP.

51. In *EC – Hormones*, the Appellate Body found fault with the Panel’s conclusion that a measure implying a different level of protection than that reflected by international standard cannot be “based on” that standard.³¹ The Appellate Body observed that the Panel’s conclusion relied on the flawed premise that “based on” under Article 3.1 and 3.3 meant the same as “conform to” under Article 3.2.³² The Appellate Body corrected and clarified this error, noting that unlike Article 3.2, a measure under Article 3.1 does not “conform to” the international standard and does not enjoy the presumption of conformity with the SPS Agreement.³³ Furthermore, the Appellate Body clarified that assumptions that accompany measures that “conform to” international standards are not appropriate for measures “based on” that international standard under Article 3.1; specifically, the assumption that the measure achieves the same level of protection as the international standard.

²⁹ *EC – Hormones (AB)*, at para. 171.

³⁰ *EC – Hormones (AB)*, at para. 165.

³¹ *EC – Hormones (AB)*, at para. 167.

³² *EC – Hormones (AB)*, at para. 168.

³³ See *EC – Hormones (AB)*, at para. 171.

52. Thus, because a measure “based on” does not require the same assumptions as a measure determined to “conform to” the international standard, it may be possible for a measure to be “based on” an international standard, guideline or recommendation, and achieve a higher level of protection.

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

ANSWER:

53. This finding would not have a direct consequence for the remainder of Argentina’s claims. For example, the Panel would still need to address whether the United States has met its obligations with respect to Article 6’s requirements related to disease-free areas.

54. Similarly, a finding that the United States has not based its measures on international standards would not have a direct consequence for other claims. Indeed, it would not even be determinative of Argentina’s claim under Article 3.1. Under Article 3, a Member may maintain a measure not based on international standards if there is scientific justification, or as a consequence of the Member’s ALOP in accordance with Article 5.

Question 16: Please confirm your statements at the first substantive meeting that, in the United States' view, a finding of consistency under Article 3.1 would not obviate the need for the US measures to comply with the other substantive provisions of the SPS Agreement. Please support your answer with reference to the text of Articles 3.1 and 3.3 and any relevant jurisprudence.

ANSWER:

55. As discussed above in response to Panel Question 14, the Appellate Body in *EC – Hormones* determined that a measure consistent with Article 3.1 of the SPS Agreement and found to be “based on” an international standard, guideline or recommendation does not enjoy the presumption of consistency with the rest of the SPS Agreement and the GATT as a measure under Article 3.2 does.³⁴ Therefore, the U.S. measures, if found to be consistent with Article 3.1, must also be consistent with other relevant provisions of the SPS Agreement.

³⁴ *EC – Hormones (AB)*, at para. 171.

Question 17: Does the OIE's attribution of an FMD status to a specific country constitute an international standard, guideline, or recommendation for the purposes of Article 3 of the SPS Agreement? If so, is it a "standard", a "guideline" or a "recommendation"?

ANSWER:

56. The International Office of Epizootics’ (“OIE’s”) attribution of FMD status does not in itself constitute an international standard, guideline or recommendation for the purposes of Article 3 of the SPS Agreement.

57. The FMD status attributions are not standards, guidelines or recommendations in themselves as understood within the context of the SPS Agreement. Annex A(b) defines “international standards, guidelines and recommendations” as follows: “for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics.”³⁵ The International Office of Epizootics, or the OIE, codifies its standards, guidelines and recommendations in the Terrestrial Animal Health Code. As understood within the context of the SPS Agreement, a standard, guideline and recommendation encompass the same concept representing the international approach.

58. The OIE Terrestrial Code establishes the standards, guidelines and recommendations for animal health, including the framework for recognizing the FMD status of Member countries. The various articles of the code embody collective standards, guidelines and recommendations that comprise the international approach. The OIE itself classifies the Terrestrial Code as setting out “standards for the improvement of animal health and welfare and veterinary public health worldwide, including through standards for safe international trade in terrestrial animals and their products.”³⁶ It also indicates that the “development of [the] standards and recommendations” contained in the code were the result of continuous work since 1960.³⁷

59. The FMD status designations are not embodied in the Terrestrial Code and are thus not standards, guidelines or recommendations. The attribution of FMD status is a product of the OIE’s application of the standards, guidelines, and recommendations outlined by the Code.

60. During the third-party session, the EU expressed a similar understanding – that the disease-status list in itself does not embody an international standard, that is that the process and system upon which the list relies would comprise the standard, and the result of administering the system is, in essence, a finding based on the interpretation of the standard.

³⁵ SPS Agreement, Annex A(3)(b)

³⁶ “OIE: Terrestrial Animal Health Code” (Exhibit USA-144).

³⁷ “OIE: Terrestrial Animal Health Code” (Exhibit USA-144).

Question 18: In light of the explanation of APHIS' evaluation of the FMD risk from an applicant region as contained in paragraph 128 of the United States' first written submission, please explain whether and how the exposure and consequence assessments may depend on the product being exported to the United States or the region from which such product originates.

ANSWER:

61. In an exposure assessment, APHIS evaluates the biological pathway(s) necessary for exposure of animals and humans in the United States to FMD from potential imports from the exporting country and describes the potential for the exposure occurring, for example, through recycling of imported products that could be used in feeding of swine.

62. The potential exposure and its magnitude will depend on both the type of product being exported (*e.g.*, live animals versus processed meat) as well as the FMD risk status of the region from which the product originates. For example, mitigations that APHIS imposes for products derived from FMD-susceptible animals are specifically related to the FMD status of the area wishing to export such products.

63. In a consequence assessment, APHIS analyses the potential damage caused by the introduction and dissemination of the pathogenic agent into the importing country, in this case, FMD. This includes all forms of direct and indirect consequences, including costs of response, economic damage and loss, environmental damage, as well as social and psychological damage to agricultural communities.

64. Because the consequence will be related to the “amount of exposure,” the consequence assessment is therefore also indirectly dependent on what product is being exported to the United States and the FMD risk status of the region from which the product originates. For example, if the region in which the commodity originates has viral activity and a low vaccination rate and no surveillance, and the mitigations are not properly applied, the likelihood of release and subsequent exposure are increased. In turn, the extent of exposure will likely influence the consequences of the virus being introduced into the United States.

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

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

ANSWER:

65. The United States agrees that 12 months of no FMD outbreaks would provide the minimum amount of epidemiological evidence for that data point when evaluating the FMD-free (no vaccination) status of a region. However, APHIS, as well as the OIE, requires other epidemiological evidence on other data points to completely evaluate the FMD-free status of a region. Such data points include: (1) absence of viral activity for 12 months, (2) no vaccination against FMD during the last 12 months, (3) no introduction of vaccinated animals into the area since vaccination has stopped, (4) FMD surveillance data supporting the claim, and (5) data on regulatory measures supporting FMD detection, control, and prevention. In short, a claim of 12 months without FMD outbreaks is not enough data upon which to make a decision on FMD-free status; the requesting country must demonstrate its FMD-free claim through a variety of data, including regulations, surveillance activity, authority, and demonstration of controls.

66. Finally, it is not enough for a country to simply declare that it has been FMD-free for 12 months. The country must demonstrate to APHIS that the diagnoses are correctly done, samples are taken according to standards, the correct number of samples are taken (sample size should be representative), and APHIS must confirm this claim through site visits.

67. The United States notes that APHIS does not consider countries that vaccinate to be free of foot-and-mouth disease. Therefore, the time periods established under the OIE Terrestrial Code for qualification for inclusion in the list of countries that are “FMD-free with vaccination” are not relevant “for the purposes of acquiring disease-free status” from APHIS. As previously explained in the U.S. response to Panel Question 12, APHIS considers a country that vaccinates to present a greater risk than a country that APHIS determines to be free of the disease without vaccination. Accordingly, unrestricted importation of livestock or animal products from such a country would not meet the ALOP of the United States.

(b) United States – In your answer to sub-question (a) above, please consider the following statement contained in the 1997 APHIS Policy Regarding Importation of Animals and Animal Products:

A region in which all of the following factors are present would generally be considered a region of negligible risk for a restricted disease agent: The restricted agent has not been diagnosed within the region for a period of time appropriate for that agent. This period of time ... can range from 1 year for a disease such as FMD to a longer period of time for diseases with long incubation times

ANSWER:

68. The United States would like to highlight that APHIS’ 1997 policy enumerated several factors that must be considered to determine whether a region posed a risk of FMD. Under this policy, a 12 month period of no FMD outbreaks was a necessary, but not sufficient, factor to substantiate FMD-freedom.

69. The United States also notes that the 1997 APHIS Policy Regarding Importation of Animals and Animal Products is not binding as discussed in the response to Panel Question 4.

4 WHETHER THE US MEASURES ARE MAINTAINED WITH SUFFICIENT SCIENTIFIC EVIDENCE)

4.1 Article 5.7 of the SPS Agreement

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

ANSWER:

70. There are three elements to consider in answering this question: (1) the scope of the term “scientific evidence”; (2) the meaning of the term “relevant,” which modifies “scientific evidence”; and (3) “a more objective assessment of risk.”

71. First, “scientific evidence” is accepted to consist of the full range of scientific information. The Appellate Body, in *EC – Hormones*, recognized that the adjective “scientific” referred to “of, relating to, or used in science,” “broadly, having or appearing to have an exact, objective, factual, systematic or methodological basis,” “of, relating to, or exhibiting the methods

or principles of science” and “of, pertaining to, using, or based on the methodology of science.”³⁸ It further recognized the expansive breadth of the term “science” when it noted that “[d]ictionary definitions of ‘science’ include ‘the observation, identification, description, experimental investigation, and theoretical explanation of natural phenomena’, ‘any methodological activity, discipline, or study’, and ‘knowledge attained through study or practice.’”³⁹

72. Second, Article 5.7 qualifies “scientific evidence” with the term “relevant.” The Appellate Body in *Japan – Apples* elaborated that “relevance” in the context of Article 5.7 must be understood in terms of Article 5.1’s obligation to perform a risk assessment.⁴⁰ Accordingly, “relevant scientific evidence” is scientific evidence that is used for purposes of a risk assessment consistent with Article 5.1.

73. The definition of “relevant scientific evidence” for purposes of Article 5.7 is not limited by the list of factors in Article 5.2 and Article 5.3. In Article 5.2, Members, in conducting the assessment of risks “shall take into account” factors including “scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest-or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.” These categories are overlapping: for example, “scientific evidence” is the foundation for sampling and testing (data collection and statistical analysis); identification of prevalence of specific diseases or pests and existence of pest-or disease-free areas (epidemiology); relevant ecological and environmental conditions (ecology, geography, environmental science).

74. Article 5.3 refers to the obligation that a Member has to “take into account” economic factors relevant to the assessment of risk. These factors also rely upon scientific evidence: for example, the “potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease” likely requires a combination of information derived, at a minimum, from epidemiology (including effectiveness of quarantine) as well as geography.

75. Chapter 2.1 of the OIE Terrestrial Code supports this broad understanding of scientific evidence. In its discussion of the “[p]rinciples of risk assessment” at Article 2.1.3, the OIE states that a risk assessment is “flexible” and addresses “animal commodities, the multiple hazards that may be identified with an importation and the specificity of each disease, detection and surveillance systems, exposure scenarios and types and amounts of data and information.” Article 2.1.3 recognizes the broad nature of scientific evidence: “The *risk assessment* should be based on the best available information that is in accord with current scientific thinking. The

³⁸ *EC – Hormones (AB)*, at para. 187, n.172.

³⁹ *EC – Hormones (AB)*, at para 187, n.172.

⁴⁰ *Japan – Apples (AB)*, at para. 179.

assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion.”

76. Third, the phrase “a more objective assessment of risk” must be read in light of the whole sentence in which it appears: “In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.” The “objective assessment of risk” has been interpreted to refer to a risk assessment as defined by Annex A(4).⁴¹ The use of the adjective “more” reflects, in the words of the panel in *EC – Approval and Marketing of Biotech Products*, “a movement in a certain direction, that is, towards the eventual ‘objective assessment of risk as defined in Annex A(4).’”⁴²

77. The use of the phrase “a more objective assessment of risk” does not obligate a Member to have a risk assessment that would meet the definition set forth in Annex A(4) at the time that the provisional measure is in place.⁴³ The provisional measure is taken in consideration of “available pertinent information,” which is *a fortiori* information that need not be of the same character or sufficiency as that necessary for a risk assessment under Annex A(4).

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

ANSWER:

78. Yes. As discussed in the U.S. response to Panel Question 20 above, the term “scientific evidence” is not limited to any subdivision of scientific inquiry or question, as observed by the Appellate Body in *EC – Hormones*.⁴⁴ That broad definition is supported by basic principles of treaty interpretation established under the Vienna Convention on the Law of Treaties, which provides 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 in the light of its object and purpose.”

79. There is no basis in the text that supports a limited definition of “scientific evidence.” And as the United States has explained, to read Article 5.7 as not pertaining to a situation in which a Member that has previously taken a measure based on a risk assessment is presented with a claim that the evidence has changed and the measure is no longer warranted would introduce a gap in the SPS Agreement with a very serious consequence. That is, every such

⁴¹ *Japan – Agricultural Products II (AB)*, at para. 92; *EC – Approval and Marketing of Biotech Products*, at para. 7.2989.

⁴² *EC – Approval and Marketing of Biotech Products*, at para. 7.2989.

⁴³ *EC – Approval and Marketing of Biotech Products*, at para. 7.2992.

⁴⁴ *EC – Hormones (AB)*, at para. 187, n.172.

Member would automatically breach the SPS Agreement whenever the evidence allegedly changes because at that moment it will not, and cannot, have assessed the risk in relation to that changed evidence.

Question 22: In the context of a WTO dispute, does the complainant bear the burden of proving the sufficiency of the relevant scientific evidence and the inapplicability of Article 5.7 or does the respondent bear the burden of proving the insufficiency of the relevant scientific evidence and the applicability of Article 5.7?

ANSWER:

80. As a general matter, the United States understands that the respondent bears the burden of showing the applicability of Article 5.7, including the insufficiency of the relevant scientific evidence under Article 5.7. In the particular circumstances underlying this dispute, the application of this element of Article 5.7 is directly informed by the obligations established in Article 6.3. Under Article 6.3, when a Member asserts that it is free of a disease, it is obligated to bring forth the necessary evidence to show that it is and is “likely to remain” free of disease. Accordingly, Article 6.3 recognizes that when an exporting Member asserts that it is disease free, the importing Member will not have sufficient relevant scientific evidence to evaluate that assertion. In that context, the importing Member is entitled to measures that are provisional under Article 5.7.

81. Article 5.7 states that a Member has an obligation to “seek to obtain the additional information necessary,” and in this case, it means that the importing Member must take steps to cure the insufficiency of the relevant scientific evidence. Article 6.3 complements the Article 5.7 burden on the importing Member by (1) requiring that the exporting Member produce evidence and (2) provide “reasonable access” so that the importing Member can secure the data that it needs.

82. That is the situation in this dispute. Argentina asserts that it is free of disease and that it is likely to remain free of disease. Under Article 6.3 it was obligated to produce the necessary evidence. At the time of Argentina’s assertion and to date, the United States and Argentina engaged in a dialogue and exchange of information for the purpose of evaluating that assertion. Further, the United States has needed on-site visits to complete its assessment of risk. Until those visits were completed, the United States lacked the necessary information.

83. Thus, the United States has explained why it needed initial evidence to begin the risk assessment process, and why additional evidence was needed to complete the process. Argentina has not rebutted this basic showing.

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

ANSWER:

84. The applicable principle here, as stated by the Appellate Body in *Japan – Apples*, is that “the party that asserts a fact is responsible for providing proof thereof.”⁴⁵ It is Argentina that is asserting that the circumstances in the country have changed with respect to FMD. For example, Argentina states in its First Written Submission that “[t]he sanitary status of Argentina has improved radically since 2001.”⁴⁶

85. Article 6.3 speaks directly to this assertion by Argentina as well. Under Article 6.3, the Member asserting that its territory is free of a pest or disease has the burden of “provid[ing] the necessary evidence thereof[.]”

86. In this dispute, Argentina has the burden of proof with respect to showing changed circumstances because of the principle “the party that asserts a fact is responsible for providing proof thereof” and because of the direct applicability of the obligations under Article 6.3. APHIS is in the process of evaluating what any asserted changes mean in connection with its standards and the appropriate level of protection of the United States.

⁴⁵ *Japan – Apples (AB)*, at para. 157.

⁴⁶ Argentina’s First Written Submission, at paras. 102, 632 and 646.

Question 24: The United States argues that:

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

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

ANSWER:

87. The withdrawal of import authorization was based on a risk assessment pursuant to Article 5.1. That risk assessment was based on the well-established scientific literature concerning the contagious and devastating nature of FMD reflected in the Exhibits USA-1 through USA-23. At the time the United States withdrew import authorization, Argentina was in the midst of a widespread and uncontained FMD outbreak. Acknowledging this, Argentina itself suspended exports.

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

ANSWER:

88. This question raises two separate issues: (1) the underlying, fundamental risk assessment regarding the danger posed by FMD; and (2) the application of a measure to not permit FMD-susceptible imports from Argentina pending a determination of Argentina's assertion that it was free of FMD.

89. With respect to (1), there is a well-established scientific literature concerning the contagious and devastating nature of FMD reflected in the Exhibits USA-1 through USA-23, which is the basis for measures that restrict product from countries that are affected by FMD. We recall that Argentina is not challenging U.S. regulatory provisions relating to FMD as such and that Argentina does not allege that the removal of import approval at the time of any of its outbreaks was WTO-inconsistent.

90. With respect to (2), the application of a measure to not permit FMD-susceptible imports from Argentina pending a determination of Argentina's assertion that it was free of FMD was a provisional measure pursuant to Article 5.7. The application of that measure was provisional upon Argentina's application and continued to be provisional through the date of panel establishment.

91. Article 5.7 applies because the “relevant scientific evidence” was not sufficient at the time when Argentina submitted a request to the United States “for the recognition of all of Argentina as a region free of foot-and-mouth disease”⁴⁷ Article 6.3 directly informs this because it obligates the exporting Member asserting that its territory is free of a disease to provide the necessary information to the importing Member. This implies that the importing Member will not have sufficient information upon the receipt of a claim of disease freedom, but the exporting Member should know the basis on which it claims disease freedom.

92. When the United States received Argentina’s assertion of its disease-free status, the United States began to conduct its review of the situation according to the process reflected in 9 C.F.R § 92.2 and described in more detail in the APHIS document “Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking.”⁴⁸ These actions are consistent with the obligation under Article 5.7 to “seek to obtain the additional information necessary” to better assess the risk posed by Argentina.⁴⁹

93. The withdrawal of import authorization in subpart (a) to this question is conceptually distinct from the provisional prohibition of imports enacted at the time Argentina submitted its application in 2002. After APHIS withdrew import authorization from Argentina in 2001, there was no reason to believe that it needed to actively revisit that decision. However, once Argentina came forward with an application requesting import authorization for all of Argentina and its subsequent application requesting Patagonia South be recognized as FMD-free, APHIS became obligated to review the applications and make a determination. APHIS’ own regulations and practice recognize this by requiring it to complete a review and issue a risk analysis that addresses the information brought forth by the applicant.⁵⁰

94. The measure that APHIS applied in prohibiting Argentine imports pending its review of Argentina’s assertions is provisional in the plain meaning of that word. “Provisional” is defined as “arranged or existing for the present, possibly to be changed later.” It connotes that the basis upon which a situation continues is temporary. It is bounded and temporary because APHIS must complete a review, upon gathering and receiving the necessary information.

95. As of panel establishment, the measure continues to be provisional as APHIS finalizes its risk assessment and determination.

⁴⁷ Argentina’s First Written Submission, at para. 110.

⁴⁸ Exhibit USA-74.

⁴⁹ SPS Agreement, Article 5.7.

⁵⁰ See 9 CFR 92.2 (e) and (f) and (Exhibit USA-76).

Question 25: What is the significance to an argument that a measure is justified under Article 5.7 of the SPS Agreement that:

- (a) **The measure was based on a risk assessment at the time of imposition?**

ANSWER:

96. The United States notes that the level of generality of this question may lead to confusion. The FMD regulatory regime involves a number of different scientific issues, and different types of assessments. For purposes of this dispute, at least two levels of issues are involved. The first is the fundamental underlying measure to protect against FMD. The second is the issue of whether under that measure, imports should be allowed from Argentina or a part of Argentina.

97. With respect to the first, the virulence of FMD, and the need to ban imports of fresh, chilled or frozen meat from countries with outbreaks of FMD, is well established.⁵¹ It is undisputed that this is based on an assessment of the risk. And it is undisputed that when Argentina suffered its outbreaks of FMD, measures to prohibit importation of meat that could serve to introduce FMD to the United States were based on a risk assessment.

98. The second issue is the crux of this dispute: what is expected to occur when an exporting Member asserts that it is free of the FMD disease after an outbreak and seeks import authorization for its product?

99. The fact that import authorization was previously removed on the basis of a valid risk assessment demonstrates the gap in evidence that must be filled before an importing Member can evaluate the assertion of the exporting Member. It provides a basis for understanding why an assertion of disease-free status by an exporting Member necessarily raises a question that can only be answered after the review and evaluation by the importing Member of relevant scientific evidence.

100. Article 6.3, together with Article 5.7, provides the mechanism through which this gap in information is to be filled. Article 6.3 provides explicit obligations on the exporting Member claiming that its territory is free of the disease. In making this assertion, the exporting Member is obligated to provide the necessary information to the importing Member so that the importing Member can review and evaluate the assertion.

⁵¹ See U.S. First Written Submission, at paras. 18-64; See also Exhibits USA-1 through USA- 23.

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

ANSWER:

101. The United States notes that the level of generality of this question may lead to confusion. The United States provides the following response to clarify the issues it sees involved in this question.

102. The OIE standard, in particular the provisions of Article 8.6.26, supports the position that Members that are free of FMD without vaccination should not accept imports of fresh meat from FMD-infected territories.⁵² Indeed, the United States understands that Argentina and most other Members follow this approach.⁵³

103. The OIE’s own approach to issuing its FMD status designations is in accord with the principle that a Member’s claim that it is free of FMD is not sufficient, without an independent review of relevant information, to reach a conclusion that trade in products should proceed.⁵⁴ The OIE does not accept the exporting Member’s assertion of its disease status until *after* it evaluates that assertion based on information provided by the exporting Member. Thus, the OIE’s own approach is consistent with the process envisioned under Article 6.3 to evaluate any such assertion. In particular, it is appropriate and consistent that the existing measure (e.g., prohibiting importation) should be maintained at least provisionally while all of the relevant evidence is reviewed and an assessment is completed.

104. Article 5.7 sets out an equivalent approach because it permits the importing Member to hold the authorization of imports in abeyance pending the review of information necessary to evaluate the assertion of an exporting Member that its territory is now free of disease.

105. Finally, the fact that the OIE completed its own assessment of Argentina following the last outbreak in Argentina does not require that the United States to conclude its own assessment in the same time frame and does not preclude the United States from taking a provisional measure under Article 5.7.

106. With respect to this, the Appellate Body report in *US – Continued Suspension* is directly on point. It stated: “There is no indication in Article 5.7 that a WTO Member may not take a provisional SPS measure wherever a relevant international organization or another Member has performed a risk assessment.”⁵⁵ It found that the “existence of an international standard does not

⁵² Exhibit USA-23, at 11 (OIE Terrestrial Animal Health Code Article 8.6.26)

⁵³ See, e.g., Canada (Sections 7, 40 and 41(b)) (Exhibit USA-135); European Union (Exhibit USA-136); Argentina, at pp. 30-31 (Exhibit USA-133).

⁵⁴ U.S. First Written Submission, at para. 335 (see table).

⁵⁵ *US – Continued Suspension (AB)*, at para. 695.

create a legal presumption of sufficiency for purposes of Article 5.7.”⁵⁶ It recognized that different risk assessments might reach different interpretations of the same scientific evidence; and even that new information or evidence could call into question existing evidence.

(c) Other completed risk assessments exist on the same matter?

ANSWER:

107. The United States is not aware of the existence of other current risk assessments on the issue of imports of fresh bovine meat into the United States. Other risk assessments by other entities conducted at various times for particular purposes may provide relevant information to the United States. However, a close examination of the assessment and its factual basis would be required in order to determine this. A review of other risk assessments would raise questions, such as does the assessment contain specific information permitting an evaluation by another regulatory authority on the disease status of the exporting Member and does it contain specific information permitting an evaluation of control, inspection, and surveillance procedures. Conclusions drawn from a consideration of these issues would not themselves be “relevant scientific evidence” permitting a more objective assessment of risks.

108. As discussed in the response to Panel Question 25(b), the Appellate Body in *US – Continued Suspension* addressed the issue of risk assessments conducted by other entities, concluding that they did not “create a legal presumption of sufficiency for purposes of Article 5.7.”⁵⁷ The Appellate Body in *EC – Hormones* underscored the need to consider insufficiencies in the relevant scientific evidence under Article 5.7 “on their own terms.”⁵⁸

Question 26: In light of prior interpretation of the words "relevant scientific evidence is insufficient" in Article 5.7 of the SPS Agreement (in particular the Appellate Body Report in Canada/US – Continued Suspension, paragraph 678), please explain what specific scientific evidence the United States considers to be "insufficient" for the United States to conduct a risk assessment and why.

ANSWER:

109. As a preliminary matter, the United States would note that at this time, APHIS considers that it has obtained sufficient scientific evidence to conduct a risk assessment. APHIS has finished the initial risk assessment for Patagonia. And APHIS is finalizing its initial risk assessment for northern Argentina at this time. To be sure, in the normal review and public comment process, it is possible that additional necessary information may be identified.

⁵⁶ *US – Continued Suspension (AB)*, at para. 697.

⁵⁷ *US – Continued Suspension (AB)*, at para. 697.

⁵⁸ *EC – Hormones (AB)*, at para. 711.

However, the United States is not asserting that it presently is unable to conduct a risk assessment.

110. The United States would go on to emphasize that Article 5.7 contemplates that a Member must have an opportunity to analyze the scientific evidence in order to complete its risk assessment and respond appropriately. In other words, it cannot be the case that a provisional measure must be withdrawn at the precise moment that all of the necessary data is collected to conduct a risk assessment.

111. The United States also notes that the “relevant scientific evidence” for purposes of Article 5.7 (as well as the “additional information” for a more objective assessment of risk referenced in that article) is all of the evidence of a scientific nature that is taken into account as part of a Member’s assessment of risks. Articles 5.2 and 5.3, as well as Article 6, set out some of that scientific evidence, without which a risk assessment may not be able to be completed.

112. The United States appreciates this question, because it allows us a further opportunity to explain how Article 5.7 applies in this dispute. As the United States noted in its oral statement at the first meeting of the Panel, Article 6.3 explicitly contemplates that a determination of disease free status will follow a claim of such status by a Member that wishes to export. Prior to the claim and its associated scientific evidence, there may be insufficient scientific evidence for the importing Member to evaluate the disease free status of the Member that wishes to export. Further, after submission of the claim, the evidence may well not be sufficient. For example, follow up information may be required. Further, the importing Member may decide to collect additional scientific information by way of an on-site visit. Article 6.3 explicitly contemplates on-site visits.

113. In thinking about "insufficiency" in this case, it is important to recognize that the factual situation differs from that present in a number of prior SPS disputes. The science of FMD is clear – it is a devastating and easily transmitted disease.

114. In this dispute, the question of sufficiency relates to the scientific data that national regulators need. First, the United States needed information concerning the prevalence of FMD in the country. Second, the United States needed information to make scientific judgments about the technical scientific quality of Argentina’s animal health control systems. These are scientific inquiries; it is recognized as part of the inquiry under Article 6.1 (what is and is likely to be a territory’s disease status) and Article 6.3 (access to inquire into surveillance, detection, control, and other procedures). This is within the meaning of Article 5.7.

115. So, for example, on the day that Argentina submitted its claim that it was free of disease, APHIS needed to review that information, ask follow up questions, and conduct site visits. And, as the United States detailed in its first written submission, as the evaluation process continued, Argentina’s regulatory regime and its FMD situation did not remain static. With each change in circumstance, time was required for APHIS to assess it.

116. Most recently, APHIS required the following information to assess the FMD risk status of Argentina: (1) whether Argentina has the capacity to monitor and control FMD within its borders; and (2) whether Argentina's systems are sufficiently transparent and credible to provide timely notification to the United States in the event of an FMD incident. This information is relevant to determining whether products from Argentina can be imported without introducing and establishing FMD in the United States. Border controls enable a country to monitor the movement of people, animals, and goods into the country. Illegal movements of FMD-susceptible commodities or people and equipment contaminated by the virus can spread disease; therefore, a thorough understanding of the animal movement controls of a country is necessary to assess the risk of introduction of the disease. Further, biosecurity measures are critical to minimize the spread of disease should an outbreak occur. As for transparency and credibility, APHIS had to determine that Argentina had the regulatory authority, FMD contingency plans, and follow-up on suspect FMD cases (as observed during site visits) to reliably notify and control any FMD outbreak within its borders. The United States observes that this kind of scientific evidence is not something that can be divorced from a country’s history or necessarily can be determined with any confidence in a short span of time. In some situations, confirmation and trust that strong internal controls and transparency have become a permanent practice rather than a transient situation requires a demonstration over time.

Question 27: The United States argues that "[w]here the importing Member is engaged in the process of evaluating "claims of disease-free status presented by the exporting Member "within a reasonable period of time, there is no legal basis for challenging the importing Member's decision to maintain its existing measure".

(a) Is that argument based on the United States' reading of Article 5.7 of the SPS Agreement?

ANSWER:

117. Yes. Under Article 5.7, the importing Member implements a provisional measure during which it reviews an exporting Member’s claim within a reasonable period of time. If that importing Member’s review is within a reasonable period of time, and its provisional measure is based on “available pertinent information”—a standard less stringent than that required for an assessment of risk in accord with Article 5.1—then its measure does not breach the obligations at issue in this dispute. The time taken by the importing Member is “reasonable,” which also implies that the lack of a final measure is “[p]roportionate” or “[w]ithin the limits of reason; not greatly less or more than might be thought likely or appropriate; moderate[.]”⁵⁹

⁵⁹ Oxford English Dictionary, at pp. 2496 (Exhibit USA-145).

(b) What is the relevance of Article 5.7 to claims under Articles 2.3 and 5.6?

ANSWER:

118. If an importing Member has met the terms of Article 5.7 and has taken a provisional measure while reviewing an exporting Member’s claim in a “reasonable period of time,” then that analysis supports a finding that no breach of Article 2.3 or Article 5.6 has occurred.

119. In a situation in which Article 5.7 is successfully applied, then the ongoing review is “reasonable” and should not be considered to be “discriminatory” under Article 2.3. It would be contradictory to find that ongoing review was reasonable, and yet discriminatory at the same time. Likewise, if a provisional measure is justifiably taken while review is ongoing, then necessarily the outcome of that review has not been reached. If that is the case, it would be contradictory to conclude at the same time that a less-restrictive measure is available.

120. However, if a panel were to find that the importing Member’s review did not occur within a reasonable period of time, then the panel should conclude that the importing Member failed to satisfy the time requirements under Article 5.7. A panel could then address the claim under Article 2.2 and then Article 5.1.⁶⁰ If the importing Member’s actions are not consistent with those obligations, then the panel could recommend that the importer Member come into compliance. A panel could then exercise judicial economy with respect to the rest of the claims brought by the exporting Member.⁶¹

121. This approach most serves the interest of “achieving a satisfactory settlement of the matter in accordance with”⁶² the Agreement. In a situation based on a provisional measure such as this, the importing Member has not issued a fully considered and final determination on the record. Accordingly, the panel in such a situation would not have an opportunity to consider the full reasoning behind the importing Member’s decision. 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 its own scientific findings on complex regulatory issues without the benefit of a scientific evaluation by the importing Member and full record.

122. By exercising judicial economy, the panel avoids this potential pitfall. The importing Member may be held accountable because it would be obligated to come into compliance with its WTO obligations.

⁶⁰ *EC – Approval and Marketing of Biotech Products*, at para. 7.2980 and para. 7.2996. In its report, the panel stated that “Article 2.2 was not intended to apply in the situations covered by Article 5.7.” In finding that Article 5.1 was “properly viewed as a specific application of the obligations provided for in Article 2.2,” the panel concluded “Article 5.1 cannot be applicable in situations where Article 2.2 is not applicable.”

⁶¹ EU’s Third Party Written Submission, at para. 67.

⁶² DSU, Article 3.4.

(c) What are the implications of the US argument as regards the possibility for an exporting Member to challenge the importing Member's review in WTO dispute settlement?

ANSWER:

123. Under the U.S. view of the proper way to frame this dispute within the various provisions of the SPS Agreement, an exporting Member is not precluded from challenging an importing Member's review in WTO dispute settlement. A panel should review the Article 5.7 issue first, and if the Panel finds that (1) the importing Member satisfies the requirements of Article 5.7 and (2) the review is occurring within a reasonable period of time, then the exporting Member's challenge fails. This is what should happen in this dispute.

124. If the panel were to find that Article 5.7 was not met, then the panel should, in the interests of facilitating dispute settlement and avoiding premature and unnecessary entanglement in regulatory science, address the claim under Article 2.2 and Article 5.1 first, and exercise judicial economy on other claims, as discussed in the answer to Panel Question 27(b), above.

Question 28: In its first opening statement, the United States lists several "uncertainties" at the time of Argentina's 2002 request, including "whether [Argentina's] internal systems could control FMD such that exports to the United States would not pose a threat".

(a) Did these "uncertainties" still exist at the time of the establishment of the Panel? In your answer, please address APHIS' statements in the 2007 Proposed Rule for Patagonia South ("[t]he veterinary services in Argentina possess the authority, diagnostic capability, and personnel to rapid detect, contain and eradicate any incursion of FMD that might occur") and in the 2014 Risk Assessment for Patagonia ("Argentina has the infrastructure and legal authority to ... take appropriate action in case of an FMD outbreak").

ANSWER:

125. These uncertainties still existed at the time of the establishment of the Panel (January 2013) because APHIS needed to confirm that the conditions in Argentina, including the disease status, internal controls, and capacity of Argentina's veterinary services, were adequate, given that our last site visit was 2009.

126. While APHIS drew preliminary conclusions in its 2007 proposed rule that the veterinary services in Argentina were adequate, these conclusions were not final. Under U.S. law, proposed rules – such as those applicable to Argentine beef – are open to public comment from all stakeholders (including Argentina itself) before the rules become final. The public comment period is intended to provide opportunity for USDA to receive information about issues it may have overlooked.

127. And, indeed, subsequent to the publication of the proposed rule, many commenters expressed concern that allowing imports from Patagonia South would put U.S. livestock at risk for disease. Commenters expressed a lack of confidence in Argentina’s veterinary infrastructure and border controls, both nationwide and in Patagonia South specifically, noting that FMD outbreaks in Argentina in 2001 took months to be reported to international authorities. These commenters asked why APHIS believed that Argentine authorities would be able to detect FMD in Patagonia South in the event of a future outbreak. Other commenters were concerned that Argentina’s conditions for import of meat into Patagonia South did not meet U.S. standards and could result in increased risk for disease introduction into the United States. Several commenters also stated that the risk assessment provided with the proposed rule was based on out-of-date information (2003 site visit). Given these comments, APHIS needed to consider how the information provided in these comments affected its preliminary conclusions.

- (b) Please explain whether there are any further measures or actions that APHIS would expect SENASA to enact or take with respect to its application to import fresh (frozen or chilled) beef from the entire Argentine territory.**

ANSWER:

128. APHIS is finalizing its preliminary risk assessment for Argentina’s request to import product from the entire Argentine territory. Until that assessment is concluded, it would be premature to conclude whether APHIS would expect SENASA to enact or take any further measures or actions with respect to its application to import fresh beef from the entire Argentine territory.

Question 29: In reference to paragraphs 58-61 of the European Union's third party submission:

- (a) Is there a line to be drawn between "definitive" and "provisional" SPS measures?**

ANSWER:

129. The SPS Agreement contains no such taxonomy, and the United States does not see a benefit from using these terms. Rather, a measure – such as the U.S. measure at issue here – may fall within the scope of Article 5.7, and thereby not be subject to the Article 5.1 requirement to be based on a risk assessment. In that sense, the measure is “provisional.” But the key issue is whether the measure meets the requirements of Article 5.7, and not the label applied to the measure.

130. Accordingly, the United States shares the view expressed by the EU in its third party submission that a formalistic taxonomy of “definitive” and “provisional” SPS measures is an artificial approach to a situation such as that raised in this dispute. The United States agrees with

the view that “the best approach is probably to constantly read together all of the provisions relevant to a particular issue.”⁶³

131. In this instance, the core issue in this dispute is how to understand the nature of obligations under the SPS Agreement and the process that the SPS Agreement envisions unfolding in a situation in which an exporting Member asserts that it is free of a disease such as FMD. The relevant provisions for addressing this situation are Article 6.3, Article 5.2, and Article 5.7.

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

ANSWER:

132. Yes. The Appellate Body articulated one such scenario in *US – Continued Suspension*. In that dispute, the Appellate Body stated: “WTO Members should be permitted to take a provisional measure where new evidence from a qualified and respected source puts into question the relationship between the pre-existing body of scientific evidence and the conclusions regarding the risks.”⁶⁴

133. Although that statement considered a different factual scenario where the science relating to a disease may change, the principle is applicable because it directly addresses the relevance of alleged changed circumstances. In this case, a WTO Member has “put into question” its disease status by stating that the prior scientific evidence regarding disease prevalence, the Member’s control and other infrastructure has changed. In this circumstance, the importing WTO Member “should be permitted to take a provisional measure” under Article 5.7, just as the Appellate Body articulated in *US – Continued Suspension*.

(c) Can a provisional measure be maintained indefinitely?

ANSWER:

134. No. Under the plain text of Article 5.7, it is not envisioned that a measure falling within the scope of Article 5.7 would remain indefinitely within its scope. In particular, Article 5.7 requires that the Member imposing the measure seek additional information and review the measure accordingly within a reasonable period of time.

135. Article 5.7 is also clear, however, that one cannot reach conclusions about whether Article 5.7 applies based simply on the amount of time that is being taken to obtain the additional information and to review the measure accordingly. In each case, all of the facts and

⁶³ EU’s Third Party Submission, at para. 58.

⁶⁴ *US – Continued Suspension (AB)*, at para. 703.

circumstances must be evaluated to determine whether a Member has met its obligations under Article 5.7 with respect to seeking additional information and reviewing the measure.

136. In this dispute, the United States is not maintaining its provisional measure indefinitely. To the contrary, its provisional measure is subject to ongoing review. Indeed, the publication of the proposed determination for Patagonia reflects that APHIS is proceeding in this manner.

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

137. A proper understanding of Article 5.7 and Article 5.1 (including but not limited to the question of “provisional” versus “definitive”) requires that all provisions relevant to a particular issue be “constantly read together.”

138. In this instance, the core issue in this dispute is how to understand the nature of obligations under the SPS Agreement and the process that the SPS Agreement envisions unfolding in a situation in which an exporting Member asserts that it is free of a disease such as FMD. Article 6.3 speaks directly on this issue: The exporting Member that makes the assertion regarding its pest- or disease-free or low prevalence status is obligated to provide the evidence to support this assertion.

139. There is a clear textual link in the SPS Agreement between Article 6.3 and Article 5.1, which is through Article 5.2. Article 6.3 is linked to Article 5.1 because Article 5.2 states that in the “assessment of risks,” Members should take into account factors including scientific evidence, prevalence of specific diseases or pests, and existence of pest- or disease-free areas.

140. The Article 6.3 obligation is substantive and procedural. It is a substantive obligation because the evidence must be “necessary . . . to objectively demonstrate” that the territory is and is “likely to remain” in that status. It is a procedural obligation because the information must be provided to the importing Member. The SPS Agreement then must be construed as to permit the importing Member time to review the information and to evaluate it in accordance with Article 6.1 and to meet its corresponding obligations under Article 5.1 to base a measure on an assessment of risks. Article 6 and Article 5 speak to the same obligation: that the importing Member will issue a measure, supported by a risk assessment that accounts for the potential pest- or disease-free or low prevalence status of a territory in the exporting Member.

141. Article 5.7 provides the appropriate balance between rights and obligations in the period of time triggered by the procedural obligation in Article 6.3 and the conducting of the appropriate assessment of risk under Article 5.1 (as further elaborated upon in Article 5.2). Article 5.7 allows an exporting Member to implement provisional measures (including not permitting entry of a product) pending the completion of the process envisioned under Article 6.3. The importing Member, under Article 5.7, has an obligation to seek to obtain the scientific information necessary for the assessment of risk, while the exporting Member has the complementary obligation to provide the necessary information.

142. This integrated understanding of Article 5 and Article 6 is a harmonious reading of the Agreement. It also comports with the FMD practice of other Members,⁶⁵ including Argentina, which does not permit entry of FMD-susceptible product from another Member pending the review of an application.

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

ANSWER:

143. Each part of the SPS Agreement potentially could serve as interpretative context for any other part, depending on the particular interpretive issue under examination. With that general observation in mind, the United States has the following comments.

144. First, Annex C does not apply to Article 6 disease free determinations. Because Annex C and Article 8 only apply to “control, inspection, and approval procedures,” they are substantially different from an examination of disease-free status. Such procedures are connected to products or substances, and have no direct bearing on the examinations at issue in this dispute.

145. Second, as a general matter, Article 5.1 and Annex C are focused on different types of issues. Article 5.1 states, in short, that SPS measures must be based on risk assessments. In contrast, Article 8 and Annex C apply only to “control, inspection, and approval procedures,” and these are procedures that do not necessarily involve risk assessments. Indeed, Article 8 and Annex C do not specifically mention risk assessments. Further, Annex C contains procedural obligations, where Article 5.1 does not.

146. Third, the United States notes that in contrast to Annex C, Article 5.7 must clearly be read together with Article 5.1. Reading Article 5.1 together with 5.7 results in the harmonizing of the obligation to base SPS measures on a risk assessment as appropriate to the circumstances, with the recognition that a measure may be maintained while the Member is in the process of performing a risk assessment in light of any changed circumstances.

147. Fourth, and finally, in circumstances where Article 8 and Annex C do apply to a measure subject to Article 5.1, then the “undue delay” obligation in Annex C(1)(a) may be mutually reinforcing with Article 5.7’s requirement to review an SPS measure within a reasonable period of time.

⁶⁵ See, e.g., Canada (Sections 7, 40 and 41(b)) (Exhibit USA-135); European Union (Exhibit USA-136); Argentina, at pp. 30-31 (Exhibit USA-133).

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

ANSWER:

148. As explained above in response to Panel Question 30, whether a relationship between provisions of the SPS Agreement exists is difficult to answer in the abstract. With that general observation in mind, the United States has the following comments.

149. First, Annex C does not apply to Article 6 disease free determinations. Because Annex C and Article 8 only apply to “control, inspection, and approval procedures,” they are substantially different from an examination of disease-free status. Such procedures are connected to products or substances, and have no direct bearing on the examinations at issue in this dispute.

150. Second, as a general matter, Article 5.1 and Annex C are focused on different types of issues. Article 2.2 states, that “Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.” In contrast, Article 8 and Annex C apply only to “control, inspection, and approval procedures,” and Annex C does not impose similar requirements in relation scientific principles and evidence.

4.2 Articles 2.2, 5.1, and 5.2 of the SPS Agreement

Question 32: Argentina claims that the US representative has suggested before the SPS Committee that new risk assessments on the FMD situation in Argentina have been completed after the filing of Argentina's request for authorization of imports of fresh (chilled or frozen) beef (in 2002). Has APHIS completed any risk assessments with respect to the FMD situation of Argentina as a whole after the filing of Argentina's request?

ANSWER:

151. No. Although APHIS has advanced its risk analysis of the FMD situation of Argentina as a whole, it has not completed its assessment due in part to Argentina’s troubled history of preventing and controlling the disease.

152. Exhibit ARG-22 (Summary of the WTO SPS Committee Meeting of June 30 – July 1, 2011) contains language from the U.S. representative regarding the status of the risk assessment of the region north of the 42nd parallel. To clarify the statements as reflected in the meeting summary, APHIS in fact had done substantial work in updating its risk analysis, but had not completed the assessment in its entirety. Thus, at the time of the mid-2011 SPS Committee Meeting, APHIS had made significant process in advancing its assessment. The statements by the United States were intended to indicate that APHIS hoped to complete its risk analysis and draft a proposal to allow beef imports soon thereafter.

Question 33: The United States argues that "the risk assessment" underlying the 2001 Regulations and the resulting amendment of 9 CFR 94.1(b) imposing a ban on all ruminant and swine products from Argentina consisted of the scientific information concerning the dangers associated with FMD and the 2000-2002 outbreaks in Argentina. Please identify which specific scientific evidence the United States is referring to and explain the "objective situation that persists and is observable" between the risk assessment and the measure.

ANSWER:

153. In *EC – Hormones*, the Appellate Body discussed the meaning of an objective situation that persists in the context of its analysis of the phrase “based on”:

“We believe that ‘based on’ is appropriately taken to refer to a certain objective relationship between two elements, that is to say, to an objective situation that persists and is observable between an SPS measure and a risk assessment.”⁶⁶

154. Here, the objective scientific evidence was the undisputed dangerousness of FMD as recognized by the OIE, and the presence and vast outbreaks of FMD in Argentina at the time. Initially, Argentina detected an outbreak in a bull herd of 300, and soon after reported that the number of confirmed disease cases increased steadily, affecting five provinces.⁶⁷

155. The United States introduced an emergency response based on Argentina’s notification of the ongoing FMD outbreak epidemic. The OIE took a similar response. In accordance with the standards set out in the Terrestrial Code, the OIE takes immediate, systematic steps to remove the country from the FMD-free list when it reports an outbreak. Argentina itself suspended its own exports. Thus, the U.S. approach was related to and based on the objective and specific scientific evidence of FMD in Argentina at the time.

156. As the U.S. explained in its first written submission and during the first Panel meeting, under the structure of the U.S. regulatory system, this 2001 measure was taken on the basis of a risk assessment as appropriate to the circumstances. U.S. law permitted and directed APHIS to evaluate a claim of disease free status – that is, that relevant scientific evidence had changed – upon receipt.⁶⁸ When Argentina made that claim, APHIS began its review of the application by examining the information provided by Argentina. The temporary measure has been maintained while the U.S. actively seeks the requisite additional information to make a more objective assessment of risks.

⁶⁶ *EC – Hormones (AB)*, at para. 189.

⁶⁷ Exhibit ARG-29

⁶⁸ See Exhibit USA-76.

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

ANSWER:

157. The phrase “take into account” within the context of Articles 5 and 6 obliges Members to consider particular disease evaluation techniques and guidelines developed by relevant international organizations. The obligation to “take into account” does not require Members to utilize these techniques and guidelines in conducting their own evaluations, however. Indeed, in *Australia – Apples*, the Appellate Body found that Article 5.1 does not require Members to base or conform their assessments to the international techniques and guidelines.⁶⁹

158. In *China – GOES*, the Appellate Body considered the meaning of the word “consider” within the context of Articles 3 and 15 of the Anti-Dumping Agreement.⁷⁰ It is important to note that the AD Agreement is a fundamentally different agreement from the SPS Agreement. In particular, under the AD Agreement, administrative determinations are reviewed based on whether such determinations are supported by the administrative record before the authority. In that context, the questions of exactly what the authority did or did not consider is inextricably tied to the standard of review of inherent in disputes under the AD Agreement. Further, the AD Agreement involves a specific type of administrative proceeding involving a specific type of calculation. The agreement contains specific procedural rules, including the requirement that authorities make preliminary and final determinations. The authority’s reasoning must be set out in the determinations and be disclosed to interested parties.

159. In contrast, SPS disputes do not involve the review of administrative records, and the SPS Agreement does not contain similar procedural obligations to explain administrative determinations. Accordingly, it is questionable that findings or interpretations related to the AD Agreement standard of review or to AD Agreement procedural obligations would be relevant to interpretation of the SPS Agreement.

160. Notwithstanding these inherent differences, the Appellate Body’s findings in *China – GOES* on this specific issue do not reach a different result than that reached by the Appellate

⁶⁹ *Australia – Apples (AB)*, para. 246.

⁷⁰ See *China – GOES (AB)*, at paras. 129-169.

Body in *Australia – Apples*. In *China – GOES*, the Appellate Body found that the phrase “take into account” could be associated with the word “consider.” The Appellate Body stated that the obligation to consider falls short of the obligation to make a full-fledged and exhaustive analysis of factors.⁷¹ Instead, the obligation simply requires Members not to disregard contrary evidence.⁷²

161. The Appellate Body went on to explain that “an investigating authority’s consideration under Articles 3.2 and 15.2 must be reflected in relevant documentation, such as an authority’s final determination, so as to allow an interested party to verify whether the authority indeed considered such factors.”⁷³ If applied to the context of the SPS Agreement, such evidence would be reflected in risk assessment and/or the final SPS measure. In the current dispute, the U.S. system reflects this process – upon completion of the risk assessment and rulemaking process, the factors it takes into account will be reflected therein.

162. Additionally, it should be noted that the United States evaluation process is quite transparent. For example, the factors that APHIS considered with respect to Argentina’s request related to Patagonia are publicly available as part of the published proposal to recognize the FMD status of Patagonia. Further, the U.S. has been in communication with Argentina and has expressed its commitment to work with Argentina to advance the evaluation process.

Question 36: APHIS’ 1997 risk assessment for Argentina is of a quantitative nature, whereas the 2000 risk assessment is of a qualitative nature. Which approach did APHIS follow in its risk assessments with respect to other countries or regions relevant to this dispute (e.g., Uruguay, Santa Catarina (Brazil), Japan, the United Kingdom, Chile, and Patagonia)?

ANSWER:

163. Most of APHIS’ FMD risk assessments have been, and continue to be, qualitative in nature, including Santa Catarina (2009/2010 FMD-free), Japan (2011 FMD-free), the UK (2008 FMD-free), and Patagonia (2005/2013 FMD-free). The risk assessment for Uruguay (2002 commodity authorization) was quantitative.

164. In general, APHIS performs qualitative risk assessments for countries that request recognition of FMD freedom. In the past, APHIS has only done a few quantitative risk assessments—in particular, only when the request was for authorization to export commodities from countries that did not qualify for FMD-free status. Now APHIS conducts qualitative assessments for applications for authorization to export commodities from countries that did not qualify for FMD-free status. When coupled with site visit evaluations, APHIS believes that

⁷¹ *China – GOES (AB)*, at para. 154.

⁷² *China – GOES (AB)*, at para. 154.

⁷³ *China – GOES (AB)*, at para. 131.

qualitative risk assessments provide the necessary information to assess the risk of disease introduction through importation.

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

Question 39: Please comment on the relevance of APHIS' statement in Exhibit ARG-56, quoted at paragraphs 512 and 555 of Argentina's first written submission, to a determination as to whether the sanitary conditions in Patagonia South and Chile are "identical or similar" within the meaning of Article 2.3 of the SPS Agreement.

ANSWER:

165. This question refers to the statement in the APHIS 2007 proposed rule regarding Patagonia South (Exhibit ARG-56) that “[t]he animal health status of Chile and Patagonia South are equivalent.” It would be incorrect to view this statement as a finding by APHIS on the disease-free status of Patagonia. Rather, this statement simply referred to the fact that Chile and Patagonia had the same OIE animal health status recognition. As the United States has explained, however, APHIS – while taking account of OIE designations – makes its own determination of disease-free status. Accordingly, unless and until APHIS makes a final determination regarding Patagonia South, APHIS will not have made any determination that can be compared to any APHIS determination for Chile.

166. Further, similar OIE designations are not conclusive for purposes of Article 2.3.

167. Having an OIE FMD-free status simply means that:

- (1) The OIE has accepted documentary evidence showing: (a) a record of regular and prompt animal disease reporting; (b) surveillance for FMD and FMDV infection in accordance with Articles 8.6.42 to 8.6.47 and Article 8.6.49 is in operation; and (c) regulatory measures for the early detection, prevention and control of FMD have been implemented; and
- (2) The OIE has accepted the country’s self-declaration and documentary evidence that: (a) there has been no outbreak of FMD during the past 12 months; (b) no evidence of FMDV infection has been found during the past 12 months; (c) no vaccination against FMD has been carried out during the past 12 months; and (d) no vaccinated animal has been introduced since the cessation of vaccination; and
- (3) The OIE has accepted the country’s detailed description of the boundaries and measures of a protection zone, if applicable.

168. Meeting these requirements, however, does not lead to a conclusion that all the relevant sanitary conditions in two countries are “identical or similar” to each other. For example, two countries could meet the minimum requirement of not having had an outbreak in the past 12

months. But, one country could have a history of extensive outbreaks annually for a decade prior to the past 12 months while the other country could have a history of no outbreaks for a century (e.g., due to porous borders, being surrounded by FMD affected countries, etc.). Similarly, one country could be wholly surrounded by water, while the other wholly surrounded by countries that have present FMD epidemics. Or, one country might supplement their national meat supply or herd by importing fresh meat or livestock from FMD-infected regions, while the other does not.⁷⁴ And although both countries would have submitted documentary evidence of having implemented regulatory measures for the early detection, prevention and control of FMD, the specifics of the veterinary systems and controls or the challenges associated with preventing the introduction of FMDV could be highly divergent. Thus, it is quite possible that two countries could have the same OIE animal health status, but not have identical or similar sanitary conditions for purposes of determining what SPS measures are required to meet the United States’ ALOP with respect to the risk of FMD posed by imports from those countries.

169. Furthermore, OIE disease status recognition does not necessarily mean that conditions in the country are, in fact, as they are have been represented in the documents, or, more usually, are implemented consistently, especially where the OIE does not conduct a site visit. And in the infrequent event that the OIE conducts a site visit, the OIE does not examine all of the factors APHIS examines when it visits the country (for example, controls on the movement of animals or likelihood of compliance with APHIS requirements). Site visits are an important vehicle in accurately assessing the risk of FMD posed by the factual situation present at that moment in the country. In its substantial experience in evaluating countries’ requests for FMD-free status, APHIS has found through site visits that country compliance and implementation of policies or procedures, which seemed adequate on paper, is lacking. For example, during a site visit for one applicant country, APHIS found evidence of significant smuggling of animals from a bordering country; evidence that the country was not able to comply with slaughter mitigations; and evidence that veterinary authorities did not apply their own regulations (related to FMD prevention) consistently.

170. In sum, APHIS must confirm for itself with an acceptable level of confidence that the relevant sanitary conditions in a region, as set forth in 9 C.F.R. 92.2, meet APHIS’ requirements.

171. Finally, the United States notes that assuming that two countries that have the same OIE FMD-free status *a priori* is sufficient evidence that identical or similar conditions prevail for purposes of Article 2.3 would not be a tenable interpretation of the SPS Agreement. If this position were accepted, every country with OIE FMD-free status necessarily would have to be subject to the same SPS measures, without allowing the importing country an opportunity to assess for itself each applicant country’s sanitary conditions. It also would deny importing countries to take sanitary measures necessary for the protection of animal health.

⁷⁴ See, e.g., 9 C.F.R. 94.11.

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

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

(b) United States – Please express your views as to whether Article 5.4 contains binding obligations.

ANSWER:

172. Article 31 of the Vienna Convention, which reflects customary rules of interpretation of public international law, states: “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 in the light of its object and purpose.”

173. That is what the panel in *EC – Hormones* did in interpreting the terms "should" and "objective" in accordance with the ordinary meaning of the terms. It stated: “Guided by the wording of Article 5.4, in particular the words "should" (not "shall") and "objective", we consider that this provision of the SPS Agreement does not impose an obligation.”⁷⁵

174. As the Appellate Body in the same case noted: “The fundamental rule of treaty interpretation requires a treaty interpreter to read and interpret the words actually used by the agreement under examination, and not words which the interpreter may feel should have been used.”⁷⁶

175. The panel in *EC – Hormones* used sound reasoning, and thus its finding on this issue was both correct and persuasive.

⁷⁵ *EC – Hormones (US)*, at para. 8.166.

⁷⁶ *EC – Hormones (AB)*, at para. 181.

Question 42: In its first written submission, the United States refers to the inability of the OIE standard and/or Argentina's proposed alternative measures to satisfy its ALOP. Conversely, Argentina argues that the United States has not articulated a consistent and clear ALOP.

What is the US ALOP with respect to FMD? Is the US ALOP articulated or set forth in any legal instruments? How is the US ALOP achieved by the measures in force with respect to Uruguay, Santa Catarina (Brazil), Chile, Japan, and the United Kingdom?

ANSWER:

176. The ALOP of the United States is set out in the Animal Health Protection Act (“AHPA”) at 7 U.S.C. Section 8303, which is the main statutory basis for 9 CFR 92 and 9 CFR 94. Imports of FMD-susceptible animals and animal products into the United States must be safe, meaning they must not introduce into or disseminate within the United States the FMD virus.

177. The measures taken by the United States to achieve its ALOP have been successful, as evidenced by the fact that there has not been an outbreak of FMD for over 80 years. Due to FMD’s high morbidity and ease of transmission, a single outbreak of FMD may devastate U.S. animal herds.

How is the US ALOP achieved by the measures in force with respect to Uruguay, Santa Catarina (Brazil), Chile, Japan, and the United Kingdom?

ANSWERS:

178. APHIS completed its risk analyses with respect to Chile, Japan, the United Kingdom, and the Santa Catarina region of Brazil and concluded that these regions are FMD-free without vaccination. In order to achieve the U.S. ALOP, APHIS has imposed certain restrictions on importation of meat and other animal products from these regions under 9 C.F.R. 94.11. These restrictions are needed to meet the U.S. ALOP because one or more of the following conditions occur: (1) these countries/regions supplement their national meat supply by the importation of fresh (chilled or frozen) meat of ruminants or swine from regions that APHIS considers to be affected with foot-and-mouth disease; (2) they have a common land border with regions considered by APHIS to be affected with foot-and-mouth disease; or (3) they import ruminants or swine from regions considered to be affected with foot-and-mouth disease under conditions less restrictive than would be acceptable for importation into the United States. These conditions mean that animal products from these regions may be commingled with the animal products derived from animals from an FMD-affected region, which – without certain restrictions – would result in an undue risk of introducing FMD disease into the United States.

179. APHIS has therefore determined that subjecting these animal products to the additional mitigations listed in 9 C.F.R. 94.11 will enable the safe importation of these products into the United States.

180. APHIS has also completed its risk analysis with respect to Uruguay and has determined that Uruguay is not FMD-free because of the potential for the disease to exist among vaccinated animals. Accordingly, meeting the U.S. ALOP requires certain restrictions on imports from Uruguay. In particular, APHIS has determined that certain animal products from Uruguay may be safely imported subject to the following conditions set out in 9 C.F.R. 94.22.

181. Finally, the United States would note that the U.S. ALOP does not mean “zero risk.” Instead, the United States has imported FMD-susceptible animals and products from a number of Members, but only after completing the APHIS review of the scientific evidence. This process has been successful for over 80 years, and thus we have 80 years of evidence that U.S. import regulations have been working.

Question 43: In the most recent risk assessment for Patagonia, submitted to the Panel as Exhibit USA-133, APHIS describes "the overall risk of FMD to US animal health" from imports of FMD-susceptible animals and products from the Patagonia Region as being "very low". Is that an expression of the US ALOP as applied to the risk of FMD? What is the relationship between APHIS' determination and the US ALOP?

ANSWER:

182. As discussed in the U.S. response to Panel Question 42, the U.S. acceptable level of protection with regard to FMD is reflected in the AHPA at 7 U.S.C. Section 8303.⁷⁷ Imports of FMD-susceptible animals and animal products into the United States must be “safe,” meaning they must not introduce into or disseminate within the United States the FMD virus.

183. In its most recent risk assessment for the Patagonia region, APHIS found that the overall risk posed to U.S. animal health from imports from Patagonia would be “very low.” This level meets the U.S. ALOP that the products must be safe. The United States notes, however, that the risk found in any particular risk assessment does not itself define the U.S. ALOP. So, in this instance, “very low” risk (as found for Patagonia) is not equivalent to the U.S. ALOP. Rather, as the United States has explained, the U.S. ALOP is that imports of FMD-susceptible animals and animal products must not introduce into or disseminate within the United States the FMD virus.

⁷⁷ Exhibit USA-75.

Question 44: Please express your views concerning the Appellate Body's reasoning in *Australia – Apples* with respect to the Panel's role in making an assessment under Article 5.6 of the SPS Agreement as to whether the alternative measure proposed by the complainant would achieve the importing Member's appropriate level of protection⁷⁸, and the relevance of that reasoning for the Panel's analysis. In your answers, please address how the Panel should evaluate any scientific evidence adduced by the parties with respect to this analysis.

ANSWER:

184. Argentina failed to meet its burden⁷⁹ to establish that the U.S. measure is inconsistent with Art. 5.6.

185. The Appellate Body stated in *Australia – Apples*, “we cannot conceive of how a complainant could satisfy its burden of demonstrating that its proposed alternative measure would meet the appropriate level of protection under Article 5.6 without relying on evidence that is scientific in nature.”⁸⁰ The United States views this Appellate Body finding as well-founded, and fully consistent with the text of the SPS Agreement.

186. Applying that finding to the facts of this dispute, Argentina has not made this showing. It merely asserts that either the OIE guidelines or the set of measures applied to Uruguay would meet the appropriate level of sanitary protection of the United States. But Argentina has not submitted any scientific evidence on the record that establishes that the scientific analysis that applies to Uruguay is applicable to Argentina and that therefore the measure is scientifically appropriate for meeting the U.S. ALOP.

Question 45: The United States argues that "products from countries that are FMD-free with vaccination do not meet the acceptable level of protection (ALOP) of the United States". In light of the above, please explain why pursuant to 9 CFR 94.22, fresh (chilled or frozen) beef from Uruguay, a country classified by the OIE as FMD-free with vaccination, is allowed to be imported into the US territory.

ANSWER:

187. As this question notes, the United States does allow imports of beef from Uruguay. However, as detailed in the above response to Panel Question 42, the United States imposes a number of important, scientifically justified requirements on such imports. Without such requirements, import of beef from Uruguay would not meet the U.S. ALOP.

⁷⁸ *Australia – Apples (AB)*, at paras. 354-356 and 360-366.

⁷⁹ *Australia – Apples (AB)*, at paras. 360

⁸⁰ *Australia – Apples (AB)*, at para. 364

188. The quotation contained in Panel Question 45 thus refers to importation without the restrictions currently imposed on beef from Uruguay. In particular, in paragraph 299 of the U.S. first written submission states that “OIE guidelines for importation of products from countries that are FMD-free with vaccination do not meet the acceptable level of protection (ALOP) of the United States.” The OIE guidelines only require “the presentation of an international veterinary certificate attesting that the entire consignment of meat comes from animals which: (1) have been kept in the FMD free country or zone where vaccination is practiced, or which have been imported in accordance with Article 8.6.12, Article 8.6.13 or Article 8.6.14; and (2) have been slaughtered in an approved abattoir and have been subjected to ante- and post-mortem inspections for FMD with favorable results.” As the United States has explained in its first written submission and in its answer to Panel Question 12, the United States does not consider countries that are recognized by the OIE as FMD-free with vaccination as free of the disease.

189. And, as the United States explained in its answer to Panel Question 42, additional restrictions that the United States requires for beef imported from Uruguay mitigate the risk from such imports to a level where the United States believes importations will meet its ALOP.

Question 46: Argentina argued at the first substantive meeting that the import protocols for Uruguay set forth 9 CFR 94.22 are equivalent to those the OIE recommends for products from FMD-infected areas. Please explain why the application to Argentina of import protocols identical or similar to those applied to Uruguay would not meet the US ALOP.

ANSWER:

190. As an initial matter, the United States would clarify that the import protocols for Uruguay set forth in 9 CFR 94.22 are similar to the mitigations the OIE recommends for importation from FMD - infected countries or zone where an official control program for FMD, involving compulsory systematic vaccination of cattle, exists. (OIE Article 8.6.25) These are not mitigations that the OIE recommends for importation from FMD-infected countries.

191. This question perfectly illustrates the fundamental mismatch between Argentina’s claim under Article 5.6 and the core facts of this case. For the question being asked – whether applying the mitigation protocols for Uruguay’s meat imports to Argentina’s meat imports would, or would not, meet the United States’ ALOP – is the precise type of question that APHIS is at this very moment analyzing. To be sure, APHIS has made substantial progress on this type of issue. Yet, until the analysis is completed, it remains an open scientific question.

192. To determine whether and what, if any, mitigation protocols are necessary for proposed imports from Argentina, APHIS must obtain and analyze information on the FMD risk posed by such imported products. APHIS does not derive this data solely from a country’s OIE FMD status. The United States cannot simply assume, because Uruguay and Argentina have the same OIE FMD status, that the application to Argentina of import protocols identical or similar to those applied to Uruguay would meet the U.S. ALOP. As discussed above, the fact that two countries have the same OIE FMD status does not mean that the veterinary systems and sanitary

conditions in both countries are the same or that the FMD risk posed by that country is the same for purposes of determining what mitigations would reduce that risk to meet the United States' higher ALOP.

193. Rather, APHIS must obtain and independently analyze empirical information based on the 8 factors that it has described previously to determine what SPS measures are necessary to meet the United States' high ALOP. To that end, APHIS must evaluate, among other things, the country's risk of having FMD introduced in the export region; the country's prevention measures and the rigor of their implementation; the country's detection capabilities, surveillance and reporting systems; the country's emergency response and control systems to combat FMD in the export region should FMD be introduced to the region; and the potential that undetected FMD-infected cattle could be presented for slaughter, processing, and export.

194. Further, in the context of commodity import mitigations, APHIS must also assess another factor: the country's capability to effectively and consistently mitigate these risks through appropriate processing procedures and control and inspection measures at slaughter facilities. This information is extremely important to the United States, as the effectiveness of these mitigations is entirely dependent on their consistent and correct application by the slaughter facilities and the proper and consistent oversight of the country's veterinary services over these slaughter facilities' implementation of the mitigations. The OIE FMD status review does not assess the capabilities and practices of the countries' slaughter facilities. When granting FMD status, OIE does not obtain detailed information from the country regarding practices at its slaughter facilities (such as the practices and internal controls that would be necessary to conduct the FMD mitigations or the necessary precautions that must be taken after processing to avoid contact of the meat products with meat and meat products sourced from a country with a different risk categorization that could be a potential source of FMD virus).

195. In sum, with regard to meat imports from Uruguay, APHIS has determined that the level of risk posed by Uruguay can be sufficiently mitigated to meet the appropriate level of protection of the United States by, among other things, undertaking the proper deboning and maturation of beef and Uruguay has appropriate processing procedures and control and inspection measures to consistently ensure that ante and post-mortem inspection as well as deboning and maturation are properly performed by the slaughter facilities in conformity with APHIS' requirements. In order to decide whether the application to Argentina of import protocols identical or similar to those applied to Uruguay would meet the appropriate level of protection of the United States, APHIS must make a similar assessment of Argentina, which it has not yet completed.

7 REGIONALIZATION (ARTICLE 6 OF THE SPS AGREEMENT)

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

ANSWER:

196. Article 6.3 is directly relevant to Argentina’s case because Argentina asserts that it is free of FMD. The fact that Argentina’s request concerns Argentina as a whole does not remove the request from the scope of Article 6. On this point, the SPS Agreement is clear: Article 6 applies to pest- or disease-free areas, and Annex A defines pest- or disease-free area as “an area, **whether all of a country, part of a country, or all or parts of several countries**” in which a specific pest or disease does not occur. Further, Article 6.1 likewise specifies that an “area” may be “all of a country, part of a country, or all or parts of several countries.” Thus, regardless of whether Argentina claims a breach of Article 6 with respect to its pending request concerning Argentina as a whole, Article 6 – by its plain language – applies to the Argentina’s pending request for Argentina’s territory as a whole.

197. The fact that Argentina did not make a *legal claim* of a breach of Article 6 with respect to the area of Argentina as a whole is not relevant to whether the obligations of the exporting and importing Member under Article 6 apply to an analysis informing Article 6.1 and Article 5. Article 6.3, in using the term “claim” is not referring to “claim” in the sense of a “legal claim” under the DSU. Rather, this refers to a request made to an importing Member to recognize a disease free status.⁸¹ In other words, Article 6.3 is addressing the situation in which a Member comes forth asserting that areas within its territory are pest- or disease-free or low pest or disease prevalence. In those circumstances, the Member shall provide the “necessary evidence.”

⁸¹ The term “claiming” as used in Article 6.3 is the participle form of the verb “to claim,” which is defined as to “state or assert that something is the case, typically without providing evidence or proof.” This definition is most appropriate because Article 6.3 recognizes that the Exporting Member “claiming” or asserting that an area is pest-or disease-free or of low pest or disease prevalence “shall provide the necessary evidence.” Oxford English Dictionary, “Claim” (Exhibit USA-146).

Question 49: What is the relationship between Articles 6.1, 6.2 and 6.3 of the SPS Agreement? Do the Article 6.3 requirements only apply to claims of inconsistency with Article 6.1? Is there a relationship between Articles 6.1 and 6.2 and Article 5.1?

ANSWER:

What is the relationship between Articles 6.1, 6.2 and 6.3 of the SPS Agreement?

198. Each of the three paragraphs under Article 6 should be read together. Those paragraphs provide context for each other. Article 6 must be read so that it works as a coherent whole, while the language in each of the three paragraphs is respected.

199. Article 6.1 sets out the general principle that Members have an obligation to ensure that their measures are adapted to the conditions of the area from which products originate and to which the product is destined. The word “adapt” is defined as “[f]it, adjust (*to*); make suitable (*to* or *for*)” in the Oxford English Dictionary. It connotes a dynamic process by which Members receive relevant information, evaluate it, and adjust their measures to fit appropriately the sanitary or phytosanitary characteristics of an area.

200. Article 6.3 describes the process and the obligations for operationalizing Article 6.1’s obligation to “ensure” measures are “adapted” where the adaptation in those measures concerns either areas that are pest- or disease-free or areas of low pest or disease prevalence. This dynamic of adapting the measure begins when the exporting Member asserts that an area is “pest- or disease-free” or of “low pest or disease prevalence.”⁸² The exporting Member must submit the necessary evidence that demonstrates “that such areas are and are likely to remain at the asserted status. Article 6.3 obligates the exporting Member to allow access to the territory of the exporting Member for “inspection, testing and other relevant procedures.”

201. Article 6.2 of the SPS Agreement provides that Members are required to recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. It establishes a basic obligation that a Member accept the general notion of pest- or disease-free areas and areas of low pest or disease prevalence. Article 6.2’s obligation to “recognize the concept” of such types of areas informs the obligation in Article 6.1 to adapt measures to conditions of a specific area.

202. This understanding of Article 6 is coherent and recognizes the realities of what national regulators face in attempting to make the complex determination regarding the current sanitary or phytosanitary situation in another country and the likelihood that it will remain in that situation. This understanding recognizes that it is the exporting Member that is most likely to have directly relevant information concerning, for example, “level of prevalence of specific diseases or pests” and the “existence of eradication or control programmes.” Accordingly,

⁸² The SPS Committee's Guidelines to Further the Practical Implementation of Article 6 (Document G/SPS/48 of 16 May 2008) (Exhibit USA-128) confirms this. See U.S. Response to Panel Question 51.

Article 6.3 appropriately obligates the exporting Member to provide that information so that the importing Member can adapt its measures to current conditions.

Do the Article 6.3 requirements only apply to claims of inconsistency with Article 6.1?

203. No. Article 6.3 also informs the understanding of any claim involving an alleged failure to accept a request that all or part of a Member’s territory is entitled treatment as a pest- or disease-free area, including claims involving risk assessment obligations under Article 5. Article 5.1 obligates Members to ensure that their measures are based on a risk assessment. Article 5.2 identifies “prevalence of specific diseases or pests” and the “existence of pest- or disease-free areas” as factors to “take into account” in conducting a risk assessment.

204. The repetition of “prevalence of specific diseases or pests” and “existence of pest- or disease-free areas” in Article 5.2 and in Article 6.3 demonstrates the relationship between the obligation of an importing Member to have a risk assessment and the fact that it is the exporting Member that often is the only party that has access to the relevant information. In fact, it is not likely that an importing Member would be able to conduct a risk assessment concerning an assertion of the prevalence of a disease in the exporting Member without the exporting Member providing scientific evidence, including inspection, sampling and testing data, and epidemiological data. Article 6.3 recognizes this fact and requires the exporting Member to provide access to the importing Member so that it can conduct activities to seek to evaluate the exporting Member’s assertion of disease status and its likelihood of remaining in that disease status.

Is there a relationship between Articles 6.1 and 6.2 and Article 5.1?

205. As an initial matter, the United States considers that this question applies equally to all of Article 6, including Article 6.3, as well as to Article 5.1 and Article 5.2.

206. Article 5.1 sets out that Members are obligated to have their measures based on an assessment of risks. Article 5.2 elaborates upon factors that the assessment of risks shall take into account, including “available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases and pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment” (emphasis supplied).

207. In a situation such as that at issue in this dispute, in which an importing Member’s measure in question is connected to the sanitary and phytosanitary characteristics in another Member, the risk assessment called for in Article 5.1 intersects with the processes and obligations defined in Article 6 as a whole.

208. When a Member is seeking to ensure its measures are “adapted to the sanitary or phytosanitary characteristics of an area . . . from which the product originated,” Article 6.1 states that the Member shall take into account “the level of prevalence of specific diseases or pests,” as well as “the existence of eradication or control programmes.” The overlap of these factors with

those listed in Article 5.2 illustrates that an importing Member’s inquiry into adapting measures to the sanitary characteristics of an exporting Member could be part of the process of assessing risk under Article 5.1.

209. The process of adaptation of an importing Member’s measures to the sanitary characteristics of the exporting Member is informed by Article 6.3. When an exporting Member seeks to export product referred to in Article 6.1 and asserts that the product originates from “pest- or disease-free areas or areas of low pest or disease prevalence,” then the exporting Member, under Article 6.3, must come forth with the information that shows that such areas “are, and are likely to remain, pest or disease-free areas or areas of low pest or disease prevalence[.]”

210. Because Article 6.2 establishes the basic obligation that a Member recognize the general notion of pest- or disease-free areas and areas of low pest or disease prevalence, Article 6.2 generally informs the obligation in Article 6.1 to adapt measures to conditions of an area. Any such “determination of those areas” that would be made in the process of operationalizing Article 6.1 would be based on factors “such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.” These factors are also largely reflected in Article 5.2 when it addresses factors such as “inspection, sampling and testing methods,” “existence of pest- or disease-free areas,” “relevant ecological and environmental conditions,” and “quarantine and other treatment.”

211. This reflects the reality that when a Member is adapting its measure under Article 6 it may also be in the process of conducting an Article 5.1 risk assessment. In the process of conducting that Article 5.1 risk assessment, it takes into account factors in Article 5.2 that are clearly similar to those factors that are being considered throughout Article 6.

212. This understanding that the inquiry in Article 6 may be intertwined with the inquiry under Article 5 gives insight into how Article 5’s risk assessment provisions should be understood in the period after an exporting Member asserts that conditions have changed and it is now a disease-free area. Article 6 reflects this dynamic: that the adaptation of the measure is made subsequent to the importing Member’s evaluation of relevant information provided by the exporting Member.

Question 50: Is Article 6 of the SPS Agreement the only applicable provision with respect to "pest- or disease-free areas"? In your answer, please refer to Article 5.2.

ANSWER:

213. As the question implies, Article 6 should be read together with other relevant articles, including Article 5.2. Article 5.2 directly addresses “pest- or disease-free areas” and states that the existence of such areas shall be taken into account in conducting an assessment of risks. Article 5.2 is an elaboration on the assessment of risks, which Members are obligated to perform under Article 5.1.

214. As discussed in response to Panel Question 49, Article 6.3 and Article 5.2’s reference to “pest- or disease-free areas” demonstrates the relationship between the obligation of an importing Member to have a risk assessment and the fact that it is the exporting Member that often is the only party that has access to relevant information necessary to conduct that assessment.

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

ANSWER:

215. The United States views the Guidelines as informative with respect to the process that Members should follow when there is a request to facilitate trade on the basis of an assertion or claim that an area is pest- or disease-free or of low pest or disease prevalence under Article 6.1, Article 6.2 and Article 6.3. The Guidelines were adopted by the SPS Committee without objection and took into account the work of the OIE. The Guidelines are “intended to provide assistance” to members “*in the practical implementation of Article 6*”⁸³ but do not provide “legal interpretation.”⁸⁴

216. The Guidelines reflect the generally recognized and common-sense approach that should characterize the process by which an importing Member reviews a claim or assertion by an exporting Member for the recognition of pest- or disease-free areas or areas of low pest or disease prevalence. The significance for the Panel of the Guidelines are these four key principles:

- First, the process of determining import authorization based on such a claim or assertion **begins with a request by the exporting Member**. The Guidelines state: “The importing Member should, **upon request**, enter into discussions with the exporting Member with the aim of clarifying the importing Member’s general process and the information generally required to facilitate a request for the recognition of a pest- or disease-free area or area of low pest or disease prevalence.”⁸⁵
- Second, the importing Member can legitimately restrict the entrance of the importing Member’s product pending the completion of the import authorization process. The Guidelines state: “Where its evaluation of the evidence provided by the exporting Member results in recognition of the pest- or disease-free area or area of low pest or disease prevalence, the importing Member **takes the**

⁸³ Exhibit USA-128, at para. 1.

⁸⁴ Exhibit USA-128, at para. 2.

⁸⁵ Exhibit USA-128, at paras. 13, 20 - 21.

necessary administrative or legal steps to facilitate trade from the exporting Member.”⁸⁶ (This makes particular sense in the case of FMD, given its hardness and ease of transmissibility. If a Member were required to allow unrestricted import of FMD-susceptible product upon a mere assertion by the importing Member that it did not have FMD during the pendency of the import authorization application review process, then the likely outcome would be that most countries would become infected with the disease.)

- Third, the Guidelines acknowledge that the import authorization decision is based on a series of exchanges between the importing and the exporting Members, as well as on-site verification to consider “[t]he strength and credibility of the veterinary or phytosanitary infrastructure of the exporting region.”⁸⁷
- Fourth, past experience with the exporting Member is a factor to consider. The Guidelines state: “The importing Member should take into account any relevant knowledge of and prior experience with the authorities of the exporting Member.”⁸⁸

217. The actions of the United States are in accord with these four key principles discussed, which reflect what is needed “in the practical implementation” of Article 6.

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

ANSWER:

218. Article 6.1 refers to an “area” in requiring Members to adapt SPS measures, and refers to a “region” in discussing the characteristics that Members should take into account. Because Article 6.1 uses different words, it is conceivable that different meanings are intended. However, in the context of this dispute, there does not appear to be any issue that turns on the potential difference between these two terms.

⁸⁶ Exhibit USA-128, at para. 31.

⁸⁷ Exhibit USA-128, at para. 27.

⁸⁸ Exhibit USA-128, at para. 9.

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

ANSWER:

219. As discussed in the answer to Panel Question 17, a country’s OIE disease status does not fall within the scope of an “international standard, recommendation or guideline” as used in Article 3 and Annex A. Likewise, OIE status does not fall within the scope of “criteria or guidelines” under Article 6.1.

220. With regard to a guideline: the definition of the term “guideline” is “a directing or standardizing principle laid down as a guide to procedure, policy, etc.”⁸⁹ A country or region’s OIE disease status is not a “principle, standard, test” or a “directing or standardizing principle” in the ordinary meaning of those words. Rather, it is a specific conclusion concerning a particular applicant.

221. With regard to criteria: Similarly, a country or region’s OIE disease status does not fall within the scope of the term “criteria.” A “criteria” or “criterion” is “A principle, standard, or test by which a thing is judged, assessed, or identified.”⁹⁰ A country or region’s OIE disease status is the outcome of applying a set of criteria to a particular country or region’s conditions. The OIE disease status is an example of one entity’s determination.

222. In its regulations, APHIS does take notice of information provided by the OIE, for example by examining reports of “outbreaks of the disease . . . from the World Organization for Animal Health (OIE).”⁹¹ In the recent risk assessment by APHIS accompanying its notice for the proposal to designate Patagonia as free of FMD, APHIS took notice of the OIE disease status of Patagonia.⁹² APHIS also took notice, for purposes of the risk assessment, the OIE disease status of regions adjacent to Patagonia.⁹³ OIE actions can be relevant and helpful for APHIS in making its independent determination.

⁸⁹ Oxford English Dictionary (1993), “Guideline” (Exhibit USA-130).

⁹⁰ Oxford English Dictionary (1993), “Criteria” (Exhibit USA-129).

⁹¹ 9 C.F.R. § 94.1(a)(2)) (Exhibit USA-134).

⁹² Exhibit USA-133, at pp. 7, 27

⁹³ Exhibit USA-132, at p. 23.

Question 54: What is the meaning, under the customary rules of interpretation of public international law, of the following terms in Article 6:

(a) "adapt to" in Article 6.1, first sentence?

ANSWER:

223. Article 6.1 states, in relevant part, that “Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area[.]” This does not compromise the Member’s right to set its appropriate level of protection. Rather, Article 6.1 supports that right by having Members make those adaptations to their measures that are appropriate to the circumstances, including their ALOP.

224. The Oxford English Dictionary (OED) defines “adapt” as “[f]it, adjust (*to*); make suitable (*to* or *for*).” The customary rules of treaty interpretation reflected in the Vienna Convention on the Law of Treaties provide 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 in the light of its object and purpose.”⁹⁴

225. The process of adapting measures, or making them suitable, to the sanitary or phytosanitary characteristics of an area is informed by, and may only be able to resolved based on, information supplied by the exporting Member. “Adapt to” describes a **dynamic** process where an existing measure is adjusted to the characteristics of an area. This implies that information is brought to the attention of an importing Member and that the importing Member engages in a process by which it evaluates the information and amends its measures so that they are adjusted to the characteristics of the area. Accordingly, the “adapt to” language of Article 6.1 is informed by the process by which the exporting Member brings forth information necessary for that determination to the importing Member under Article 6.3.

(b) "recognize" in Article 6.2, first sentence?

ANSWER:

226. Article 6.2 states, in relevant part: “Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence.”

227. The Oxford English Dictionary (OED) defines “recognize” as “acknowledge the existence, legality, or validity of, esp., by formal approval or sanction; accord notice or attention

⁹⁴ Vienna Convention on the Law of Treaties, Art. 31.1.

to[.]”⁹⁵ It also defines “concept” as “an idea of a class of objects, a general notion; a theme, a design.”⁹⁶

228. The obligation in “recognizing” or acknowledging the existence of the *idea* or *notion* of pest- or disease-free areas is met by APHIS regulation 9 C.F.R. § 94.1. In particular 9 C.F.R. § 94.1(a)(2) states that “APHIS will add a region to the list of those it has declared free of . . . foot-and-mouth disease . . . after it conducts an evaluation of the region in accordance with § 92.2 of this subchapter and finds that the disease, or diseases, are not present.”⁹⁷ A “region” is defined as “[a]ny defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of the following: (1) A national entity (country); (2) Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.); (3) Parts of several national entities combined into an area; or (4) A group of national entities (countries) combined into a single area.”⁹⁸

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

ANSWER:

229. The context of the terms “based on” as used in Article 6.2 is substantially different from that in Article 3.1 (based on international standards), and somewhat different from that in Article 5.1 (based on an assessment of the risk). Thus, the phrase “based on” in Article 6.2 conceivably could have a somewhat different meaning. That said, the United States is not aware of a reason not to use the ordinary meaning of “based on,” as has been found for Articles 3.1 and 5.1 of the SPS Agreement. The Appellate Body in *EC – Hormones* stated that “based on” means something “stands” or is “founded” or “built” or “is supported” by something else.⁹⁹ It elaborated in *US – Continued Suspension*, that for measures to be “based on” a risk assessment in the context of Article 5.1, the risk assessment should “reasonably support” the SPS measure.¹⁰⁰ The wider scope of “based on” is in distinct contrast to “conform to” which the Appellate Body concluded, in part, as requiring “following[ing] in form or nature.”¹⁰¹ The Appellate Body rejected that the meaning of “based on” and “conform to” were identical.¹⁰²

⁹⁵ Oxford English Dictionary, at p. 2503 (Exhibit USA-147).

⁹⁶ Oxford English Dictionary, at p. 467 (Exhibit USA-148).

⁹⁷ 9 C.F.R. § 94.1(a)(2) (Exhibit USA-134).

⁹⁸ 9 C.F.R. § 94.0. (Exhibit USA-71).

⁹⁹ *EC – Hormones (AB)*, at para. 163.

¹⁰⁰ *US – Continued Suspension (AB)*, at para. 528.

¹⁰¹ *EC – Hormones (AB)*, at para. 163.

¹⁰² *EC – Hormones (AB)*, at para. 163.

230. In addition, the United States observes that “based on” in Article 6.2 is followed by the phrase “such as,” which connotes that the list that follows is illustrative and not exhaustive.

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

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

ANSWER:

231. No. The obligations under Annex C(1)(b) pertaining to “transmit[ing] as soon as possible the results of the procedure in a precise and complete manner to the applicant so that the corrective action may be taken if necessary” do not arise where there are no final results. This understanding is supported by the Panel’s findings in *EC – Approval and Marketing of Biotech Products*. In that dispute, the panel determined that there were no final results for the EU to communicate; therefore the EU did not act inconsistent with this obligation.¹⁰³

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

ANSWER:

232. The United States has two initial comments. First, as the United States has explained, Annex C, when properly construed, does not apply to claims under Article 6.3 of disease-free status. Thus, the term “applicant” as used in Annex C was not intended to include Members that have made claims of disease-free status.

233. Second, if the premise of this question is that the United States has not communicated otherwise with Argentina, then the United States would not agree with that premise. In fact, the United States and Argentina have had many exchanges regarding Argentina’s claims of disease-free status. Throughout the evaluation process, the United States has responded to Argentina in a timely manner.¹⁰⁴

234. That said, with respect to the Panel’s specific question, the answer is yes. Nothing in Annex C(1)(b) excludes statements made in the SPS Committee. However, such statements are not given any special weight under the Annex.

¹⁰³ *EC – Approval and Marketing of Biotech Products*, at para. 7.1595.

¹⁰⁴ U.S. First Written Submission, at paras. 131-163.

235. Argentina raised its issues related to its requests in the SPS Committee as a Special Trade Concern. In response to Argentina’s comments and questions, the United States responded to communicate the stage of the evaluation process. Furthermore, throughout its submission, Argentina acknowledged multiple statements made by the United States in the SPS Committee regarding the stage of the evaluation procedure. However, the majority of communication between the United States and Argentina has occurred between APHIS and SENASA and not in the SPS Committee.

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

ANSWER:

236. A finding that the measures of the United States are consistent with Article 8 and Annex C(1)(a) would provide support for a finding that the measures of the United States are also consistent with Articles 2 and 5. As the United States has explained, the “undertake[] and complete[] without undue delay” obligation in Annex C is comparable to the “review . . . within a reasonable period of time” obligation in Article 5.7. Accordingly, a finding that the United States did not breach the “undue delay” element of Annex C would support a finding that the United States likewise acted consistently with the “reasonable period of time” element of Article 5.7. Furthermore, a finding that the U.S. measure fell within the scope of Article 5.7 would support a finding that the United States did not breach Article 2 and Article 5.1.

237. The United States also notes that both Annex C and Article 5.7 contemplate that measures may be maintained while a Member is in the process of conducting a risk assessment. With respect to undue delay under Annex C, the premise of examining undue delay in an approval procedure is that a product will not be approved – and thus will be subject to an SPS measure – until the process is completed.¹⁰⁵ *EC – Approval and Marketing of Biotech Products* is the best example of this. Thus, while a Member is engaged in the approval process, and while any associated risk assessment is underway, there is no basis for arguing that the SPS measure must be based on the not-yet-completed risk assessment.

238. Similarly, when a measure meets the requirements of Article 5.7, that measure does not need to be based on a risk assessment under Article 5.1 because a risk assessment is either in process, or unable to be made because of a lack of information. Further, a measure that meets Article 5.7 requirements would then come within the exception for Article 5.7 in Article 2.2.

¹⁰⁵ See, e.g., Annex C(1): “Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.”

What would be the implications of a finding that the US measures are inconsistent with Article 8 and Annex C(1)(a) and/or not justified by Article 5.7?

ANSWER:

239. Annex C(1)(a): A finding that the United States engaged in undue delay under Annex C(1)(a) does not in itself substantiate Argentina’s substantive claims. A determination that the United States has not acted with sufficient pace would indicate that the United States has not acted consistent with its procedural commitments under Annex C of the SPS Agreement. However, a finding of procedural inconsistency does not require such a finding with respect to Argentina’s substantive claims.

240. Article 5.7: If the panel were to find that the review of the United States did not occur within a reasonable period of time under Article 5.7, then the panel should conclude that the importing Member failed to satisfy the time requirements under Article 5.7. The panel would then address the claim under Article 2.2 and then Article 5.1. The panel could then appropriately exercise judicial economy with respect to the rest of the claims brought by Argentina.¹⁰⁶

241. This approach most serves the interest of “achieving a satisfactory settlement of the matter in accordance with”¹⁰⁷ the Agreement. 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.

Question 58: The United States' argues that determinations involving disease-free areas fall outside the scope of Article 8 and Annex C of the SPS Agreement.

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

ANSWER:

242. As the United States explained in its first written submission, the measures falling into the purview of Annex C(1) and Article 8 are limited to control, inspection and approval procedures. This is clear from the text of Article 8, as well as the title of Annex C.

¹⁰⁶ EU’s Third Party Written Submission, at para. 67.

¹⁰⁷ DSU, Article 3.4.

243. The U.S. application system applies to determinations of the health status of a region, not particular products or substances of which Annex C(1) contemplates. Further, Article 8 does not indicate that control, inspection or approval procedures were intended to involve the examination of disease-free status.

244. With respect to the respective scopes of coverage of the two provisions, they share the same scope. The only manner in which Annex C is expressly incorporated is through the text of Article 8. As a logical matter, Article 8 and Annex C must have the same scope.

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

ANSWER:

245. The answer depends on precisely what question is being addressed by the risk assessment. For example, if the risk assessment involves the approval of a food additive, then the assessment of the risk associated with the additive would be covered by Annex C. This is clear from the text of the Annex, which explicitly refers to the approval of food additives. On the other hand, an assessment of the risk associated with a claim of disease-free status does not involve an approval procedure within the meaning of Annex C. Accordingly, the procedures associated with conducting this type of risk assessment are not subject to the requirements of Annex C.

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

ANSWER:

246. The amount of time taken by other Members is of no special relevance with respect to the Panel’s determination of whether the U.S. acted with undue delay in evaluating Argentina’s requests. “Undue delay” must be evaluated based on the specific facts and circumstances involving the particular procedure at issue. For example, one Member may require specific scientific information in order to reach a decision, and the procedure may be delayed for a substantial period while the information is being prepared. This delay – even if of substantial length – would not be undue as long as the Member legitimately requires the scientific information to meet its particular ALOP. A different Member may not require such information to meet its ALOP, and thus may reach a decision in a substantially shorter period of time. The resulting difference in the processing period, standing alone, is not instructive with regard to whether or not the first Member acted with undue delay.

247. In this dispute, Argentina – aside from indicating differences in time periods – has failed to demonstrate how or why time taken for a U.S. review of a claim of disease-free status should be the same as the time taken by Chile and the EU. The following discussion further elaborates on the deficiencies in Argentina’s argument that other Member’s determinations of disease-free status are instructive with regard to U.S. determinations.

248. *Application Systems*

- As explained above in response to Question 13(b), *infra*, the U.S. application system is based on the OIE Terrestrial Code. Additionally, the U.S. application system, as set out in Section 92.2., requires a uniform, transparent regulatory process in addition to the risk evaluation process. This process involves a thorough evaluation of the region’s FMD situation -- an assessment the U.S. implements to ensure imports satisfy its heightened level of protection. Not only is such a system reasonable, it is substantively consistent with the U.S. obligations under the SPS Agreement.
- Here, Argentina provides information on the time periods taken by Chile and the European Union to authorize its imports following FMD outbreaks in 2002 and 2006. Argentina presumes that the U.S. evaluation period has been unreasonable because it has not resembled these time periods. What Argentina fails to demonstrate is the basis for comparing these time periods. Nowhere in the record does Argentina show that the U.S. application system is similar to the systems employed by Chile and the EU. For example, there is no indication that Chile and the EU implement a comparable, transparent regulatory framework that allows stakeholders to provide information during the process.

249. *Argentina’s Requests*

- Argentina has submitted three requests to the United States: (1) an application for the recognition of Argentina (as a whole) as FMD-free in 2002; (2) an application for the recognition of Patagonia as an FMD-free region in 2003; and (3) an informal request to extend of its pre-existing request to include Patagonia North B in 2007.
- Argentina has not provided any support that its application process to Chile and the EU has involved the same complicated and disjointed process.

250. *Appropriate Level of Protection*

- Another failing in Argentina’s argument is that Argentina seems to presume, without any evidence, that the U.S. appropriate level of protection is exactly the same as that in the EU or Chile.

Question 60: In its first written submission, Argentina cites an APHIS webpage stating that APHIS' review process of applications "can take several years". Does the United States have a "standard" or "average" time-period required for the completion of the review process of applications for authorization of imports of FMD-susceptible products? If so, is such a time-period specified in any legal instrument?

ANSWER:

251. The United States does not have a “standard” or “average” time-period required for the completion of the review process of applications for authorization of imports of FMD-susceptible products. As discussed in greater length in the United States’ answer to Panel Question 66, the length of time can and does vary and depends on the specific situation.

Question 61: Please explain in detail:

(a) Why there was a 4-year gap between APHIS' site visit to Patagonia in 2003 and the publication of the proposed rule for Patagonia in 2007?

ANSWER:

252. APHIS’ site visit to Patagonia South occurred December 1-5, 2003. The proposed rule for Patagonia South was published January 5, 2007. During these three years, a number of significant events occurred, including that Argentina’s OIE FMD-free with vaccination designation was suspended by the OIE following an outbreak reported in the Salta province in December 31, 2003. APHIS met two times in 2004 with SENASA to discuss the new situation and requested additional information, to which SENASA responded in November 2004. Based upon this information, APHIS drafted its risk assessment, which it concluded in June 2005. After completing the risk assessment, but prior to publication of the proposed rule, APHIS prepared an analysis to comply with the Regulatory Flexibility Act, as well as separate reviews for Executive Order 12988, addressing legal and judicial effects of the proposal, and for the Paperwork Reduction Act, addressing information collection and recordkeeping requirements.

253. Concurrent with these demands, the same APHIS technical experts assigned to the Patagonia South application were also simultaneously processing Argentina’s application for import authorization for fresh, chilled, and frozen beef. The proposed rule was published in January 2007, approximately 1 ½ years after the conclusion of the June 2005 risk assessment.

(b) Why there was a 6-year gap between APHIS' site visits of September 2006 and the proposal for a new site visit made in November 2012?

ANSWER:

254. To clarify, APHIS conducted site visits to Argentina in 2003, 2005, 2006, 2009, and 2013. After the site visit in 2005, APHIS finished its initial risk assessment and prepared and published the proposed rule for Patagonia in January 2007. The rule, as discussed in the U.S. response to Panel Question 28, evoked a number of concerns expressed by interested parties.

Consequently, APHIS determined it was necessary to conduct another site visit to resolve these concerns. Argentina finally permitted this site visit in February 2009. APHIS was in the process of updating and finalizing the risk assessment to cover both Patagonia South and North B, when Argentina filed a request for WTO consultations in August 2012. During this WTO litigation, which has occupied a considerable amount of time of APHIS’ technical experts, APHIS has been able to finalize and publish the notice proposing to recognize the Patagonia region as FMD-free and is very close to finalizing its initial risk assessment for commodities imported from Northern Argentina.

(c) What information was missing, prior to APHIS’ site visit to Argentina in November 2013, to complete the risk assessment for Patagonia?

ANSWER:

255. At the time of the last site visit in 2009, the revisions introduced under Resolution No. 1282 had not been completely implemented.¹⁰⁸ As a result, the United States was unable to completely assess the impact of the changes on Argentina’s FMD status.

256. Moreover, APHIS’ November 2012 request to conduct another site visit was not solely because information was missing. The visit was also necessary ensure that information from the 2005 and 2006 site visits for Northern Argentina and the 2009 site visit for Patagonia South and North B was current.

Question 62: Please explain in detail the reasons for which the delay in APHIS’ reviews of Argentina’s applications is not undue. In particular, please identify the specific instances in which, in your view, Argentina contributed to the delay.

ANSWER:

257. APHIS review of Argentina’s applications has proceeded in a manner consistent with U.S. obligations under the SPS Agreement. Argentina’s contributions to the delays fall into 3 categories: (1) informational response time; (2) changing conditions on the ground; and (3) reformulated requests.

258. Lag in informational response time: Upon receiving the first application from Argentina, for the whole territory, APHIS began its review and scheduled its site visits. Argentina contributed to the length of the review process by not providing information requested in October 2003 until October 2004.¹⁰⁹ With respect to Patagonia South, its initial submission failed to provide sufficient information on the FMD status of adjacent regions, animal movement

¹⁰⁸ See U.S. First Written Submission, at paras. 210-211.

¹⁰⁹ U.S. First Written Submission, at para. 140.

control and biosecurity, surveillance, and laboratory capacity.¹¹⁰ A similar informational request was also delayed nearly a year, from March 2004 to December 2004.¹¹¹

259. Changing conditions on the ground: Argentina’s FMD situation was not stable after 2002. Outbreaks in 2003 and 2006, further delayed review because they called into question APHIS’ findings up to that point, and required revised analysis. The changing conditions were not simply related to animal disease – SENASA itself suffered a labor strike in 2005, which caused APHIS to enquire as to how these strikes would impact its ability to maintain internal controls.¹¹²

260. Reformulated requests: Argentina changed the terms of its requests to APHIS multiple times throughout this process. It first submitted an application for the whole territory of Argentina, but only with respect to one commodity, fresh, chilled and frozen bovine meat. Shortly after that, it reformulated its request to ask APHIS to evaluate Patagonia South as a region completely free from FMD, noting that it did not vaccinate. Under APHIS rules, this application is not simply a request for commodity authorization, it also may include within its scope the permission to import live animals. APHIS was now obligated to conduct two partially overlapping reviews. Then Argentina changed the rules again, asking that Patagonia North B be included into the Patagonia South review.¹¹³ In doing this, Argentina wanted APHIS to shift consideration of Patagonia North B, which was in the territory of Argentina not including Patagonia South, into the Patagonia South application. This created, in essence, the need to review three pieces separately, taking one piece (Patagonia North B) out of the northern Argentina section and into the Patagonia section. These constant reformulations by Argentina slowed the pace under which APHIS staff could proceed.

261. Paragraphs 131-162 of the U.S. First Written Submission describe these developments in detail.

Question 63: With respect to the 2007 Proposed Rule for Patagonia South following the 2005 risk assessment for the region, why did APHIS not publish the final rule after the expiration of the 60-day period for public comments? What kinds of comments did APHIS receive and from whom? Please provide the comments to the Panel.

ANSWER:

262. The purpose of the 60-day period for public comments is to provide the public an opportunity to express its view on the proposed regulatory action. During the comment period,

¹¹⁰ U.S. First Written Submission, at para. 151.

¹¹¹ U.S. First Written Submission, at para. 152.

¹¹² U.S. First Written Submission, at para. 238.

¹¹³ U.S. First Written Submission, at para. 160.

the public often raises valid concerns or highlights significant issues that may prompt an administrative agency to review its proposal.

263. In this case, after the proposed rule was published, interested parties expressed significant concerns regarding the potential risks of the spread of FMD to the United States. U.S. cattle and sheep producers, a State animal industry board, a stockyard operator, U.S. beef and sheep industry associations, a U.S. meat importers’ association, an Argentine meat industry association, an Argentine Government agency, and private citizens all submitted a total of 45 comments on the rule. As discussed in the U.S. answer to Panel Question 28, many commenters expressed concern that allowing imports from Patagonia South would put U.S. livestock at risk for disease. Some commenters expressed a lack of confidence in Argentina’s veterinary infrastructure and border controls, both nationwide and in Patagonia South specifically, noting that FMD outbreaks in Argentina in 2001 took months to be identified. These commenters asked why APHIS believed that Argentine authorities would be able to detect FMD in Patagonia South in the event of a future outbreak. Other commenters were concerned that Argentina’s conditions for import of meat into Patagonia South did not meet U.S. standards and could result in increased risk for disease introduction into the United States. Several commenters also stated that the risk analysis provided with the proposed rule was based on out-of-date information (2003 site visit), and noted that the risk analysis was concluded in 2005, eight months before Argentina suffered another FMD outbreak.¹¹⁴

264. When APHIS receives significant comments, it reviews the proposed regulatory document in light of these comments and revises the regulatory document as appropriate. Given these comments, APHIS needed additional time to update and reconfirm its conclusions.

265. Since the publication of the proposed rule, USDA has consulted with interest parties, both domestic and international, to review the potential risk of FMD from products from Argentina. This consultation is proper and necessary risk communication “to ensure the open exchange of explanatory information and opinions that lead to better understanding and decisions.”¹¹⁵

¹¹⁴ All of the public comments in the U.S. rulemaking process are kept in a public docket, which may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2005-0096>. Due to time constraints, the United States has not included copies of relevant comments with these answers, but the United States will submit them as exhibits no later than with the U.S. second submission. In addition, the United States is prepared to provide these exhibits earlier, should the Panel so request.

¹¹⁵ WTO SPS Training Module, Chapter 2, 2.1 “Risk Analysis” (noting that risk communication implies the open exchange of explanatory information and opinions that lead to better understanding and decisions and that risk communication is one of four steps of risk analysis.) (available at http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c2s5p1_e.htm).

Question 64: With respect to Argentina's request for authorization of imports of fresh (chilled or frozen) beef, when was the last time APHIS asked for additional information from Argentina?

ANSWER:

266. APHIS asked Argentina for permission to conduct a site visit in November 2012. Argentina did not agree to a site visit date earlier than November 2013. In advance of that site visit, APHIS provided to SENASA a list of questions for which it requested SENASA prepare data or answers.

267. The additional, essential information obtained during the November 2013 site visit allowed APHIS to progress and conclude its risk assessment of Patagonia, which led to the issuance of the notice of proposed determination on January 23, 2014.

Question 65: On 19 July 2010, APHIS communicated to SENASA that it was "currently drafting a proposed rule that will allow the importation of fresh, chilled or frozen Argentinean beef under certain circumstances". What is the current status of this proposed rule? Why has it not yet been finalized?

ANSWER:

268. APHIS has been analyzing the information it has gathered from its November 2013 site and incorporating the data into its risk assessment for northern Argentina. APHIS is currently finalizing the assessment and expects to draft a Federal Register notice to publish this assessment for public comment in the near future.

Question 66: The United States explains, in its first written submission that the length of time required to complete the regulatory finalization process "is not a decision on the merits" of an applicant country's request. Please explain what determines the length of time required.

ANSWER:

269. The length of time required to act on an application – from the time of the original request to Federal Register publication of a final rule or notice – will depend on the specific circumstances of each case. Importing Members, as well as Members that make claims of disease-free status for all or part of their territories, have unique sanitary and phytosanitary circumstances that may also be affected by law, policy, governance, and veterinary infrastructures.

270. As outlined in detail earlier, APHIS' evaluation is a science-based and analytical process that culminates in a completed risk analysis and publication of a final decision.

271. The process requires significant information gathering and evaluation. The length of time at each stage is dependent on a number of variables, such as the completeness of the information provided by the applicant; the responsiveness of the applicant to follow up

questions; changing conditions in the territory in question; and the availability and timing of site visits.

272. Based on the information gathered in the first stage, a risk analysis document is drafted. That analysis can be lengthy and time-consuming because it requires APHIS to integrate all its information and evaluate it. Once that is completed, APHIS must prepare the administrative document to propose its decision. As discussed earlier, this also includes other information disclosures required by law (for example, environmental impact analyses), as well as legal and policy reviews within APHIS and USDA to ensure all obligations were complied with.

273. Once the proposed regulatory document is published, a comment period opens. Frequently, a comment period can be extended to allow more time for parties to prepare and file their views. After that period is closed, APHIS considers the comments and, if appropriate, a revised version of the regulatory document is published to address the comments received and announce APHIS’ decision.

274. Times vary at different stages of this process depending on individual case circumstances.

Question 67: In the United States' first written submission, it is stated that the diagnosis of FMD during the 2001 outbreak in the United Kingdom was "[d]elayed". What was the "delay"? did this "delay" affect the time required for APHIS to review the United Kingdom application for reinstatement of its status as FMD-free without vaccination, in particular did it affect APHIS's determination as to whether the United Kingdom had appropriate veterinary controls in place?

ANSWER:

275. The United Kingdom’s 2001 epidemic was confirmed in pigs at a slaughterhouse on February 20, 2001. The oldest lesions in affected pigs at the slaughterhouse were estimated to have been approximately five days old. Traceback from the slaughterhouse was started immediately and concluded that pigs were infected after arrival at the slaughterhouse. Thus, tracings were initiated on all premises that had supplied livestock to the slaughterhouse during the previous two weeks. The infection source was believed to be on a swill-fed pig operation - pigs had been sent from these premises to the slaughterhouse.

276. The investigation into the source of infection has led officials to conclude that there was a “delay” in detecting the disease. The disease was estimated to have been introduced into the swill-feeding operation around the beginning of February. Airborne spread of the virus from this index premise was thought to have infected sheep, which do not generally exhibit typical signs of the disease. These sheep were subsequently moved through two markets, and the disease was spread through these movements such that by the time FMD was confirmed, disease had already been spread widely across the country. It was estimated that eight of the 12 epidemics of the disease in the United Kingdom were already infected before the first case was diagnosed.

277. This “delay” in detection in the United Kingdom was substantively different from Argentina's. While detection of the disease may have taken few extra days, the United Kingdom immediately notified the disease and took appropriate control and eradication measures. On the other hand, Argentina undertook a deliberate, coordinated effort on the part of the government to delay reporting, and conceal the outbreaks. In addition, the United Kingdom immediately imposed movement restrictions on the entire country, effectively prohibiting the movement of any livestock in the United Kingdom except under official control. It also banned any markets, fairs, or similar gatherings, where animals would be congregated. Moreover, the United Kingdom immediately followed their FMD contingency plan, which contributed further to the control and eradication of disease. Therefore, the United Kingdom's delayed detection did not raise the same types of concerns about government oversight and credibility that Argentina's delay did, and it did not materially affect the time required for APHIS to review the United Kingdom's application for reinstatement of its FMD status.

278. APHIS and the Canadian Food Inspection Agency (“CFIA”) conducted a joint site visit to the United Kingdom to evaluate the eradication efforts. APHIS concluded that the United Kingdom had implemented adequate surveillance and control measures to eradicate the disease.

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

(b) Could APHIS have conducted a risk assessment of Patagonia on the basis of model projections as to the regulatory changes that had yet to be implemented? If not, why not?

ANSWER:

279. APHIS does not conduct its risk assessments based on “model projections” of the impact of the regulatory changes that have not actually, in fact, been fully implemented. Nor has Argentina presented any evidence or arguments showing that “model projections” would be sufficient to meet the U.S. ALOP. Under APHIS procedures, the United States examines an exporting Member’s regulatory regime based on the actual evidence. During site visits, to assess the operations of the veterinary services, APHIS observes specific government offices’ and other relevant actors’ implementation of and compliance with SENASA’s laws and regulations.

280. As the new regulation had not been completely implemented at the time of APHIS’ 2009 site visit, APHIS was not able to confirm such laws were properly implemented in the field. More importantly, at that time, the new regulation prevented Argentina from complying with APHIS’ requirements at 9 CFR 94.11 for countries that have a common land border with regions considered to be affected with FMD or import ruminants or swine from regions considered to be affected with FMD under conditions less restrictive than would be acceptable for importation into the United States. Section 94.11 would have been applied to the Patagonia South region at the time of the site visit because Patagonia South bordered North B, which, although recognized

by OIE, had not yet been evaluated by APHIS for FMD-freedom without vaccination. Therefore, APHIS considered it to be a region affected with FMD.

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

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

ANSWER:

281. The panel in *EC – Approval and Marketing of Biotech Products* examined a claim under Article 10.1, and considered what is necessary for a claimant to meet its *prima facie* burden. The panel acknowledged that an importing Member has the obligation to take into account the needs of developing country Members. The panel’s interpretation of the obligations under Art. 10.1, which the United States generally views as sound, were as follows:

- **Communicate “Special Needs”:** The only way a regulatory authority can take account of special needs is if the developing country Member makes those special needs known to the authority.¹¹⁶ Here, there is no evidence on the record that Argentina ever made any sort of assertion to APHIS that Argentina had any special needs that APHIS should take into account.
- **Burden of Proof:** The burden of proof is on the developing country Member to prove its claim that the developed country Member did not take into account its special needs. The panel explained that “well-established rules on burden of proof” state that it is for the developing country to prove that the importing Member did not take account of its needs.¹¹⁷ Here, Argentina has failed to meet its burden.
- **Take into Account:** The importing Member must only “take account” of developing country Members’ needs; Article 10.1 does not prescribe a specific result to be achieved; Article 10.1 does not provide that the importing Member must invariably accord special and differential treatment in a case where a measure has led, or may lead, to a decrease, or a slower increase, in developing country exports.” Thus, it is inaccurate for Argentina to assert that it deserves a particular result in this dispute.

¹¹⁶ *EC – Approval and Marketing of Biotech Products*, at para. 7.1625.

¹¹⁷ *EC – Approval and Marketing of Biotech Products*, at para. 7.1625.

282. Article 10.2 is also instructive, in that it provides some context for the interpretation of Article 10.1. Most notably, Article 10.2 provides that any accommodations only where allowed by the importing Member’s ALOP.

Question 72: Is the requirement to "take account of the special needs of developing countries" a requirement to take account of developing countries' special needs as a group or take account of the special needs of each individual developing country?

ANSWER:

283. As explained in response to Panel Question 71, the starting point for the application of Article 10.1 is that the developing Member (or Members) must make their special needs known to the regulatory authority of the importing Member. Thus, whether the “special needs” apply to one Member, or a group of Members, will depend on what special needs have been identified, and on which Members have requested that the importing Member take account of special needs.

Question 75: Does the United States have any relevant documentation that shows its consideration of Argentina's "special needs"?

ANSWER:

284. As explained above, Argentina did not identify to the United States any special needs.

10 PROCEDURE AND TIMETABLE

Question 76: Please express your views as to:

- (a) Whether the Panel should seek scientific and/or technical advice from experts and/or international organizations;**

ANSWER:

285. Based on the evidence and arguments submitted to date in this dispute, the United States has difficulty in seeing how the views of experts or international organizations would facilitate the Panel’s work. The nature of FMD as a disease and any related aspects of FMD are well established and not in controversy. The status of various actions taken or statements made by an international organization such as the OIE and its relationship to the SPS Agreement are legal questions, not questions of a scientific or technical nature. Further, the OIE’s own views as to the appropriate legal conclusions under the SPS Agreement of the OIE’s own actions are questions of interpretation of the WTO Agreement, and not within the OIE’s scope of responsibility or expertise.

286. The core issue in this case is about timeliness and undue delay. At this juncture, the United States has explained in full how it has acted within a reasonable period of time under Article 5.7, and (to the extent that the Panel finds Annex C to be applicable) without undue

delay; the United States has difficulty in seeing how experts would be of assistance in helping the Panel evaluate such issues.

287. Other questions raised by claims under the SPS Agreement are not ripe for consideration by experts. Because APHIS has not taken a final decision or issued a final risk assessment document, experts (and this Panel itself) would be considering questions that are best left in the first instance to national regulators and risk assessors: that is, the granular observations and judgments at a field level regarding another country’s sanitary situation and veterinary structure are not appropriately made in the first instance by outside experts.

Question 77: Annexed to these questions are proposed Working Procedures and a Timetable relating to the next phases of the current proceedings if experts are consulted. Please provide your comments on the attached.

ANSWER:

288. As discussed above, the United States does not view experts as necessary in this dispute. However, should the Panel decide it would need to seek expert advice to understand better the evidence submitted by the parties on specific issues, the United States has provided its views on the Panel’s draft timetable and working procedures in redline as an attachment to this submission. While the United States will not explain all of its comments in detail here, it would like to highlight a few points for the Panel’s consideration.

289. Timetable: The United States would like to make four comments with respect to the Panel’s draft timetable. First, in the event that the Panel decides that it is not necessary to consult with experts in this dispute and adopts a more streamlined timetable than the Panel’s draft currently envisions, the United States would request an opportunity to comment on any subsequent dates included in such a timetable before they are adopted by the Panel.

290. Second, the United States notes that the date that the Panel has currently proposed for a potential meeting with experts conflicts with the U.S. Labor Day holiday. Accordingly, the United States respectfully requests that this meeting and the related dates for the second meeting of the Panel be moved back one week until September 8, 10, and 11, respectively.

291. Third, the United States respectfully requests that the Panel provide the parties with two weeks to provide comments on the responses of the other party to the Panel’s second set of questions. Given the fact-intensive nature of this dispute and the need for the United States to coordinate its answers with the relevant regulating agencies, it is important that the Panel provide adequate time to ensure that it receives responses conducive to its goal in producing a high-quality report.

292. Fourth, the United States believes that the parties should have an opportunity to submit to the Panel comments on the Panel’s draft questions to the experts. This would support the Panel’s work and provide the parties with a chance to highlight key issues. It could also save time by helping to clarify the questions posed and so help ensure that the questions avoid any potential

ambiguity or unnecessary disagreement between the parties. Similarly, the United States respectfully requests that the time permitted for parties to comment on the experts’ written responses be extended by the time noted in the attachment. Depending on the length of expert responses, the parties may need a significantly longer period of time to consult with their own technical experts and to prepare comments.

293. Working Procedures: With respect to the Panel’s draft Working Procedures, the United States refers to its comments in the attachment.

Question 78: The Panel has reviewed the parties’ comments on the chronology and consolidated them into one document, which is annexed to these questions. Please provide any further comments, if you have any, with your answers on 25 February 2014.

ANSWER:

294. The United States has also attached its additional comments on the Panel’s proposed chronology.

11 GATT 1994

11.1 Article I:1 of the GATT 1994

Question 79: Do you agree that the products at issue in the present dispute are "like"?

ANSWER:

295. Argentina has failed to meet its burden to establish that the products at issue are in fact “like.” In its first written submission, Argentina concludes that the products at issue, fresh (chilled or frozen) beef from Argentina, are like fresh (chilled or frozen) beef from other WTO Members because it believes there are of “no meaningful distinctions.”¹¹⁸ Without offering *any* supporting evidence, Argentina concludes that Argentina’s fresh beef products are similar to fresh beef products from Uruguay in nature, quality and physical identity. Argentina argues that the end-uses of the product and its tastes and habits are perceived similarly by consumers. This asserted fact is also unsupported.

296. Argentina makes similar unsubstantiated conclusions in its argument that the products in question with respect to Patagonia are “like” products from Brazil (Santa Catarina), Chile, Japan and the United Kingdom.¹¹⁹ Argentina asserts that there is “no meaningful difference” and “no consumer perception of any difference” between animals, meat and products from animals susceptible to FMD from Patagonia than such animals, meat and products from the

¹¹⁸ Argentina’s First Written Submission, at para. 370.

¹¹⁹ Argentina’s First Written Submission, at paras. 582-584.

aforementioned regions.¹²⁰ Based on these conclusive statements and without any supporting evidence, Argentina argues that the products in question are like.

297. It is evident that Argentina’s claims are simply mere assertions. Because it has failed in demonstrating that the products in question are like, Argentina’s Article I:1 must fail.

298. Additionally, accepting Argentina’s unsubstantiated assertions would set a troubling framework for interpreting Article I:1. Argentina’s argument is nothing short of a presumption of likeness. However, the undisputed evidence of FMD has proven that the virus appears in seven different strands, and can impact susceptible animals in a variety of manners. Additionally, the controls regions apply are instrumental in determining the risk posed by the disease. Argentina has not acknowledged these differences, let alone provided proof that the products are like or subject to like treatment in these regions. Thus, a presumption of likeness is not appropriate; this element must be proven to exist, and Argentina has failed to do so.

11.2 Article XX of the GATT 1994

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

ANSWER:

299. As the EU noted in its third party submission, Article 2.4 of the SPS Agreement contains relevant language concerning the presumption of consistency of conforming SPS measures with the Article XX(b) of the GATT 1994. Article 2.4 reads:

Sanitary and phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary and phytosanitary measures, in particular the provisions of Article XX(b).¹²¹

300. Thus, an SPS measure determined to be consistent with the *relevant provisions* of the SPS Agreement is presumed consistent with Article XX(b) of the GATT 1994. The inverse is not necessarily true; that is, an SPS measure that does not conform with the relevant provisions of the SPS Agreement is presumed inconsistent with Article XX(b) of the GATT 1994. The Agreement does not expressly provide for such a conclusion. Additionally, as reflected in Article 2.4, the drafters would have included such a presumption if one were intended.

¹²⁰ *Id.*

¹²¹ SPS Agreement, Article 2.4

Question 81: The United States argues that because it has a rationale for having the Application System in place, the measures are not capricious or random and therefore consistent with the chapeau of Article XX of the GATT 1994. Can the United States explain whether the application of its System to Argentina satisfies the requirements of the chapeau?

ANSWER:

301. The *chapeau* of Article XX(b) obliges Members to ensure that its measures do not constitute (1) a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or (2) a disguised restriction on international trade.

302. In *Brazil – Retreaded Tyres*, the Appellate Body explained that a measure may be determined to be arbitrary and unjustifiable discrimination if: (a) the application of the measure results in discrimination; (b) the discrimination is arbitrary or unjustifiable in character; and (c) the discrimination occurs between countries where the *same* conditions prevail.¹²² All three conditions must be met to find arbitrary and unjustifiable discrimination.

303. The Application System applies to all countries applying to the United States for the recognition of a region free of FMD. The process depends largely on the information provided by the requesting country in its application. Because different countries have different experience with FMD and different control systems, the U.S. application process may not proceed in precisely the same manner. Nonetheless, Argentina has not demonstrated that any variations experienced during the process are either arbitrary or unjustifiable.

304. The Appellate Body has recognized that a responding party may show that a measure is not arbitrary or unjustifiable by demonstrating that it is not capricious or random.¹²³ Furthermore, the Appellate Body stated that this may be shown by focusing on the “cause of the discrimination, or rationale” for the measure.¹²⁴

305. In the instant dispute, as the United States has stated, it has compelling rationale for having the Application System in place. FMD poses a significant risk to a country’s cloven-hoofed animals, due to the disease’s ease of transmission and potentially devastating impact on animal health. The Application System is in place to ensure that each requesting country does not pose a significant risk of introducing FMD into the United States. Considering Argentina’s long history in battling FMD, the Application System is in place to ensure that the country provides sufficient information on its FMD status and the measures taken to prevent the disease from spreading to the United States.

¹²² *Brazil – Retreaded Tyres (AB)*, at para. 215.

¹²³ *Brazil – Retreaded Tyres (AB)*, at para. 215.

¹²⁴ *See Brazil – Retreaded Tyres (AB)*, at para. 226.

306. The Application System is also not a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail because Argentina’s conditions are unique. The record is replete with detail of Argentina’s extensive history of FMD, and details the various outbreaks across the country. Patagonia has not reported an FMD outbreak since submitting its application; however, the region north of 42° parallel has. Argentina has introduced multiple resolutions to rearrange geographic borders and revise control measures effecting Patagonia. As illustrated in the United States First Written Submission, Argentina has a unique history with FMD, which indicates that the conditions therein are not the same as other requesting countries.

307. For these reasons, the U.S. evaluation process is not a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail.

308. The final requirement to justify a measure under the *chapeau* of Article XX of the GATT is that the measure must not be a disguised restriction on international trade. The Application System does not serve a protectionist objective and is therefore not a disguised restriction on international trade.

309. In *EC – Asbestos*, the Panel considered whether a Decree satisfied the *chapeau* of Article XX of the GATT 1994. The Panel recognized that the “key to understanding what is covered by ‘disguised restriction on international trade’ is not so much the word ‘restriction’, inasmuch as, in essence . . . the word “disguised.”¹²⁵ Furthermore, the Panel stated that “a restriction which formally meets the requirements of Article XX (b) will constitute an abuse if such compliance is in fact only a disguise to conceal the pursuit of trade-restrictive objectives.”¹²⁶

310. The United States does not have a trade-restrictive objective. As explained above, *infra*, the U.S. evaluation system was installed to achieve one stated objective: to ensure that a requesting country demonstrates that it can safely import fresh beef products, and avoid introducing FMD to the United States. The objective is strictly to satisfy an animal life and health concern and the United States has granted beef access for dozens of exporting countries. Because the Application System does not have the trade-restrictive objective, it is not a disguised restriction on international trade.

311. For the foregoing reasons, the U.S. application system, as applied to Argentina, satisfies the requirements of the *chapeau* of Article XX.

¹²⁵ *EC – Asbestos (Panel)*, at para. 8.236.

¹²⁶ *EC – Asbestos (Panel)*, at para. 8.236.