WORLD TRADE ORGANIZATION

WT/DS447/R/Add.1

24 July 2015

(15-3740)

Original: English

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

REPORT OF THE PANEL

Addendum

This *addendum* contains Annexes A to C to the Report of the Panel to be found in document WT/DS447/R.

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LIST OF ANNEXES

ANNEX A

WORKING PROCEDURES OF THE PANEL

Contents		Page
Annex A-1	Working Procedures of the Panel	A-2
Annex A-2	Additional Working Procedures on consultations with experts and the World Organisation for Animal Health (OIE)	A-7

ANNEX B

ARGUMENTS OF THE PARTIES

ARGENTINA

Contents		Page
Annex B-1	First part of the integrated executive summary of the arguments of Argentina	B-2
Annex B-2	Second part of the integrated executive summary of the arguments of Argentina	B-14

UNITED STATES

Contents		Page
Annex B-3	First part of the integrated executive summary of the arguments of the United States	B-25
Annex B-4	Second part of the integrated executive summary of the arguments of the United States	B-37

ANNEX C

ARGUMENTS OF THE THIRD PARTIES

Contents		Page
Annex C-1	Integrated executive summary of the arguments of Australia	C-2
Annex C-2	Integrated executive summary of the arguments of Brazil	C-6
Annex C-3	Integrated executive summary of the arguments of China	C-9
Annex C-4	Integrated executive summary of the arguments of the European Union	C-13

ANNEX A

WORKING PROCEDURES OF THE PANEL

Contents		Page
Annex A-1	Working Procedures of the Panel	A-2
Annex A-2	Additional Working Procedures on consultations with experts and the World Organisation for Animal Health (OIE)	A-7

ANNEX A-1

WORKING PROCEDURES OF THE PANEL[1]

Adopted as modified on 23 May 2014[2]

1. In its proceedings, the Panel shall follow the relevant provisions of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU). In addition, the following Working Procedures shall apply.

General

2. The deliberations of the Panel and the documents submitted to it shall be kept confidential. Nothing in the DSU or in these Working Procedures shall preclude a party to the dispute (hereafter "party") from disclosing statements of its own positions to the public. Members shall treat as confidential information submitted to the Panel by another Member which the submitting Member has designated as confidential. Where a party submits a confidential version of its written submissions to the Panel, it shall also, upon request of a Member, provide a non-confidential summary of the information contained in its submissions that could be disclosed to the public. Non-confidential summaries shall be submitted no later than ten days after the written submission is presented to the Panel, unless a different deadline is granted by the Panel upon a showing of good cause.

3. The Panel shall meet in closed session. The parties, and Members having notified their interest in the dispute to the Dispute Settlement Body in accordance with Article 10 of the DSU (hereafter "third parties"), shall be present at the meetings only when invited by the Panel to appear before it.

4. Each party and third party has the right to determine the composition of its own delegation when meeting with the Panel. Each party and third party shall have the responsibility for all members of its own delegation and shall ensure that each member of such delegation acts in accordance with the DSU and these Working Procedures, particularly with regard to the confidentiality of the proceedings.

Submissions

5. Before the first substantive meeting of the Panel with the parties, each party shall submit a written submission in which it presents the facts of the case and its arguments, in accordance with the timetable adopted by the Panel. Each party shall also submit to the Panel, prior to the second substantive meeting of the Panel, a written rebuttal, in accordance with the timetable adopted by the Panel.

6. A party shall submit any request for a preliminary ruling at the earliest possible opportunity and in any event no later than in its first written submission to the Panel. If Argentina requests such a ruling, the United States shall submit its response to the request in its first written submission. If the United States requests such a ruling, Argentina shall submit its response to the request prior to the first substantive meeting of the Panel, at a time to be determined by the Panel in light of the request. Exceptions to this procedure shall be granted upon a showing of good cause.

7. Each party shall submit all factual evidence to the Panel no later than during the first substantive meeting, except with respect to evidence necessary for purposes of rebuttal, answers

[1] Depending on the Panel's decision on the need to consult experts, the Panel may, after consulting the parties, supplement the above working procedures at a later stage in the dispute with provisions governing expert selection and consultation.

[2] The Panel modified paragraph 23(d) of the Working Procedures of the Panel that had been adopted on 30 August 2013.

to questions or comments on answers provided by the other party. Exceptions to this procedure shall be granted upon a showing of good cause. Where such exception has been granted, the Panel shall accord the other party a period of time for comment, as appropriate, on any new factual evidence submitted after the first substantive meeting.

8. In order to facilitate the work of the Panel, each party and third party is invited to make its submissions in accordance with the annexed WTO Editorial Guide for Panel Submissions, to the extent that it is practical to do so.

9. To facilitate the maintenance of the record of the dispute and maximize the clarity of submissions, each party and third party shall sequentially number its exhibits throughout the course of the dispute. For example, exhibits submitted by Argentina could be numbered ARG-1, ARG-2, etc. If the last exhibit in connection with the first submission was numbered ARG-5, the first exhibit of the next submission thus would be numbered ARG-6.

Questions

10. The Panel may at any time pose questions to the parties and third parties, orally in the course of a meeting or in writing, including prior to each substantive meeting.

Substantive meetings

11. Each party shall provide to the Panel the list of members of its delegation in advance of each meeting with the Panel and no later than 5.00 p.m. (Geneva time) the previous working day.

12. The first substantive meeting of the Panel with the parties shall be conducted as follows:

a. The Panel shall invite Argentina to make an opening statement to present its case first. Subsequently, the Panel shall invite the United States to present its point of view. Before each party takes the floor, it shall provide the Panel and other participants at the meeting with a provisional written version of its statement. In the event that interpretation is needed, each party shall provide additional copies for the interpreters, through the Panel Secretary. Each party shall make available to the Panel and the other party the final version of its statement, preferably at the end of the meeting, and in any event no later than 5.00 p.m. (Geneva time) on the first working day following the meeting.

b. After the conclusion of the statements, the Panel shall give each party the opportunity to ask each other questions or make comments, through the Panel. Each party shall then have an opportunity to answer these questions orally.

c. The Panel may subsequently pose questions to the parties. Each party shall then have an opportunity to answer these questions orally.

d. Once the questioning has concluded, the Panel shall afford each party an opportunity to present a brief closing statement, with Argentina presenting its statement first.

e. Following the meeting, the Panel shall send in writing, within a timeframe to be determined by it, any questions to the parties to which it wishes to receive a response in writing. Each party shall be invited to respond in writing to such questions within a deadline to be determined by the Panel. Likewise, each party shall send in writing, within a timeframe to be determined by the Panel, any questions to the other party to which it wishes to receive a response in writing. Each party shall be invited to respond in writing to the other party's written questions within a deadline to be determined by the Panel.

13. The second substantive meeting of the Panel with the parties shall be conducted as follows:

a. The Panel shall ask the United States if it wishes to avail itself of the right to present its case first. If so, the Panel shall invite the United States to present its opening statement, followed by Argentina. If the United States chooses not to avail itself of that right, the

Panel shall invite Argentina to present its opening statement first. Before each party takes the floor, it shall provide the Panel and other participants at the meeting with a provisional written version of its statement. In the event that interpretation is needed, each party shall provide additional copies for the interpreters, through the Panel Secretary. Each party shall make available to the Panel and the other party the final version of its statement, preferably at the end of the meeting, and in any event no later than 5.00 p.m. (Geneva time) of the first working day following the meeting.

b. After the conclusion of the statements, the Panel shall give each party the opportunity to ask each other questions or make comments, through the Panel. Each party shall then have an opportunity to answer these questions orally.

c. The Panel may subsequently pose questions to the parties. Each party shall then have an opportunity to answer these questions orally.

d. Once the questioning has concluded, the Panel shall afford each party an opportunity to present a brief closing statement, with the party that presented its opening statement first, presenting its closing statement first.

e. Following the meeting, the Panel shall send in writing, within a timeframe to be determined by it, any questions to the parties to which it wishes to receive a response in writing. Each party shall be invited to respond in writing to such questions within a deadline to be determined by the Panel. Likewise, each party shall send in writing, within a timeframe to be determined by the Panel, any questions to the other party to which it wishes to receive a response in writing. Each party shall be invited to respond in writing to the other party's written questions within a deadline to be determined by the Panel.

Third parties

14. The Panel shall invite each third party to transmit to the Panel a written submission prior to the first substantive meeting of the Panel with the parties, in accordance with the timetable adopted by the Panel.

15. Each third party shall also be invited to present its views orally during a session of this first substantive meeting, set aside for that purpose. Each third party shall provide to the Panel the list of members of its delegation in advance of this session and no later than 5.00 p.m. (Geneva time) the previous working day.

16. The third-party session shall be conducted as follows:

a. All third parties may be present during the entirety of this session.

b. The Panel shall first hear the arguments of the third parties in alphabetical order. Third parties present at the third-party session and intending to present their views orally at that session, shall provide the Panel, the parties and other third parties with provisional written versions of their statements before they take the floor. Third parties shall make available to the Panel, the parties and other third parties the final versions of their statements, preferably at the end of the session, and in any event no later than 5.00 p.m. (Geneva time) of the first working day following the session.

c. After the third parties have made their statements, the parties may be given the opportunity, through the Panel, to ask the third parties questions for clarification on any matter raised in the third parties' submissions or statements.

d. The Panel may subsequently pose questions to the third parties. Each third party shall then have an opportunity to answer these questions orally.

e. Following the third party session, the Panel shall send in writing, within a timeframe to be determined by it, any questions to the third parties to which it wishes to receive a response in writing. Each third party shall be invited to respond in writing to such

questions within a deadline to be determined by the Panel. Likewise, each party shall send in writing, within a timeframe to be determined by the Panel, any questions to a third party to which it wishes to receive a response in writing. Each third party shall be invited to respond in writing to these questions within a deadline to be determined by the Panel.

Descriptive part

17. The description of the arguments of the parties and third parties in the descriptive part of the Panel report shall consist of executive summaries provided by the parties and third parties, which shall be annexed as addenda to the report. These executive summaries shall not in any way serve as a substitute for the submissions of the parties and third parties in the Panel's examination of the case.

18. Each party shall submit an integrated executive summary of its arguments as presented in its written submissions, statements and responses and comments to questions in two parts. The parties shall submit the first part of the integrated executive summary following the first substantive meeting at the latest on the date provided for in the timetable. The parties shall submit the second part of the integrated executive summary at the latest on the date provided for in the timetable. The total number of pages of the integrated executive summary, both parts combined, shall not exceed 30 pages. Within those limits, parties are free to determine the structure of the two parts of their integrated executive summary.

19. Each third party shall submit an executive summary of its arguments as presented in its written submission and statement in accordance with the timetable adopted by the Panel. This summary may also include a summary of responses to questions, where relevant. The executive summary to be provided by each third party shall not exceed 6 pages.

Interim review

20. Following issuance of the interim report, each party may submit a written request to review precise aspects of the interim report and request a further meeting with the Panel, in accordance with the timetable adopted by the Panel.

21. In the event that no further meeting with the Panel is requested, each party may submit written comments on precise aspects of the interim report, in accordance with the timetable adopted by the Panel. Subsequently, each party may submit written comments on the other party's written interim review comments.

22. The interim report, as well as the final report prior to its official circulation, shall be kept strictly confidential and shall not be disclosed.

Service of documents

23. The following procedures regarding service of documents shall apply:

a. Each party and third party shall submit all documents to the Panel by filing them with the DS Registry (office No. 2047).

b. Each party and third party shall file 5 paper copies of all documents it submits to the Panel. However, when exhibits are provided on CD-ROMS/DVDs, 4 CD-ROMS/DVDs and 4 paper copies of those exhibits shall be filed. The DS Registrar shall stamp the documents with the date and time of the filing. The paper version shall constitute the official version for the purposes of the record of the dispute.

c. Each party and third party shall also provide an electronic copy of all documents it submits to the Panel at the same time as the paper versions, preferably in Microsoft Word format, either on a CD-ROM, a DVD or as an e-mail attachment. If the electronic copy is provided by e-mail, it should be addressed to *****@wto.org, with a copy to *****.*****@wto.org, *****.*****@wto.org, *****.*****@wto.org,

*****.*****@wto.org, and *****.*****@wto.org. If a CD-ROM or DVD is provided, it shall be filed with the DS Registry.

d. Each party shall serve any document submitted to the Panel directly on the other party. However, in the case of submissions that must be filed contemporaneously, each party shall file the documents for the other party only with the DS Registrar, in the same manner as set forth in paragraph 23(b). The DS Registrar will serve the documents on the other party only after having received the submissions of both parties. Each party shall, in addition, serve on all third parties its written submissions in advance of the first substantive meeting with the Panel. Each third party shall serve any document submitted to the Panel directly on the parties and all other third parties. Each party and third party shall confirm, in writing, that copies have been served as required at the time it provides each document to the Panel.

e. Each party and third party shall file its documents with the DS Registry and serve copies on the other party (and third parties where appropriate) by 5.00 p.m. (Geneva time) on the due dates established by the Panel. A party or third party may submit its documents to another party or third party in electronic format only, subject to the recipient party or third party's prior written approval and provided that the Panel Secretary is notified. As noted in paragraph 23(d), if the submissions of both parties are to be filed contemporaneously, each party shall serve the copies only on the DS Registrar by 5:00 p.m. (Geneva time) and the DS Registrar will serve the documents on the other party after having received the submissions of both parties.

f. The Panel shall provide the parties with an electronic version of the descriptive part, the interim report and the final report, as well as of other documents as appropriate. When the Panel transmits to the parties or third parties both paper and electronic versions of a document, the paper version shall constitute the official version for the purposes of the record of the dispute.

ANNEX A-2

ADDITIONAL WORKING PROCEDURES ON CONSULTATIONS WITH EXPERTS AND THE WORLD ORGANISATION FOR ANIMAL HEALTH (OIE)

Adopted on 4 March 2014

Should the Panel determine that there is a need to seek expert advice, the following procedures shall apply:

1. Consistent with Article 13 of the DSU and Article 11.2 of the SPS Agreement, the Panel may seek expert advice from experts and from international organizations, as appropriate.

2. The Panel may ask the Secretariat of the World Organization for Animal Health (OIE) as well as the parties for suggestions of possible experts. Parties shall not engage in direct contacts with individuals suggested with respect to the matters at issue in this dispute.

3. The Panel will provide the parties with a list of the names of possible experts, their *curricula vitae,* and declarations of potential conflicts of interest.

4. Parties will have an opportunity to present their comments and to make known any compelling objections to any particular expert at the time designated by the Panel.

5. The Panel will select the experts on the basis of their qualifications and the need for specialized scientific expertise, and shall not select experts that the Panel has determined have a relevant conflict of interest. The Panel will decide the number of experts in light of the number and type of issues on which advice will be sought, as well as of the different areas on which each expert can provide expertise.

6. The Panel will inform the parties of the experts it has selected. Individual experts shall act in their personal capacities and not as representatives of any entity. They shall be subject to the DSB's *Rules of Conduct for the Understanding on Rules and Procedures Governing the Settlement of Disputes* (WT/DSB/RC/1), an electronic copy of which will be provided to them by the Panel.

7. The Panel may also seek information from the OIE with regard to its relevant standards, guidelines, recommendations and procedures. The OIE will be asked to confirm, in writing to the WTO, that its officials, in assisting the Panel, will abide both by its own staff rules of conduct and by the WTO Rules of Conduct. The WTO will provide a copy of the WTO Rules of Conduct to the OIE and ask it to provide the Panel with a copy of its staff rules of conduct.

8. The Panel will prepare written questions for the experts and relevant organizations. Parties will have the opportunity to provide suggested questions to the Panel before the Panel decides on the final questions to be sent to the experts and the OIE. The Panel may provide the experts and the OIE, on a confidential basis, with relevant parts of the parties' submissions, including exhibits, as well as with any additional information deemed necessary. The experts and the OIE will have the opportunity to request, through the Panel, additional factual information or clarifications from the parties, if it will assist them in answering the Panel's questions.

9. Experts and the OIE will be requested to provide responses in writing within a time-period specified by the Panel. Experts and the OIE will be requested only to respond to questions on which they have sufficient knowledge. Copies of the responses will be provided by the Panel to the parties. The parties will have the opportunity to comment in writing on the responses from the experts and the OIE. The Panel will provide the parties with a compilation of the experts' and the OIE's answers for use in citation.

10. The Panel may schedule a meeting with the experts and the OIE, prior to the second substantive meeting with the parties. Prior to this meeting, the Panel will ensure that: (i) the parties' comments on the experts' responses are provided to the experts and relevant

organizations; (ii) the experts are individually provided with the other experts' and the organizations' responses to the Panel's questions; (iii) if they desire the parties may prepare "advance" questions to be communicated to the experts and relevant organizations through the Panel to assist them in preparation for the meeting.

11. During the meeting, the Panel will pose questions to the experts and the OIE. The Panel will then invite the parties to pose questions to the experts and the OIE including, but not limited to, the "advance" questions sent by the parties. The Panel may schedule additional meetings with the experts and the OIE if necessary and appropriate.

12. The Secretariat will prepare a compilation of the experts' and the OIE's written replies to questions, as well as a transcript of any meeting with the experts and the OIE for inclusion in the record of the Panel proceeding. The experts and the OIE will be given an opportunity to verify the drafts of these texts to ensure that they actually reflect the information they provided before the texts are finalized. The parties will likewise be given an opportunity to verify that the transcript of any meeting with the experts and relevant organizations accurately reflects the parties' own interventions.

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ANNEX B

ARGUMENTS OF THE PARTIES

ARGENTINA

Contents		Page
Annex B-1	First part of the integrated executive summary of the arguments of Argentina	B-2
Annex B-2	Second part of the integrated executive summary of the arguments of Argentina	B-14

UNITED STATES

Contents		Page
Annex B-3	First part of the integrated executive summary of the arguments of the United States	B-25
Annex B-4	Second part of the integrated executive summary of the arguments of the United States	B-37

ANNEX B-1

FIRST PART OF THE INTEGRATED EXECUTIVE SUMMARY
OF THE ARGUMENTS OF ARGENTINA

I. INTRODUCTION

1. There are three major aspects of this case. First, the United States maintains a prohibition on imports of fresh (chilled or frozen) beef from Argentina as a whole. This is a product-specific ban, the maintenance of which is being challenged by Argentina. Second, the United States has maintained a ban on imports of animals, meat and animal products from the Patagonia Region – comprising the areas known as Patagonia South and Patagonia North B. Third, while Argentina considers that the fundamental issue here is the denial of rights that is the core issue, it is also indisputable that there has been undue delay in the processing of Argentina's requests for import authorization for fresh beef and for the recognition of the Patagonia Region as FMD-free.

2. This is an "as applied" case. Rather than challenging the U.S. law or regulations related to the importation of animal and animal products in the United States "as such", Argentina is challenging the maintenance for over 11 years of the application of those regulations to imports from Argentina, without a valid risk assessment. The application of those measures lack scientific justification, constitute an arbitrary discrimination and a straight-forward restriction on international trade.

3. The import prohibitions on the subject products have been maintained by the United States without a valid risk assessment for more than a decade despite evidence that Argentina has been FMD-free for over seven years as a country and the Patagonia Region has been FMD-free for more than 20 years. Indeed, Argentina is recognized by the OIE as FMD-free: Patagonia South has been recognized by the OIE as FMD-free without vaccination since 2002, in 2007 the OIE extended the recognition of FMD-free zone up to the río Negro (to include Patagonia North B); the rest of the country is recognized as FMD-free with vaccination since 2007. These designations are annually renewed and the United States joined the consensus in all of these OIE decisions.

4. The United States has never enunciated a clear and consistently applied appropriate level of protection ("ALOP"). The United States is then required to conduct a valid risk assessment. The United States has taken neither of those steps. Prior to the establishment of the Panel, the United States has only conducted a risk assessment for Patagonia South in 2005 and it was favorable; it then failed to finalize its regulatory processes. In addition, the United States has stated and implied on various occasions that it has sufficient scientific evidence to press ahead favorably on all of Argentina's pending requests. It simply has failed to actually do so.

5. Further, in processing Argentina's pending applications the United States has acted with undue delay and let politics interfere with, and derail, the regulatory process. The United States clearly has recognized these failures to move its processes forward in its statements to Argentina and the SPS Committee.

II. THE UNITED STATES IMPORT AUTHORIZATION SYSTEM

6. The United States system is based on an assumption regarding the existence of foot-and-mouth disease in the world. The general ban is set forth in Section 94.1 of Title 9 of the U.S. Code of Federal Regulations ("C.F.R."). Section 94.1(a) states that APHIS, the U.S. competent administrative agency, considers FMD to exist in all the regions of the world, except for those countries and regions listed under Section 94.1(a)(1). Then, in Section 94.1(b), APHIS bans all imports of "any ruminant or swine or any fresh (chilled or frozen) meat of any ruminant or swine," from all countries and regions other than those on the list referenced in Section 94.1(a)(1), except as otherwise provided §94.1(b)(4). However, in §94.1(b)(4) APHIS has inserted certain provisions to authorize imports of certain products from other countries or regions where vaccination is practiced. Until 2001, §94.21 allowed imports of fresh beef from Argentina. Currently, §94.22 allows imports of beef and ovine meat from Uruguay and APHIS has proposed to also grant import rights for fresh beef to a region of 14 Brazilian states through a similar addition to Part 94.

7. The United States regulations in 9 C.F.R. §94 are structured in a fundamentally different manner than the OIE standards, guidelines and recommendations. The OIE specifically recognizes two distinct categories of FMD-free status: there are countries and zones that are FMD-free without vaccination and FMD-free with vaccination. These two categories stand as co-equals in the scheme of the OIE standards, guidelines and recommendations. In contrast, the United States does not recognize the whole category of FMD-free with vaccination. Under the U.S. regulations, such countries or zones are considered FMD-infected. As applied to Argentina, the difference is even more stark; the United States imposes a ban on imports which is contrary to the OIE standards, guidelines and recommendations which, in fact, would allow imports from Argentina.

8. The regulatory process for seeking approval to import a particular product from a country or region *(i.e.* a commodity request) or for the recognitions of a region as FMD-free (*i.e.* a regionalization request) is governed by a different part of the C.F.R. – Section 92.2. The United States applies §92.2 equally to requests for authorization to import a particular commodity and requests for recognition of FMD-free status and those regulations are *the only path* for a country or region to obtain approval to import in the United States.

III. BACKGROUND ON THE U.S. BAN ON IMPORTS FROM ARGENTINA AND ITS MAINTENANCE FOR OVER 11 YEARS

A. Request for Import Authorization for Fresh Beef

9. In 1997, the United States approved imports of fresh (chilled or frozen) beef from Argentina, under a protocol with multiple layers of protections against the risk of FMD. Argentina unilaterally suspended its exports in 2001 following an FMD outbreak. The United States published an interim rule on June 4, 2001 and on December 11, 2001, APHIS imposed the ban indefinitely, as a final rule. The effect of the 2001 Regulations was that Argentina became subject again to the prohibition contained at 9 C.F.R. § 94.1(b). The 2001 Regulations and the application to Argentina of the prohibition contained at 9 C.F.R. § 94.1(b) are still in full force and effect today.

10. In November 2002, Argentina's National Service of Agricultural Food Health and Quality ("SENASA"), submitted a formal request to APHIS under 9 C.F.R. §92.2, to allow the importation of fresh beef from Argentina into the United States.[1] This was a commodity approval request for fresh beef, filed under the applicable regulations at §92.2.

11. Two limited and quickly reported and contained FMD outbreaks occurred in the Northern part of Argentina in 2003 and 2006. The first one was limited to Tartagal (Salta) and the latter, in February 2006, occurred in one department of the Province of Corrientes, in proximity of Argentina's border with Paraguay. In response to a request from APHIS, SENASA promptly provided information regarding the outbreak. The information provided by Argentina was then reviewed by APHIS and following the 2006 outbreak, APHIS requested a site visit in September 2006. APHIS' report of that visit was favorable, including many positive assessments of SENASA. The 2006 outbreak was the last sanitary event in Argentina and was limited to a single department in Corrientes – San Luis del Palmar. It was very limited both geographically and quantitatively. The EU, for instance, closed its market only in respect of the 8 departments of the province of Corrientes declared in sanitary emergency by SENASA in March 2006. Other WTO Members have had outbreaks in the same time frame and even more recently and have been able to access the U.S. regulatory system and regain the right to export to the United States.

12. In May 2007, the OIE restored the status of "FMD-free zone with vaccination" to the Argentine territory located North of the 42nd Parallel South. Moreover, the same OIE Resolution recognized the extension of the FMD-free zone without vaccination from the 42nd Parallel South up to the río Negro (covering the area known as Patagonia North B).

13. Despite these positive developments in Argentina's sanitary status, after the 2006 site visit by APHIS there has been a complete breakdown in the U.S. regulatory process as applied to

[1] While this application was titled "Information provided by SENASA for the recognition of Argentina as a Region comprised in Article 92.2 Title 9, Code of Federal Regulations in regards to FMD" (ARG-31), consistent with the name of the 92.2 regulations, Argentina's request was treated by the United States as one for the approval of imports of fresh (chilled or frozen) beef from Argentina and not a request to recognize all of Argentina as FMD-free under 9 C.F.R. §94.1(a)(1).

Argentina. Despite repeated formal requests from Argentina, to complete the approval process started under §92.2, a risk assessment was never issued and the rulemaking was never initiated. Not coincidentally, the inaction of APHIS came in the context of intense political pressure opposing action to allow imports of Argentine beef. A prime example of this political pressure is reflected in Section 737 of the 2009 appropriations law.[2] Section 737 essentially imposed a ban on such imports until "the Secretary of Agriculture has reviewed the domestic animal health aspects of the pending proposal to allow the importation of such products into the United States and has issued a report" to Congress.

14. In June 2011 and October 2011, statements by the U.S. delegate to the SPS Committee in response to inquiries by Argentina assured Argentina that a risk analysis was completed and that a draft rule allowing importation was forthcoming. But as with the preceding decade, there was no action taken by the U.S. Government. The facts clearly show that the United States has maintained, for more than eleven years, the application of the prohibition on imports of fresh beef from Argentina without a valid risk assessment.

B. Request to Recognize Patagonia As FMD-Free

15. On August 28, 2003, SENASA submitted a request under 9 C.F.R. §92.2 for the recognition of Patagonia South as a region free of FMD. There have been no outbreaks of FMD in Patagonia South since 1976, and in Patagonia North B since 1994. In May 2002, the OIE recognized the territory below the 42nd Parallel South as an FMD-free zone where vaccination is not practiced and in 2007 extended the recognition to include Patagonia North B. The Patagonia region was not affected by the limited outbreaks in 2003 and 2006.

16. In December 2003, APHIS made a technical visit to Patagonia South, with the objective of assessing the sanitary status of that region. In follow-up to the site visit, in November 2004, SENASA submitted additional information requested by APHIS. Then, on June 5, 2005, APHIS issued a risk analysis finding that the likelihood of an outbreak was "low."

17. On January 5, 2007, APHIS published the proposed rule to recognize Patagonia South as FMD-free. However, following the 60 days comment period there was no final rulemaking by APHIS. Instead, more than one a half years later APHIS requested another visit to Patagonia. Argentina accepted this visit to include Patagonia North B, due to the international recognition of its sanitary status as FMD-free without vaccination.

18. Another site visit took place in February 2009, and it included livestock breeding establishments and control posts in Patagonia South and Patagonia North B. Following that visit, APHIS sent a letter to SENASA confirming that APHIS had all the information it needed to complete a risk assessment. However, instead of proceeding, the United States again failed to act. Section 737 of the Appropriations Act blocked APHIS from taking any action on Argentina's applications and thus the ban on imports of animals and animal products from the Patagonia Region continues. The U.S. delegate at the SPS Committee assured Argentina in October 2011 that APHIS had completed and updated the risk analysis for Patagonia, but that also has proved incorrect as the bans remain in place.

19. After the establishment of the Panel, in December 2014 APHIS released a new risk assessment for the Patagonia Region and rulemaking notice proposing to recognize the Patagonia Region as FMD-free and confirming its previous positive assessments of SENASA, among other things. However, the fact remains that as of the establishment of the Panel, the United States has maintained, for more than eleven years, the application of the prohibitions on imports of animals, meat, and other animal products from Patagonia, without scientific justification. In fact the maintenance of the ban for 11 years is in direct conflict with APHIS' findings on the risk of FMD associated with imports from Patagonia.

[2] 2009 Omnibus Appropriations Act, H.R. 1105, 111th Congress. (ARG-45)

IV. LEGAL CLAIMS

A. The U.S. Measures Prohibiting Imports of Fresh Beef Are Inconsistent With the SPS Agreement and the GATT 1994

20. It is inconsistent with the SPS Agreement to apply and maintain for more than 11 years the ban contained in 9 C.F.R. §94.1(b) to Argentina (the "U.S. Measure against Argentine Beef") without a current, valid risk assessment. Argentina also challenges the continued application of the 2001 Regulations which removed the previous authorization to import Argentine beef, contained in 9 C.F.R. §94.21.

21. The U.S. Measure against Argentine Beef and the 2001 Regulations are SPS measures in the sense of Article 1.1 of the SPS Agreement as they aim to protect the health and life of animals in the U.S. territory from risks arising from the entry, establishment or spread of FMD. In addition, application of the "U.S. Measure against Argentine Beef", as an import ban, directly affects international trade and is inconsistent with, *inter alia*, Articles 2, 3, 5 and 10 of the SPS Agreement. Thus, application of the "U.S. Measure against Argentine Beef" and of the 2001 Regulations is inconsistent with Article 1.1.

22. Application of the ban on imports of fresh beef from Argentina, as contained in 9 C.F.R. §94.1(b), is inconsistent with Article 3.1 of the SPS Agreement. The OIE sets standards and procedures for imports of beef from FMD-free countries or regions: Article 8.6.22 of the OIE Code provides for importation from countries that are FMD-free without vaccination, and Article 8.6.23 provides for importation from countries or zones that are FMD-free with vaccination. The U.S. failure to recognize FMD-free with vaccination status renders Terrestrial Code 8.6.25 also relevant. It is worth noting that in all cases the OIE aimed to preserve trade, with mitigating protocols when needed. In contrast, the United States takes a qualitatively different approach and does not recognize the category "FMD-free with vaccination," which is the status recognized by the OIE for Argentina, north of Parallel 42nd. Because the application of the "U.S. Measure against Argentine Beef" has the exact opposite meaning and effect of the international standards it cannot be said to be "based on," "standing upon" or having been "built" or "founded upon" the OIE Code standards, as required under Article 3.1 and interpreted by the Appellate Body in *EC – Hormones*.[3] Similarly, the 2001 Regulations were imposed permanently and have been maintained for over 11 years without any reference to, or reliance upon, OIE standards, guidelines and recommendations, contrary to Article 3.1 of the SPS Agreement.

23. While the United States claims that its regulations are based on OIE standards, guidelines or recommendations in the sense of Article 3.1, that argument is flatly contradicted by APHIS' rulemakings. APHIS has affirmatively stated that it does not base its FMD standards on the OIE standards.[4] The United States permits beef imports from Uruguay, a country recognized by the OIE as FMD-free with vaccination, but only pursuant to a risk assessment and rulemaking conducted according to APHIS' own "stringent standards."

24. In *EC – Hormones*, the Appellate Body found that Article 3.3 is not an exception from Article 3.1, but an autonomous right of Members. However, that does not alter the basic structure and plain language of Article 3.1 that posits a binary choice: either Article 3.1 applies or Article 3.3 applies. Accordingly, the prohibition resulting from application of the "U.S. Measure against Argentine Beef" is not based on international standards and, as discussed below, is not otherwise justified by Article 3.3. In order for the United States to be found acting in a manner consistent with the requirements of Article 3.3, which allows a Member to apply a higher standard than the international ones, it must have based its measure banning the imports of Argentine beef on a valid risk assessment based on the appropriate level of risk determined by the Member.

25. However, the United States cannot possibly meet the requirements of Article 3.3. The application of the prohibition in §94.1(b) is not justified by scientific evidence. Moreover, the U.S. has not even articulated what it considers to be an appropriate level of sanitary protection against the threat of FMD that could encompass imports of fresh beef. Thus, application of the "U.S. Measure against Argentine Beef" is not a consequence of a level of sanitary protection determined

[3] Appellate Body Report in *EC- Hormones* at ¶ 163.
[4] *Importation of Beef from Uruguay*, 68 Fed. Reg. 31940, 31946 (USDA/APHIS May 29, 2013) (ARG-8).

by the United States in accordance with paragraphs 1 through 8 of Article 5. Consequently, the "U.S. Measure against Argentine Beef" and the 2001 Regulations are inconsistent with Article 3.3.

26. Article 5.1 of the SPS Agreement requires, among other things, that import measures be based on a risk assessment. Article 5.2 contains a list of factors that must be taken into account in a risk assessment. Yet, here, like in *U.S. – Poultry (China)*, the Panel is faced with a situation where there is no current U.S. risk assessment for beef from Argentina. Consequently, application of the prohibition contained in 9 C.F.R., Part 94.1(b) without a risk assessment is clearly contrary to the provisions of Article 5.1 of the SPS Agreement. Given the lack of a risk assessment and of sufficient scientific evidence underpinning the "U.S. Measure against Argentine Beef", the United States is also in violation of Article 5.2.

27. The same conclusion applies for the 2001 Regulations that re-imposed the general ban contained in 9 C.F.R. § 94.1(b). The 2001 Regulations were nothing more than a recitation of facts, as well as a statement of the potential negative economic impact of an FMD outbreak. As the United States admitted in the *United States – – Poultry (China)*, this approach does not constitute a valid risk assessment. .

28. As the Appellate Body has reaffirmed in *Australia – – Apples*, a measure that is inconsistent with the requirements of Articles 5.1 and 5.2 because it is not based on a proper risk assessment will also necessarily be inconsistent with Article 2.2. Because the "U.S. Measure against Argentine Beef" has been maintained for many years without any risk assessment at all, it follows that the United States has not based the application of the measure on the scientific evidence. Indeed, the U.S. delegate to the SPS Committee has indicated that there is, in fact, sufficient scientific evidence to support a *favorable* risk assessment for Argentine beef. Additionally, the measure is applied in a manner far more restrictive than is necessary for the protection of animal health. This is demonstrated, among other ways, by comparison to Uruguay, a country that is essentially in the same sanitary situation as Argentina North of the río Negro, but which is allowed to import into the United States subject to certain protocols, similar to those applied to Argentina in 1997.

29. Argentina has also demonstrated that Article 5.7 does not apply in regard to the 2001 Regulations or the prohibition contained in 9 C.F.R., Part 94.1(b) on imports of beef from Argentina. In *Japan – Agricultural Products II*, the Appellate Body laid out four cumulative steps to the Article 5.7 analysis; [5]a failure to meet any one will mean the measure is not a provisional measure within the meaning of Article 5.7. A Member may avail itself of Article 5.7 only in cases where "the scientific evidence is insufficient." Here, as both parties have acknowledged and the OIE makes clear, FMD is a well-known disease. To the extent that "scientific evidence" may be read to encompass evidence on the ground in Argentina regarding the risk of importation for FMD, the United States has not indicated any lack of information from Argentina. To the contrary, the U.S. delegates to the SPS Committee have indicated the only delaying factors to be domestic concerns, not lack of data. Furthermore, by ejecting Argentina from the U.S. regulatory system in 2001 and requiring Argentina to reapply *de novo* as if it had never had import permission, the United States failed to satisfy the requirement under Article 5.7 to take the initiative and seek out the scientific information that it considered to be lacking.

30. Finally, the extended lapse of time since the ban was imposed means that the prohibition applied through 2001 Regulations and the "U.S. Measure against Argentine Beef" cannot be a valid provisional measure. The prohibition was re-imposed after an FMD outbreak in 2001. In its rulemaking for Uruguay, the United States rejected even a three to five-year waiting period, stating that such a long period was unnecessary. Its guidelines say one year is sufficient. In this context, even the United States' own positions and statements are conclusive that the measure is not being applied as a provisional measure after all the years that have passed.

31. Contrary to the United States' position, this case has nothing to do with Article 5.7. The U.S. argument on Article 5.7 completely distorts its meaning and its functioning. Instead of the Member imposing the measure indicating what information it needed and then seeking it out in a reasonable period of time, the United States' approach would simply erase those obligations and shift the burden to the exporting Member. In other words, the United States' approach is to impose a permanent ban that leaves the exporting Member without recourse. The exporting Member has to initiate a new regulatory application and present its information to the importing

[5] Appellate Body Report in *Japan – Agricultural Products II* at ¶ 89.

Member, as if it had never exported that product to the United States. The Panel should reject such a distorted reading of Article 5.7.

32. The U.S. measures fail also the obligations of Article 5.4. The United States does not approach the establishment of an ALOP in a coherent manner so as to allow Members to understand which ALOP they should measure against. Therefore, the United States cannot possibly claim to minimize negative trade effects and act consistently with Article 5.4, where Members are left in the dark as to the applicable ALOP. Moreover, the application of the "U.S. Measure against Argentine Beef" to Argentina, which should reflect the U.S. ALOP in regards to FMD, results in a ban on imports that maximizes negative trade effects and is inconsistent with the requirement set in Article 5.4. This constitutes both a direct violation of Article 5.4 and should inform the interpretation of the remainder of the SPS Agreement in evaluating the maintenance of the application of the "U.S. Measure against Argentine Beef" to Argentina.

33. We recall that the "U.S. Measure against Argentine Beef" imposes a total prohibition on imports of fresh (chilled or frozen) beef from Argentina. By definition, therefore, the application of the "U.S. Measure against Argentine Beef" is not only more restrictive than necessary to meet the U.S. ALOP as required under Article 5.6, but it is *the most* trade restrictive possible. Under an Article 5.6 analysis the issue becomes whether there are any measures that (i) are reasonably available taking into account technical and economic feasibility (ii) achieve the Member's ALOP and (iii) are significantly less trade restrictive. [6] Because these three conditions are met, the application of the U.S. measures is inconsistent with Article 5.6.

34. There are reasonably available alternative measures the United States could use instead of the complete prohibition on imports. The United States could use the OIE guidelines to establish alternative measures for imports from Argentina; alternatively, the United States could establish mitigating protocols for imports of fresh beef from Argentina, such as those provided in 9 C.F.R. § 94.22 for imports of fresh beef from Uruguay. Because they already work for imports from Uruguay, they clearly are technically and economically feasible. These alternative measures would also achieve the U.S. ALOP in regards to FMD, considering that they already achieve that level in respect to imports from Uruguay; Uruguay and the territory of Argentina located north of the río Negro are in essentially similar sanitary situations. It goes without saying that permitting imports subject to appropriate protocols, such as the Uruguay protocols, is less trade restrictive than a total prohibition on imports which is what the United States currently applies to beef from Argentina. Thus, because there are alternative measures that are technically feasible, would achieve the appropriate level of sanitary protection and would be less trade restrictive than the prohibition currently applied to Argentine beef, the United States is not in conformity with its obligations under Article 5.6 of the SPS Agreement.

35. The application of the "U.S. Measure against Argentine Beef" is inconsistent with Article 2.3. It is manifestly discriminatory because Argentina is in a similar position to its neighbor Uruguay which is FMD-free with vaccination and is permitted imports of beef into the United States under a protocol similar to the one applied to Argentina prior to 2001. In regards to the substantive discrimination, Argentina (the part of the country north of the Patagonia Region) and Uruguay are in essentially similar sanitary situations. Both are FMD-free with vaccination as recognized by the OIE. The physical and institutional situations in both countries are similar, as has been recognized by APHIS. Yet, Uruguay is permitted to export beef to the United States under protocols similar to those previously applicable to Argentina, and the U.S. is also about to grant approval to imports of beef from 14 Brazilian States, while application of the "U.S. Measure against Argentine Beef" to Argentina results in a total prohibition on imports of Argentine beef.

36. From the perspective of the regulatory process, a risk assessment and final favorable rulemaking were conducted for Uruguay within two years of the last outbreak in that country. In contrast, it has been over seven years since there was an outbreak in Argentina, yet the U.S. ban is still applied to Argentine imports. Yet, Argentina is totally blocked from access to the regulatory process despite repeated promises and assurances from the U.S. Government. The restrictions on commerce entailed in the prohibition on Argentine beef exports are disguised only in the sense that they purport to be SPS measures. However, there is no rational, logical or scientific basis for the continued application of the "U.S. Measure against Argentine Beef". The ban maintained for

[6] Appellate Body Report in *Australia – Apples* at ¶ 337; citing Appellate Body Report, *Australia – Salmon*, ¶ 194

eleven years is a straight-forward restriction on international trade. For all these reasons, the application of the "U.S. Measure against Argentine Beef" is inconsistent with Article 2.3 of the SPS Agreement.

37. Last, the United States has not accorded Argentina special and differential treatment in the application of its SPS measures on beef imports, as required by Article 10.1. Article 10.1 imposes a broad and unqualified obligation to take account of the special needs of developing country Members, with a view to maintain trade flows from developing country Members to the maximum extent possible, as specified in Article 10.2. However, in the present case, the United States has taken every effort to ***stop*** the flow of trade from Argentina, on a commodity of particular trade interest for Argentina, not maintain it. Argentina has been effectively denied access to the U.S. administrative process. In contrast to the high level of access and speed accorded to developed country Members, the United States has responded to repeated requests and pleas for access from Argentina with years of delays and false promises. This is exactly the opposite of the special and differential treatment that should be accorded to Argentina. Therefore, the United States has failed to accord Argentina special and differential treatment in application of its SPS measures as required by Article 10.1 of the SPS Agreement.

38. The facts here show that the United States has offered advantages to other Members that it has not accorded Argentina immediately and unconditionally. These include the advantage provided Uruguay to export fresh beef subject to certain protocols, while Argentina is subject to a prohibition maintained through the "U.S. Measure against Argentine Beef". The United States has accorded other Members, including Uruguay, Brazil, the United Kingdom and Japan, prompt and efficient access to the regulatory processes, while Argentina has been denied access to these administrative processes for years. The products at issue are clearly like and the same advantages have not been accorded to Argentina immediately and unconditionally; indeed, the advantages have been denied seemingly in perpetuity. Accordingly, the "U.S. Measure against Argentine Beef" is being applied in a manner inconsistent with the U.S. obligations under Article I:1 of the GATT 1994.

39. The analysis in regard to Article XI:1 is straight-forward. Application of the "U.S. Measure against Argentine Beef" results in a prohibition on importation of fresh (chilled or frozen) beef from Argentina.[7] This operates as a zero quota and thus clearly is prohibited by Article XI of the GATT 1994.

40. Argentina has demonstrated that the application of the "U.S. Measure against Argentine Beef" and the 2001 Regulations are inconsistent with Articles 1.1; 2.2; 2.3; 3.1; 3.3; 5.1; 5.2; 5.4; 5.6; and 10.1 of the SPS Agreement as well as with Articles I:1 and XI:1 of the GATT 1994.

B. The Prohibitions on the Imports of Animals, Meat and Animal Products from the Patagonia Region Are Inconsistent with the SPS Agreement and the GATT 1994

41. Argentina challenges the application of the prohibitions contained in Part 94 Title 9 of the C.F.R., that have been maintained by the United States for more than eleven years, on imports of animals, meat and other animal products from the Patagonia region, as a result of the United States' failure to recognize this region as FMD-free (the "U.S. Patagonia Measure").

42. The "U.S. Patagonia Measure" is an SPS measure because it aims to protect the health and life of animals in the U.S. territory from risks arising from the entry, establishment or spread of FMD. In addition, as an import ban, application of this measure directly affects international trade and is inconsistent with, *inter alia*, Articles 2, 3, 5, 6 and 10 of the SPS agreement. Thus, the U.S. Patagonia Measure is inconsistent with Article 1.1.

43. The U.S. Patagonia Measure is not based on international standards, guidelines or recommendations as required under Article 3.1. While the United States has promulgated regulations that appear to recognize OIE standards in regard to regionalization, in regard to Argentina they are empty words. The favorable risk assessment for Patagonia South in 2005 and the proposed rulemaking in 2007 have not been followed up with final rulemaking.

[7] Panel Report in *U.S. – Poultry (China)* at ¶¶ 7.456-7.457.

44. The United States cannot claim that it has based its measures on international standards simply because it speaks words along those lines. It must apply them in practice. In regards to Argentina and the issue of regionalization, the United States has acted in the exact opposite manner of the OIE standards. OIE standards expressly embrace regionalization and have been applied to Argentina for over a decade. The United States, however, has studiously avoided the regional approach to Argentina for more than 11 years. A measure cannot be said to be based on, built upon or supported by that which it is opposite to. Thus, it is clear that application of the "U.S. Patagonia Measure" is not based on the OIE standards for regionalization and is, therefore, inconsistent with Article 3.1 of the SPS Agreement.

45. There has been no FMD outbreak in Patagonia for over 20 years – since 1976 in Patagonia South and since 1994 in Patagonia North B. The 2005 risk assessment for the region has been positive; another risk assessment issued after the establishment of the Panel is also positive, therefore, the continuing application of the prohibitions cannot be based on a valid risk assessment justified by the scientific evidence. The import prohibitions on animals, meat and other animal products resulting from the application of the "U.S. Patagonia Measure" are not a consequence of the U.S. ALOP determined in accordance with Article 5. Thus, application of the "U.S. Patagonia Measure" is inconsistent with Article 3.3 of the SPS Agreement.

46. In order to be consistent with Articles 5.1 and 5.2 there must be a rational and objective relationship between the U.S. Patagonia Measure and the risk assessment. For Patagonia South, a region that has been FMD free since 1976 and for which APHIS issued a favorable risk assessment in 2005, it is clear that there can be no such rational and objective relationship. To the contrary – the only risk assessment is favorable but the U.S. measure is applied to Argentina as a prohibition. For Patagonia North B, as of the date of establishment of the Panel APHIS had not issued a risk assessment despite having the necessary information to do so. However, even if the Panel considered the favorable 2014 risk assessment for the entire Patagonia region, its results are at odds with the U.S. measure. Accordingly, the U.S. Patagonia Measure is not rationally and objectively related to the risk assessment under Article 5.1

47. With respect to Article 5.2, to the extent the risk assessor consulted the scientific evidence, such evidence supported the *opposite* conclusion from the prohibitive measure that is being applied. APHIS has issued a risk assessment for Patagonia South, its conclusions do not support the measure at issue, in the sense of Article 5.1. Additionally, the prohibitions are applied to Patagonia North B with no underlying risk assessment. Thus, in the absence of sufficient scientific evidence supporting the import prohibitions imposed by application of the measure at issue, the United States is also in violation of its obligations under Article 5.2 of the SPS Agreement**.**

48. Argentina considers that, since the application of the "U.S. Patagonia Measure" is inconsistent with Articles 5.1 and 5.2 of the SPS Agreement, by implication it is also inconsistent with Article 2.2. Moreover, even if one assumes, *arguendo*, that there has been a risk assessment conducted and applied in support of the prohibitions of imports of animals, meat and animal products from Patagonia, it is clear that the "U.S. Patagonia Measure" is applied beyond what is necessary to protect animal life or health and is not based on scientific principles nor maintained with sufficient scientific evidence. Both the 2005 and the 2014 risk assessments for Patagonia South and Patagonia up to the rio Negro, respectively, were favorable to recognition of the region as FMD-free. Considering the previous panel and Appellate Body views that a measure not supported by a valid risk assessment is necessarily not supported by scientific evidence within the meaning of Article 2.2, it must follow that application of the "U.S. Patagonia Measure" in a manner inconsistent with Articles 5.1 and 5.2 is also inconsistent with Article 2.2.

49. Argentina has also demonstrated that Article 5.7 does not apply. In *Japan – Agricultural Products II*, the Appellate Body laid out four cumulative steps to the Article 5.7 analysis; [8]a failure to meet any one will mean the measure is not a provisional measure within the meaning of Article 5.7. The United States has concurred at the OIE that the scientific information justified designation of the Patagonia region as FMD-free without vaccination. The United States conducted a risk assessment in 2005 and confirmed its view of the scientific evidence in regard to Patagonia South. The United States has received updated information on Patagonia South, as well as Patagonia North B, in 2008 and has conducted further site visits in 2009. Certainly, there is no contrary scientific evidence on the Patagonia region. Thus, the United States has acknowledged

[8] Appellate Body Report in *Japan – Agricultural Products II* at ¶ 89.

that there is sufficient information to evaluate the risks and, therefore, has failed to fulfill the first step of the requirements for a provisional measure. If any further evidence is required, the United States has not sought it; the United States has put the full burden on Argentina, thus flipping the whole structure of Article 5.7 upside down. And, finally, because the application of measure has been maintained far beyond a reasonable period of time, it is not justified as a provisional measure under Article 5.7, therefore application of the "U.S. Patagonia Measure" is not consistent with Article 2.2 of the SPS Agreement.

50. Under Article 5.4, the United States has an obligation to establish its ALOP with a goal of minimizing negative trade effects. By not determining its ALOP in a consistent and properly articulated manner to allow Members to understand which ALOP they should measure against, the United States cannot possibly claim to minimize negative trade effects and act consistently with Article 5.4. Moreover, the application of the "U.S. Patagonia Measure" to Argentina, which reflects the U.S. ALOP in regards to FMD, results in a ban on imports that maximizes negative trade effects. This constitutes a direct violation of Article 5.4.

51. Application of the U.S. Patagonia Measure is more restrictive than necessary to meet the U.S. ALOP, as required under Article 5.6. Therefore, the issue becomes whether there are other measures reasonably available taking into account technical and economic feasibility to achieve the U.S. ALOP, that are significantly less trade restrictive.[9] Such alternative measures exist. First, the United States can easily apply the available OIE recommendations on zoning and on recognition of a region' sanitary status. Second, as Argentina demonstrated, the Patagonia region should be treated as FMD-free in the same manner as the Brazilian State of Santa Catarina. The sanitary situation in Santa Catarina is similar in that it is internationally classified as FMD-free without vaccination although it borders regions that are FMD-free with vaccination. The only conditions imposed on imports from Santa Catarina are the requirements of 9 C.F.R. § 94.11 which are applicable to a number of countries and regions in proximity to FMD-affected areas. These would be acceptable and sufficient to achieve the United States' ALOP in regard to imports from the Patagonia region too. Clearly, they would also be less trade restrictive that the total import prohibition currently in place. Therefore, the application of the "U.S. Patagonia Measure" is inconsistent with Article 5.6 of the SPS Agreement.

52. Further, application of the "U.S. Patagonia Measure" arbitrarily or unjustifiably discriminates against imports from Patagonia and constitutes a disguised restriction on international trade inconsistent with Article 2.3. This discrimination takes two forms. On the one hand, Argentina has been denied effective access to the United States regulatory processes while other Members, including Brazil, Japan, the United Kingdom and Uruguay have had ready access.

53. On the other hand, in regard to substantive discrimination, Patagonia has been arbitrarily or unjustifiably discriminated against, as compared to the Brazilian State of Santa Catarina and Chile. The United States has affirmatively stated that the situation in Patagonia South is the same as in Chile. Given the subsequent international recognition that Patagonia North B is in the same sanitary situation as Patagonia South, it follows that the Patagonia region is similar to Chile for these purposes. In regard to Santa Catarina, the sanitary situations are similar; the only distinction is that Brazil was able to obtain access pursuant to a settlement of an unrelated WTO dispute. Finally, the application of the prohibitions purports to be SPS-based and has been maintained for more than eleven years. However, considering the OIE classification of the Patagonia region, the way other Members have been treated and the sort of concerns expressed in relation to the 2007 proposed rule, the application of the "U.S. Patagonia Measure" obviously is politically driven and is a disguised restriction on international trade. For those reasons, Argentina considers that the "U.S. Patagonia Measure" is inconsistent with Article 2.3 of the SPS Agreement.

54. The United States has failed to observe the regionalization obligations in Articles 6.1 and 6.2. First, the United States has not accorded proper consideration to the long periods of FMD-free status of the Patagonia region. While this was taken into account for Santa Catarina, it was obviously not for the Patagonia region. The United States has repeatedly stated its confidence in the Argentine veterinary service SENASA, yet it was not properly considered. Given that the U.S. Patagonia Measure is not adapted to the sanitary characteristics of the Patagonia Region and does not take into account the level of prevalence of specific diseases or pests nor the appropriate

[9] Appellate Body Report in *Australia – Apples* at ¶ 337; citing Appellate Body Report, *Australia – Salmon*, ¶ 194

criteria or guidelines of the OIE, the U.S. Patagonia Measure is not consistent with Article 6.1. Further, because the obligations contained in Article 6.2 particularize and supplement the more broad obligations established by Article 6.1, there is also a violation of Article 6.2. From the language of the provision and its location within Article 6, it is clear that the lack of recognition of the Patagonia region demonstrates that the recognition of the concept of disease-free areas by the United States is not based on the factors listed in Article 6.2. However, given the favorable nature of all these factors, which have essentially been agreed to by the U.S. authorities, it is clear that the United States, in maintaining the application of the prohibitions contained in Part 94, Title 9 of the CFR to Patagonia Region has not acted in conformity with its obligations under Article 6.2.

55. The United States has not accorded Argentina special and differential treatment in the application of the U.S. Patagonia Measure. Article 10.1, read together with Article 10.2, imposes a broad and unqualified obligation to take account of the special needs of developing country Members, with a view to maintain trade flows from developing country Members. Here, the United States acted swiftly to reopen access to the U.S. market to imports from developed countries like Japan and the U.K. after they experienced an outbreak. In contrast, the Patagonia Region has not enjoyed full and effective access to the U.S. regulatory processes despite being FMD-free for more than 20 years. This is exactly the opposite of the special and differential treatment that should be accorded Argentina. As a developing country it should have better access for risk assessments and rulemakings, not pushed aside for years while developed country Members have their interests taken care of promptly. Therefore, the United States has failed to accord Argentina special and differential treatment in application of its SPS measures as required by Article 10:1 of the SPS Agreement.

56. Last, the United States has acted inconsistently with its obligations under Articles I:1 and XI:1 of the GATT 1994. As to Article I:1, the United States has offered advantages to other Members that it has not accorded immediately and unconditionally to Argentina. These include the advantage provided Brazil (and its State of Santa Catarina) in its ability to export subject to certain protocols, while Argentina's territory located south of the río Negro is subject to several prohibitions maintained through the "U.S. Patagonia Measure". Furthermore, the United States has accorded other Members, including Uruguay, Brazil, the United Kingdom and Japan, prompt and efficient access to the required regulatory processes while Argentina has been denied access to these administrative processes for years. The products at issue are clearly like and the advantages have not been accorded to Argentina immediately and unconditionally. In regard to Article XI, the analysis is straight-forward. The U.S. Patagonia Measure applies and maintains a prohibition on importation on animals, meat and other animal products from the FMD-free region of Patagonia. This operates as a zero quota and thus clearly is prohibited by Article XI:1 of the GATT 1994.

57. Argentina has demonstrated that the application of the "U.S. Patagonia Measure " is inconsistent with Articles 1.1; 2.2; 2.3; 3.1; 3.3; 5.1; 5.2; 5.4; 5.6; 6.1; 6.2 and 10.1 of the SPS Agreement as well as with Articles I:1 and XI:1 of the GATT 1994.

C. Undue Delay in the Approval Procedures at §92.2

58. The U.S. has failed to comply with the requirements of Article 8 and Annex C(1)(a) of the SPS Agreement. These provisions require that "with respect to any procedure to check and ensure fulfillment of sanitary and phytosanitary measures, … such procedures are undertaken and completed without undue delay …" The APHIS procedures to (1) allow the importation of fresh beef from Argentina and (2) for the recognition of the Patagonia Region as FMD-free, initiated under APHIS' regulations at 9 C.F.R. § 92.2 (the "Approval Procedures") are subject to the requirements of Article 8 and Annex C.

59. First, the regulatory process under §92.2 is an "approval procedure" under the SPS Agreement. Annex C broadly defines "approval procedures" as including, *inter alia*, procedures for "sampling, testing and certification." Because imports of a specific commodity or of all animals or animal products from a region or country are conditioned upon the evaluation of its animal health status under 9 C.F.R. § 92.2, these procedures are analogous to those exemplified in Annex C. Second, the Approval Procedures are imposed to "ensure" that the U.S. prohibitions in Part 94 to allow importation only from those countries and regions which APHIS has declared free of FMD, or has approved imports of a particular product from a region not considered FMD-free, are met. In other words, the approval process in § 92.2 serves to "check and ensure" that the prohibitions on imports in 9 C.F.R. part 94 are maintained consistent with APHIS' regulations.

Therefore, the Approval Procedures must comply with Article 8 and Annex C, including the obligation that such procedures be "undertaken and completed without undue delay."

60. The U.S. claims that the procedures at 9 C.F.R. §92.2 to determine the sanitary health status of a region are not within the scope of Article 8 and Annex C because they are not enumerated along with "control, inspection and approval procedures," but Annex C(1) expressly provides a general obligation to ensure that "*any procedure*", which aims to check and ensure the fulfillment of SPS measures complies with those obligations. As the Panel in *US-Poultry* explains, Annex (C)(1) does not specify nor exclude any type of procedure, as long as it is aimed at checking and ensuring the fulfillment of SPS measures. Nor does Article 8 or Annex C(1) distinguish between procedures covering a specific product or multiple products as the U.S. claims.

61. The term undue delay is not defined in Annex C. The Appellate Body in *Australia – Apples* explained that Annex C(1)(a) requires that relevant procedures "are undertaken and completed with appropriate dispatch, that is, that they do not involve periods of time that are unwarranted, or otherwise excessive, disproportionate or unjustifiable."[10] To recall the rationale of the Panel in *EC – Biotech*, "it is therefore important always to bear in mind that Annex C(1)(a), first clause, implies as a core obligation the obligation to come to a decision on an application."[11] The United States is in breach of that obligation.

62. The time taken by APHIS on Argentina's request to allow the importation of fresh beef clearly exceeds what is reasonably necessary. Between November 2002 and end of 2006, APHIS made additional requests for information to which SENASA responded fully, APHIS made two site visits to Argentina to confirm the information received and seek out data for a quantitative risk assessment. However, since the visit in September 2006, there has been no further progress. The inaction of APHIS was not explained to Argentina, despite specific requests to do so, and is all the more unjustifiable as the sanitary conditions in Argentina continued to improve. This is evidenced by (a) the absence of an outbreak since February 2006; (b) the recognition of Argentina as FMD-free by the OIE: since 2002, Patagonia South is classified as FMD-free without vaccination, and that recognition was extended up to the río Negro in 2007, the rest of the country is FMD-free with vaccination since 2007; (c) and the change in leadership and strengthening of SENASA after the 2001 outbreak. While the period of inaction on Argentina's request coincides with political measures in the U.S., such as Section 737, aimed at blocking imports of Argentine beef, the political pressure does not legally excuse nor justify the delay. APHIS completed its risk assessment of Uruguay for FMD purposes in the span of one year from its last outbreak. In contrast, Argentina is still waiting for a risk assessment almost seven years after its last outbreak, far longer than is reasonably necessary.

63. Similarly, there is no justification for the U.S. delay to complete the Approval Procedures to recognize the Patagonia region as an FMD-free zone. Patagonia South has been FMD-free since 1976 and Patagonia North B since 1994. The formal approval process was initiated over a decade ago and as of early 2007 it was only one step short of being completed – that is, the only step missing was the final rulemaking. APHIS' 2005 risk assessment provided a favorable assessment of the sanitary status of Patagonia South. On the basis of this assessment animals, meat and other animal products from Patagonia South should have been allowed access on the U.S. market more than seven years ago. In the six years since 2007, nothing has changed except that the in May 2007, the OIE extended the recognition of Patagonia as a region free of FMD up to the rio Negro to include Patagonia North B. APHIS's site visit in February 2009 to Patagonia, including Patagonia North B, confirmed that all requirements for the recognition of Patagonia as FMD-free have been met all along. Considering that all the information regarding Patagonia is favorable to the proposed action, APHIS' failure to take the final step in the approval process – *i.e.* the issuance of the final rule – is a clear example of undue delay. Thus, the failure to complete the Approval Procedures for the importation of fresh beef and for the recognition of the Patagonia Region as FMD-free without undue delay is a violation of Annex C(1)(a) and consequently of Article 8 of the SPS Agreement.

64. The U.S. is also in breach of its procedural obligations under Annex C(1)(b) and consequently in violation of Article 8. With respect to both of Argentina's pending requests under §92.2 the U.S. never communicated the anticipated processing period despite Argentina's specific inquiries on this matter. Following APHIS' site visit to Corrientes in September 2006 there has

[10] Appellate Body Report, *Australia – Apples*, para. 437.
[11] Panel Report, *EC – Approval and Marketing of Biotech Products*, at para. 7.1523.

been no further communication to Argentina on the results of APHIS' sanitary assessment. This is also true for the Patagonia Region. Following APHIS' site visit in February 2009, APHIS indicated that it did not require additional information to proceed, but no risk assessment was produced as of the date of the Panel establishment. Thus, the results of APHIS' evaluation have not been promptly communicated to Argentina so that corrective action may be taken if necessary. Finally, the U.S. has not explained the delays in the regulatory process for either of Argentina's pending applications.

65. Therefore, the United States has breached its obligations under Annex C(1)(b) to: (i) communicate the processing period, (ii) transmit as soon as possible the results of the procedure in a precise and complete manner, and (iii) provide information about the stage of the procedure and an explanation of the delays. It follows that the United States has acted inconsistently with both Annex C(1)(b) and Article 8 of the SPS Agreement.

ANNEX B-2

SECOND PART OF THE INTEGRATED EXECUTIVE SUMMARY
OF THE ARGUMENTS OF ARGENTINA

I. INTRODUCTION

1. The principal issues in this dispute remain straightforward. The U.S. has maintained, for more than twelve years, a prohibition on imports of fresh (chilled or frozen) beef from Argentina as a whole and on imports from Patagonia, without scientific justification and has failed to act without undue delay on both of Argentina's pending applications. In fact, the maintenance of the ban for over a decade is in direct conflict with APHIS' findings in the risk assessment of FMD for the Patagonia Region. The ban on imports of beef from Argentina has been maintained without a risk assessment despite the passage of twelve years since Argentina made the request for authorization to import fresh (chilled or frozen) beef, although a recently issued "draft" risk assessment for beef from APHIS has corroborated the essential claims of Argentina.

2. The maintenance of these bans for over twelve years is not just a matter of undue delay, but a complete failure of the U.S. system as applied to Argentina. First, contrary to the U.S. arguments, the application of its measures results in a ban on trade in a situation where the OIE Terrestrial Code provides no basis for a ban. In the meeting with the Experts and the Panel, the OIE has confirmed that OIE Terrestrial Code Chapter 8.5 protocols are available alternative measures scientifically accepted at an international level for imports of beef from Argentina and for imports from the Patagonia Region, such that a ban is not justified. Second, the U.S. has discriminated against Argentina as compared to its treatment of the imports of other Members. While the United States rejected the OIE protocols as alternative measures because it asserts that it sets higher standards than the OIE, it also rejected measures that the U.S. already implements with respect to imports from other Members. The OIE and the individual experts appointed by the Panel have reviewed the evidence on the record and their answers unequivocally support the validity of the alternative measures proposed by Argentina, consistent with Article 5.6 of the SPS Agreement that would allow imports from Argentina subject to certain mitigation measures. These alternative measures would guarantee the safe trade of beef from Argentina and of imports from the Patagonia Region.

3. The U.S. main defense is based on Article 5.7, which provides for a qualified exemption from the requirements of Article 2.2. However, at this stage it has become abundantly clear that there never were any U.S. measures covered by Article 5.7. The U.S. arguments have spanned a gamut of positions, one more extreme than the other, from claiming the simultaneous application of Articles 5.1 and 5.7, to the argument that the 2001 Regulations are justified by events that occurred in 2002, to an entire non-textual re-write of Article 5.7 that would support a *constructive* adoption of a measure. All of these arguments are in error as they are based on a fundamental misunderstanding of Articles 5.1 and 5.7 in regard to the 2001 Regulations and 9 C.F.R. §94.1(b), as well as the broader part 94 of Title 9 of the C.F.R.

4. Last, there has been undue delay in the processing of Argentina's requests for import authorization for fresh beef and for the recognition of the Patagonia Region as FMD-free. The undue – and, in fact, unjustifiable – delay has been so long now that the United States is left with nothing more than a technical argument that Article 8 and Annex C do not apply to the facts of this case. That is a legally unsustainable position.

II. CHRONOLOGY OF EVENTS AND MAIN FACTS

5. At all stages of these proceedings, the U.S. has mis-stated the scope and content of Argentina's claims and APHIS' regulations as well, and has followed a strategy of distracting attention from the relevant facts and characterizing Argentina's claims as being about nothing more than delay. For more than twelve years the U.S. market has been closed to imports of fresh beef from Argentina; for eleven years, Argentina has been engaged in the sole procedure under the U.S. system (the procedure at 9 C.F.R. § 92.2) by which a country or region can gain access to the U.S. market for its animal products, whether for a specific commodity –fresh beef- or for a

recognition of a region as free of FMD –Patagonia Region-. The most important facts that underlie this dispute are, first, that the United States has not issued a risk assessment for beef from Argentina since the import ban went into effect in 2001, and up to the date of Panel establishment. Second, at the time of the establishment of the Panel, the only published risk assessment for Patagonia -for Patagonia South- was completed nine years ago, and was favorable for importation. In January 2014, after the establishment of the Panel, the United States issued another risk assessment for the Patagonia Region, covering Patagonia South and Patagonia North B, which was also favorable for importation. In August 2014, APHIS further issued a final Notice for Patagonia, as well as a "draft" risk assessment and a proposed rule for beef, just days before the Second Panel meeting.

6. There is ample evidence on the record showing that the sanitary status of Argentina has improved dramatically compared to the circumstances in 2001: (a) Argentina has not had an FMD outbreak in any part of the country since 2006 (which was very limited, quickly contained and immediately reported), and has not had an FMD outbreak in the Patagonia South region since 1976 nor in Patagonia North B since 1994; (b) Patagonia South has been recognized by the OIE as FMD-free without vaccination since 2002, Patagonia North B since 2007 and Argentina has recovered OIE FMD-free with vaccination status in 2007; and those statuses have been confirmed year after year.

7. The United States has identified the supposed unreliability of SENASA as its primary excuse for not moving forward with its regulatory processes for beef and the Patagonia Region. However, this argument is yet another attempt to distract the Panel from the relevant facts. Argentina demonstrated that SENASA has been reorganized and strengthened, a fact confirmed by the assessment of other importing members such as Chile and the E.U., which found SENASA's capabilities to be adequate. These positive assessments are confirmed by the OIE, where the United States has joined in the consensus on the upgrading of Argentina's and Patagonia's officially recognized status for FMD over the past 12 years.

8. Further, the United States has specifically approved the efficacy of SENASA and its systems in the 2005 and 2014 risk assessments for Patagonia. Both of these risk assessments give a satisfactory evaluation of SENASA on a comprehensive basis, not just in relation to the Patagonia Region. This was further confirmed in the "draft" risk assessment for fresh beef issued in August 2014, which was favorable for importation under the same protocols as have been applied to fresh beef from Uruguay since 2003.

9. With respect to any progress on Argentina's commodity request for fresh beef, remarkably, the United States has very little to say. Indeed, with respect to the fresh beef claim, there has been no further progress on Argentina's request after APHIS visited the country in September 2006, when it traveled to the site of the 2006 outbreak to gather new information. In September, 2010, the U.S. assured Argentina that it was actually drafting a proposed rule for beef, but, as of the date of Panel establishment, nothing happened.

10. The U.S. now claims that it did not collect all of the information it needed for both the beef and the Patagonia requests until its site visit to Argentina in November 2013. However, in response to direct questions from the Panel, the United States was unable to identify specifically any information that was missing. Indeed, no further information was requested by APHIS after Dr. Clifford's letters of April 2009 and September 2010.

11. Argentina did not object to the entry into evidence of the 2014 risk assessments and rulemakings introduced by the United States. In particular, the risk assessment and proposed rule for authorizing beef imports from Argentina corroborate key facts and aspects of the arguments that have been made by Argentina in this dispute. Specifically, it is now corroborated and confirmed that the import measures applied to trade in beef from Uruguay would satisfy the U.S. appropriate level of phytosanitary protection ("ALOP"), whatever precisely that ALOP might be. Additionally, it cannot be disputed that the sanitary conditions relating to FMD in Uruguay are similar to those in Argentina from the perspective of Article 2.3 and that the ban on imports from Argentina was discriminatory.

12. These developments do not change the nature of Argentina's claims which are based on the measures as they existed at the time of Panel establishment. Moreover, Argentina does not have yet the ability to export any beef nor any products from the Patagonia Region to the United States.

III. ORDER OF ANALYSIS

13. The U.S. response to the evidence and arguments presented by Argentina has been to mischaracterize Argentina's claims as being subsumed in its undue delay claims. Thus, the U.S. argues that the Panel should limit its review of Argentina's claims under Articles 8 and Article 5.7. The U.S. approach is deeply flawed because it fails to distinguish between Argentina's claims and the U.S. measures being challenged. Argentina raised several substantive autonomous claims under the SPS Agreement and the GATT 1994, which do not depend on the Panel's resolution of Argentina's claims of undue delay under Article 8 and Annex C and which are based on different U.S. provisions. The Panel should proceed with the analysis of claims in the order in which Argentina has presented them in its First Written Submission.

IV. LEGAL CLAIMS

A. THE U.S. MEASURES ARE NOT BASED ON THE OIE "STANDARDS, GUIDELINES OR RECOMMENDATIONS"

14. The U.S. maintains a ban on imports of fresh, chilled and frozen beef from Argentina and on imports from the Patagonia Region which is directly the opposite of the OIE standards, guidelines and recommendations because those standards, guidelines or recommendations provide that beef from Argentina is safe to import under the conditions contained in Article 8.5.23 of the Terrestrial Code or even those in Article 8.5.25.

15. This case is not about a review of the U.S. regulations *as such*. What is legally relevant under the Article 3.1 analysis is how the U.S. measures are applied to Argentina in comparison to OIE "standards, guidelines or recommendations." The issue under Article 3.1 is that the United States imposes measures which produce the exact opposite result of the OIE standards, guidelines or recommendations. As such it cannot be said that the U.S. measures are "based on" such guidelines. Thus, the U.S. claim that its measures are based on international standards in accordance with Article 3.1 of the SPS Agreement is unsustainable.

16. Argentina is, in fact, FMD-free. This is recognized by the whole international community, including the United States, through the country status designation of the OIE General Assembly. The U.S. claims to apply a higher standard because it categorizes countries that are FMD-free with vaccination as not being FMD-free. However, even under that approach, a ban on imports is not justified. As the OIE explained, it may be impossible to eradicate FMD from a country or zone in the short term, but even then:

> However, this situation does not justify banning the export of ruminants and ruminant products from these countries. To take such a position would be contrary to the principles in the SPS Agreement, as it would be highly restrictive to trade and would not be based on science.[1]

17. The United States has consistently attempted to argue that Argentina's claims in regard to Articles 3.1 and 3.3 are based on the U.S. procedures contained in 9 C.F.R. §92.2. Those procedures, to the extent they are actually a "measure," are not the subject of Argentina's claims in regard to fresh beef and imports from the Patagonia Region.[2] Argentina's claims are based on the maintenance of the bans on those imports as provided for in the 2001 Regulations and the regulations in 9 C.F.R. Chapter 94.

18. The United States argument that the OIE's disease status recognitions are not a "standard, guideline, or recommendation" for purposes of the SPS Agreement and that Members cannot rely on them is both incorrect and illogical when read in the context of the remainder of Article 3. If the OIE country status recognitions are written out of the SPS Agreement then Members can no longer rely on the safe harbor of Article 3.2. Such an interpretation would severely undermine the OIE and prejudice the rights of the vast majority of Members who do not have the resources to conduct their own risk assessments. Further, the interpretation is incorrect based on the ordinary meaning of the term "standards, guidelines or recommendations." This term is the same in both

[1] OIE Response to Question 10.
[2] These procedures are related to the undue delay claim.

Articles 3.1 and 3.2 and there is no textual reason why the exact same term should have different meanings in these two paragraphs.

B. THE UNITED STATES HAS ACTED INCONSISTENTLY WITH ITS OBLIGATIONS UNDER ARTICLE 3.3

19. The U.S. also asserts the right under Article 3.3 to apply a higher standard than the OIE, which means that the U.S. measures can only be justified in accordance with Article 3.3. However, the text of the SPS Agreement as interpreted by the Appellate Body in *EC – Hormones* indicates that a measure is consistent with Article 3.1 *or* is covered by Article 3.3.

20. In this regard, the United States still has never explained the meaning of the term "except" in Article 3.1, unless it is meant to set up a binary, "either/or" distinction between Members who base their measures on OIE standards, guidelines or recommendations and those Members asserting a higher ALOP.

21. Argentina recalls its concern at the outset of this dispute that the United States was attempting to set up a back-door safe harbor by which it could claim that its measures were "based on" OIE standards and therefore be relieved of the obligations of the rest of the SPS Agreement. Obviously, this would be an absurd result that would allow a Member meeting the lower threshold of "based on" in Article 3.1 to have the same or better legal protection as a Member meeting the higher threshold of "conform to" in Article 3.2.

22. Argentina also notes that Article 3.3 independently requires that there be a determination by a Member of its ALOP. The United States has failed to make such a determination. The U.S. states that the *sole* standard for its ALOP is the very vague statutory authority provided in the Animal Health Protection Act found at 7 U.S.C. §8303. Read literally, this provision would mean that the ALOP is whatever the Secretary of Agriculture determines it to be at any given moment.[3] However, this provision states nothing of substance whatever, such that it is impossible to understand what the U.S. position is in regard to FMD. However, the lack of any sort of properly articulated ALOP is, in itself, inconsistent with the requirements of Article 3.3.

C. THE IMPORT BANS ARE NOT SUPPORTED BY ART. 5.1, 5.2 OR 2.2

23. Argentina's claims in regard to Article 5.1 relate to the bans contained in the 2001 Regulations and the regulations in 9 C.F.R. Chapter 94 on beef and the subject products from the Patagonia Region. The legal issue is whether the maintenance of the application of those measures over a decade later is pursuant to a valid risk assessment conducted in accordance with Article 5.1. The U.S. argues that the measures at issue were imposed pursuant to a risk assessment under Article 5.1.

24. The 2001 Regulations were a statement of facts and intentions along with a recitation of the well-known risk of FMD spread. This sort of situation has been addressed before by panels and the Appellate Body, most recently in *US – Poultry (China)*, where the Panel rejected the U.S. contention that recitations of risk combined with generalize statements of purported risk do not meet the requirements of a risk assessment under Articles 5.1 and 5.2.

25. Even assuming, *arguendo*, that the 2001 Regulations constituted a risk assessment, the facts underlying them are far out of date. The Panel in *Japan – Apples* made it very clear that risk assessments are not static; they must be reviewed or renewed as the scientific evidence evolves.[4] A Member cannot simply conduct a risk assessment and then maintain a ban on imports without the requirement of revisions, as the United States has done. It is deeply ironic that the United States could try to claim that the 2005 Patagonia risk assessment was out of date and yet still claim to rely on a purported 2001 risk assessment in 2014.

26. The appropriate time periods for conducting risk assessments are determined by the text of Article 5.1 itself, *i.e.,* as appropriate to the circumstances and taking into account the risk assessment techniques developed by the OIE. The U.S. attempt to assert that the time period for the qualified exemption in Article 5.7 controls the whole of the SPS Agreement is illogical and not

[3] US Responses to the First Questions from the Panel at para. 179.
[4] Panel Report in *Japan – Apples* at para. 7.12.

supported by the text. Argentina's approach is also supported by the terms of Article 8 and Annex C, which more broadly require that Members implement their administrative processes without undue delay.

27. For the beef claim, prior to the establishment of the Panel there has been no review or risk assessment undertaken since 2001, yet many things have changed since that time, as APHIS acknowledged in correspondence on the record. While the U.S. has raised many *ex post facto* justifications during the course of the dispute for its endless process, none of these U.S. arguments legally excuse the inaction. The United States has acted contrary to its obligations under Articles 5.1 and 5.2 to apply measures that are based on valid risk assessments.

28. With regard to Patagonia, the United States issued a favorable risk assessment in 2005, followed by a proposed rule in January 2007 to include Patagonia South in the list of FMD free regions referenced at 9 C.F.R. § 94.1(a). However, that favorable risk assessment was never acted on. Article 5.1 requires that a Member's SPS measures be based on a valid risk assessment, but that is not what happened here. There can be no valid excuse for continuing a ban on imports when the only risk assessment on the record prior to the Panel establishment was favorable. The 2014 risk assessment for Patagonia, also favorable, reinforces that conclusion.

29. Because the U.S. measures are inconsistent with the requirements of Articles 5.1 and 5.2, it is Argentina's position that they are also necessarily inconsistent with Article 2.2. In its FWS and SWS Argentina presented considerable evidence that the science of FMD provides for safe trade in beef from Argentina and for imports from the Patagonia Region.

D. ARTICLE 5.7 HAS NO APPLICABILITY TO THIS DISPUTE

30. In response to Argentina's argument that the United States failed to comply with its obligations under Article 2.2 of the SPS Agreement,[5] the U.S. has asserted that its measures were simultaneously imposed pursuant to risk assessments under Article 5.1 and provisional measures under Article 5.7. Of course, this is a literal impossibility, but it is only one of many problems with the U.S. arguments under Article 5.7 in regard to the 2001 Regulations and 9 C.F.R. Chapter 94.1(b) and in the broader part 94 of Title 9 of the C.F.R.

31. First, it is impossible to argue that Articles 5.1 and 5.7 are simultaneously applicable because the two positions are mutually exclusive. If there is *sufficient* scientific evidence to conduct a risk assessment under Article 5.1, then, by definition, there cannot be the requisite *insufficiency* of scientific evidence required to invoke Article 5.7. That is to say *either* the "relevant scientific evidence is sufficient to perform a risk assessment" to adopt a measure (Article 5.1.) *or* the relevant scientific evidence is insufficient to perform a risk assessment and the measure may provisionally be adopted under certain circumstances (Article 5.7.).

32. Second, there never were any U.S. measures covered by Article 5.7. The United States has been reduced to arguing that its 2001 Regulations were justified by events that occurred in 2002, which of course is impossible. It is an indisputable fact that the United States did not adopt any measures whatever in 2002. In response to a question from the Panel to identify the measure adopted in 2002, the U.S. could not respond. Instead, it argued for a reading of Article 5.7 that would allow for a "constructive" adoption of a measure, although there is no textual basis for this. But all that happened in 2002 was that Argentina submitted an application[6]. In essence, the U.S. approach is equivalent to saying that either the U.S. measure transformed itself upon the 2002 application by Argentina or it was Argentina that actually adopted the measure for the United States when it filed its *de novo* application under 9 C.F.R. § 92.2. The Panel should reject such a distorted reading of Article 5.7. Thus, the U.S. argument fails the most basic test under Article 5.7 that it only provides authority for Members to "provisionally adopt sanitary and phytosanitary measures." That is, there must be (1) an adoption, (2) of measures.

33. Obviously, what the United States is trying to do here is contort the language of the SPS Agreement to fit the form of the *U.S. regulations*. But that is completely backwards. The

[5] As Argentina discussed in its First Written Submission, the Appellate Body has found that a measure that was inconsistent with Articles 5.1 and 5.2 of the SPS Agreement was "by implication" also inconsistent with Article 2.2. *See* Appellate Body Report in *Australia – Apples* at para. 262, citing Appellate Body Report in *Australia – Salmon* at para. 138.

[6] Argentina also submitted an application in August 2003 for imports from the Patagonia Region.

United States must implement its measures in conformity with the SPS Agreement, not demand that the Panel twist the interpretation of the SPS Agreement to fit the U.S. measures.

34. Third, while the necessary condition to invoke Article 5.7 in the first place is insufficiency of the scientific evidence, the United States has been unable to identify any scientific evidence (regardless of the breadth of the definition of that term) that was unknown at the time. The U.S. regulations do not include any provision for the United States to seek out the allegedly missing information; instead, the United States ejected Argentina from its regulatory system and put the burden wholly on Argentina to start a *de novo* application process. There was neither insufficiency of evidence nor any temporal aspect to either the 2001 Regulations or the 9 C.F.R. § 94.1 regulations.

35. In its second round of responses to the Panel the United States admits that it did not seek out any information.[7] Rather, its procedures were triggered by the application filed by Argentina under 9 C.F.R. §92.2. Without an initiative from Argentina in the form of its application, the U.S. measures would be applied without any review. That is simply inconsistent with the requirement of Article 5.7 that the importing Member seeks out the missing evidence and review the measure. The obligation of the importing Member is not just to sit back and wait to see if some new evidence happens to be submitted. The obligation is for the importing Member to seek out the evidence to complete what it considered insufficient, when it provisionally adopted an SPS measure because of that insufficiency.

36. Another problem of the U.S. argument on regard to Article 5.7 is the implication that it can maintain a ban under Article 5.7 indefinitely until the exporting Member proves to the United States that there is sufficient evidence to support a risk assessment. That is not what Article 5.7 says. Article 5.7 applies only when there is insufficient scientific evidence. The implied U.S. position is belied by the 2001 Regulations which it asserts were fully supported by the evidence "through 2002." If the U.S. considered that there was sufficient evidence during the period from 2002 to 2013, then it was obligated to present such evidence in the form of a risk assessment. However, it has not done so.

37. Furthermore, it is obvious from these points, that, even were the original U.S. measures in 2001 characterized as provisionally adopted measures, certainly after all the passage of time and all the U.S. correspondence and statements over the past several years and the completeness of the information Argentina has submitted, the continued application of the measures cannot still be justified under Article 5.7. The United States admitted there was sufficient scientific evidence in the Clifford letters of April 2009 and September 2010 and in statements made by the U.S. Representative to the SPS Committee.

38. The United States has argued that Article 6.3 is integral to an understanding of Article 5.7. This is an incorrect statement of law. The United States' Article 6.3 and 5.7 defenses are incompatible. Article 6.3 stands as a potential affirmative defense by a respondent to claims under Articles 6.1 and 6.2. Article 5.7 applies only in the very narrow situation of insufficiency of scientific evidence and allows a Member to "provisionally adopt…measures." Thus, the two provisions cover entirely different situations and have contrary legal requirements.

39. The whole premise of the U.S.' Article 6.3 defense is that there is a process that takes place when a Member claims that areas within its territory are disease-free or of low disease prevalence. At that point, a process is begun including permitting reasonable access to the exporting Member's territory. This is an entirely different matter than when a Member provisionally adopts a measure. If the United States argues that it firmly knew about FMD risks from imports of Argentine beef in 2001, it cannot simultaneously assert the application of Article 5.7. Similarly, if the United States claims that its process was covered by the terms of Article 6.3, then, there is no issue of provisional adoption of a measure in Article 6.3. Among other things, Article 6.3 requires the applicant to take the initiative in providing comprehensive information, whereas Article 5.7 puts the burden on the importing Member to seek out the information that it finds insufficient. Clearly, the two articles cannot be interpreted to apply in the same situation because that would amount to conflicting obligations.

[7] Responses of the United States to the Panel's Questions Following the Second Panel Meeting at paras. 29-30.

40. Argentina recalls that it has raised claims under Article 6 only with respect to its Patagonia claims. Therefore, even if Article 5.7, which does not apply here, is "informed" by Article 6.3, as the U.S. argues, that interpretation of Article 5.7 would not apply with respect to Argentina's fresh beef claims.

41. Even assuming, *arguendo*, that Article 6.3 would be relevant to an interpretation of Article 5.7, based on the facts of this dispute, the United States has nothing to gain from this argument because it has not identified a single information request that remained unanswered. Argentina has satisfied every single information request made by APHIS and it has done so a long time ago. The correspondence from Dr. Clifford in 2009 and 2010 necessarily implies that APHIS has long had all the information necessary to complete the regulatory process. This was repeatedly confirmed by the U.S. statements in the SPS Committee.

E. THE U.S. HAS ACTED INCONSISTENTLY WITH ARTICLE 5.4

42. The United States has asserted that Article 5.4 imposes no affirmative obligations because it uses the word "should." However, that position is not supported by the plain language of the Article 5.4 and the ordinary meaning of "should", which, although not as strong as the imperative "shall," is affirmative in nature. The Appellate Body has confirmed that "should" can, indeed, impose affirmative obligations. Although the requirement to take something into account did not mean that a specific result must be achieved, the obligation is real, it is affirmative and it must be shown in the documentation.[8] Therefore, the U.S. has an affirmative obligation to adopt an ALOP which minimizes negative trade effects.

43. No such efforts of minimizing negative trade effects can be ascertained in this case. In its FWS and SWS Argentina demonstrated that that the U.S. was applying an ALOP in regard to Argentine beef and imports from Patagonia as if it were applying an ALOP based on "zero risk." In fact, in its Comments on the experts' responses, the United States has stated that zero risk is exactly what it is requiring of Argentina.[9]

44. The ability of the United States to impose this impossible ALOP on Argentina appears to arise from its adoption of a statement of general authorization for the Secretary of Agriculture to protect the population, as its ALOP. That has allowed the United States to arbitrarily declare that nothing Argentina does ever meet this moving standard. It also falls short of a clear and understandable ALOP. The Appellate Body has found that "the SPS Agreement contains an implicit obligation to determine the appropriate level of protection."[10] Although it need not be determined in quantitative terms, the level of protection cannot be determined "with such vagueness or equivocation that the application of the relevant provisions of the SPS Agreement … becomes impossible."[11]

45. By not determining its ALOP in a consistent and properly articulated manner so that Members can understand which ALOP they should meet, the U.S. cannot possibly claim to minimize negative trade effects and act consistently with Article 5.4. Argentina has also noted that the failure to apply a valid ALOP to imports from Argentina means that the U.S. has also not satisfied the requirements of Article 3.3 and, further, should inform the Panel's analyses of Articles 2.3 and 5.6.[12]

F. THE US MEASURES BREACH ARTICLE 5.6 BECAUSE THERE ARE REASONABLY AVAILABLE AND LESS TRADE RESTRICTIVE MEASURES

46. The U.S. has acted inconsistently with Article 5.6 because there are reasonably available measures - either the OIE Terrestrial Code recommendations or the import protocols applied by the U.S. to other members – that would achieve the U.S. ALOP (whatever that may be) because they provide a higher level of protection. These alternative measures are also less trade restrictive since they allow for safe trade.

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[8] Appellate Body Report, *China – GOES,* para. 132. The Appellate Body had previously found at paragraph 130 that the word "consider" and "taking into account" had the same meaning.

[9] U.S. Comments on Experts' Responses at paras. 18-19.

[10] Appellate Body Report, *Australia – Salmon*, paras. 205 and 207.

[11] *Id.*, at para. 203.

[12] Opening Statement of Argentina at the Second Meeting of the Panel at para. 82.

47. Argentina has suggested that OIE Terrestrial Code Chapter 8.5 protocols are available alternative measures scientifically accepted at the international level for imports of beef from Argentina and for imports from the Patagonia Region. The OIE explained in detail in its responses to the Panel that the standards within the OIE Terrestrial Code are based on the highest level of scientific knowledge and expertise. As the OIE explained,

> "the recommendations in the disease chapters … are designed to prevent the disease in question being introduced into the importing country. … Correctly applied, OIE recommendations provide for trade in animals and animal products to take place with an optimal level of animal health security based on the most up to date scientific information and available techniques."

48. Thus, it is quite clear that the OIE recommendations are designed to achieve a high ALOP. United States rejected these suggested alternative measures because it asserts that it sets higher standards than the OIE.

49. However, Argentina has also suggested that in regard to fresh beef, the U.S. could apply the protocol that it applies to Uruguay, found in 9 C.F.R. §94.22, since both Uruguay and Northern Argentina have the same OIE officially recognized FMD status of FMD-free with vaccination. In regard to Patagonia, Argentina has suggested applying the same protocols applied to the FMD free Brazilian State of Santa Catarina (found in 9 C.F.R. §94.11). Considering that the Patagonia Region and Santa Catarina have the same OIE officially-recognized FMD status of free without vaccination, application of the same protocols would respond to the same level of risk and thus provide the same risk mitigation requirements. The U.S. cannot argue that the Uruguay protocol is not a valid alternative measure under Article 5.6, when the U.S. is currently allowing imports of fresh beef from Uruguay and from the FMD free Santa Catarina under these mitigating protocols. Further, these protocols will provide for safe imports that meet the U.S. ALOP because they already do so.

50. The mitigation measure the United States applies to Uruguay beef can safely be applied to Argentine beef. It is similar in nature to the OIE recommendation for infected areas with an official vaccination program, whereas Uruguay is FMD-free with vaccination, just like Argentina. The Uruguay protocols are highly redundant and very safe. The answers provided by the OIE and the individual experts unequivocally support the validity of the alternative measures proposed by Argentina, consistent with Article 5.6, that would allow imports from Argentina subject to certain mitigation measures.

51. All the experts were in agreement that trade in fresh beef from a country that is FMD-free with vaccination pursuant to the recommendation in Article 8.5.25 of the Terrestrial Code is safe. As the United States also acknowledges, there are no known instances of beef exported under these recommendations transmitting FMD. As confirmed by a consensus of the experts, there is substantial evidence on the record in this dispute that the protocols contained in 9 C.F.R. §94.22 would provide for safe trade in imports of Argentine beef into the United States. This is corroborated by the August 2014 risk assessment and Proposed Rule for fresh beef introduced into evidence by the U.S.

52. Similarly, the protocol applied to Santa Catarina under 9 C.F.R. § 94.11 would also be an adequate safeguard for the subject products from the Patagonia Region. The United States does not even contest this, as is confirmed by the January 2014 risk assessment. This conclusion was now definitively confirmed by the United States in the recent final notice to recognize the Patagonia Region as FMD-free.

53. It is important to recall that the 2014 risk assessment for Patagonia found that the controls implemented by SENASA in northern Argentina resulted in a very low risk of introduction of FMD into the Patagonia Region. The experts examined this at the request of the Panel and concluded that the same assessment would apply to the very low risk of transmission from imports of fresh beef from northern Argentina to the United States. Dr. Cupit stated that there is no evidence on the record to detract from APHIS' conclusion that matured, deboned fresh beef imported into the Patagonia Region from zones in Argentina's territory north of the rio Negro "*has a very low risk of introducing the FMD virus into the export region.*"[13] Similarly, Dr. Batho said that "The evidence on

[13] Dr. Cupit response to Question 46 at para. 384.

the record supports the conclusion that there is a very low risk of matured and deboned fresh beef meat introducing FMD virus into Patagonia. Following on from this, it is obvious that the evidence also supports the conclusion that matured and deboned beef from the rest of Argentina poses a similar or identical risk to other markets as it does to Patagonia."[14] All of these conclusions are corroborated by the risk assessment and the proposed rule for fresh beef[15] published by the United States after the Panel establishment.

54. These alternative measures are clearly less trade restrictive than the current ban on imports from Argentina. Finally, the Panel must reject the U.S. argument that the Panel should decline to make findings in regard to Article 5.6. The United States claims that if a domestic regulator has failed to conduct a risk assessment in regard to the proposed alternative measure, then a Member can completely avoid its obligations under Article 5.6 (and Article 2.3). This is manifestly inconsistent with the plain language of Article 5.6 and also with the jurisprudence. There is ample evidence on the record that the protocols applied to Uruguay's imports of fresh beef are safe and applying them, or any similar ones, to Argentine beef would satisfy the U.S. ALOP (whatever it might be). The Panel should find that protocols similar to those in 9 C.F.R. § 94.22 would satisfy the U.S. ALOP regarding imports of fresh beef from Argentina.

G. THE UNITED STATES FAILED TO OBSERVE ITS REGIONALIZATION OBLIGATIONS IN ARTICLES 6.1 AND 6.2

55. Argentina has asserted a violation of Article 6 only with respect to its Patagonia claim. Therefore, as a jurisdictional matter, Article 6 is not applicable to the fresh beef claim. The U.S. reasoning that Article 6 applies to commodity requests because the word "product" is used in Article 6.1 is very unconvincing because the SPS Agreement in general relates to the possibility of one Member exporting a product into the territory of another Member.

56. What Article 6 directly relates to is a broad statement that Members shall ensure that SPS measures are to be adapted to the sanitary characteristics of the area. Article 6.1 requires Members to take measures that account for the fact that different exporting areas may have different characteristics. Article 6.2 requires recognition of "concepts" – specifically, the "concepts of pest- or disease-free areas and areas of low pest or disease prevalence."

57. While the U.S. claims to recognize the "concepts" of disease free areas with respect to the Patagonia Region, as illustrated by the 2005 risk assessment and the 2007 proposed rule on Patagonia South, it has failed to act on these assessments. Therefore, the U.S. conduct over the last eleven years belies the U.S. contentions on regionalization. That the United States has not complied with Articles 6.1 and 6.2 is confirmed by its failure to complete the regulatory process for the Patagonia Region prior to the date of Panel establishment, although it had all of the information necessary for its assessment following its visit in February 2009.

58. Argentina never requested a regionalization determination (i.e. to be recognized as free of FMD) for the entire country, because it knew that it would be impossible under the U.S. regulations, which do not recognize the category FDM-free with vaccination. Therefore, for beef, Argentina has simply requested an import authorization for fresh beef under certain mitigation measures. In the absence of a claim by Argentina with respect to fresh beef, neither the language of Article 6 nor logic support the application of Article 6 in reference to the fresh beef claim.

H. THE U.S. HAS ACTED INCONSISTENT WITH ARTICLE 2.3

59. There is no valid reason for the United States' disparate treatment of imports from Argentina compared with imports from other Members. This disparate treatment constitutes a breach of the first sentence of Article 2.3.

60. The U.S. measures unjustifiably discriminate against Argentine imports by maintaining a ban for more than twelve years, while imports from Argentina's neighbors such as Uruguay and Brazil are able to access the U.S. market. The United States admitted in several instances that it was, in fact, applying a zero risk ALOP to Argentina. Yet, it is clear from the record evidence that such a

[14] Dr. Batho response to Question 46, at para. 386.
[15] Exhibit USA – 168, at page 51509.

standard is not applied to other Members, such as Uruguay.[16] That failure to apply a consistent and transparent ALOP to Argentina in contrast to other Members is, in itself, a basis for finding that the United States has not complied with Article 2.3.

61. There is ample evidence on the record to confirm the United States discrimination against Argentina, both on a substantive basis and in regard to APHIS' regulatory processes. In regard to substantive discrimination, in addition to all the evidence submitted to the OIE which is scientifically valid, there is confirmation in the U.S. risk assessments and rulemakings of the essential similarity between Argentina and Uruguay and between Patagonia and Santa Catarina. In regard to the U.S. regulatory processes, it is indisputable that, countries such as the U.K. and Japan -which have had outbreaks in the same or more recent time frames-, have been given prompt access to the U.S. processes and regained the right to export to the United States, all of which was denied to Argentina.

62. In regard to the sanitary conditions, the situations in Uruguay and the north of Argentina are similar in all relevant ways. In particular, the experts confirmed that Argentina's surveillance program was effective and in full conformity with international standards, that the measures for animal identification and census produced equivalent results and that SENASA has similar or identical capacity to prevent and control FMD outbreaks in Argentina just as the veterinary authorities in Uruguay or Japan do for their own territory. Dr. Batho stated that there were no differences in conditions in northern Argentina and Uruguay and that there was no reason to have different levels of protection. Thus, the experts concluded that the evidence on the record would lead to a conclusion that the conditions in northern Argentina and Uruguay were similar and the protocols applied to beef from Uruguay would also provide for safe trade if applied to beef imported from Argentina.

63. Thus, it is clear that the import ban maintained on Argentine beef is discriminatory when compared to the permission to import beef granted to Uruguay pursuant to the protocols established in 9 C.F.R. §94.22. This is corroborated by the August 2014 risk assessment and proposed rule for beef from Argentina.

64. In regard to Patagonia, the 2005 risk assessment, the findings of which were confirmed by the 2014 risk assessment, illustrate the great similarity between Patagonia and Santa Catarina in most if not all of the criteria used by the United States in 9 C.F.R. §92.2 to grant recognition of FMD-free status. There is also consensus of the experts on this point.

65. In response to the U.S. argument that the Panel should decline to make findings on the Article 2.3 claims because the U.S. has not completed a risk assessment prior to the date of Panel establishment, that argument is unavailing. Argentina's rights cannot be denied because of the failure of the United States to comply with another provision of the SPS Agreement, in this case, the Article 5.1 requirement of a risk assessment.

I. THE U.S. DID NOT TAKE INTO ACCOUNT ARGENTINA'S SPECIAL NEEDS UNDER ARTICLE 10.1

66. Argentina's special needs under Art. 10.1 referred to (1) preferential access to the regulatory process, especially considering that beef was an export of particular interest to Argentina, or (2) in providing sanitary support, *when compared to developed country Members*. On the question of access to the processes, the United States was obligated under Article 10.1 to give Argentina special and differential treatment in this regard. Developing country economies tend to be more dependent on commodities than developed countries and beef is a well-known signature commodity for Argentina. The United States should have provided preferential access to its regulatory processes for Argentina and provided assistance on any and all issues where it claimed a shortfall in capability. There is no evidence on the record that the United States took into consideration Argentina's special needs under Art. 10.1.

[16] U.S. Comments on Experts' Responses at paras. 18-19.

J. THE U.S. MEASURES ARE INCONSISTENT WITH ARTICLES I:1 AND XI:1 OF THE GATT 1994

67. The U.S. measures are not in conformity with numerous provisions of the SPS Agreement, as Argentina has demonstrated. The United States has offered no other reasons why its measures would be consistent with GATT 1994 Articles I:1 or XI:1.

68. In regard to the GATT 1994 claims, the United States appears to have conceded the violation of Article XI:1. The products at issue are commodities, which are by definition, "like" within the meaning of Article I. Further, a comparison of the economic impact portions of the U.S. risk analyses and rulemakings shows quite clearly that the United States considers the imports from Uruguay and Argentina to be like the domestic product and, therefore, like each other. The only United States defense to the GATT 1994 claims is an assertion of the affirmative defense of Article XX(b). However, the United States has not been able to carry its burden to demonstrate that the bans on imports were necessary in light of the less trade restrictive measures that would support safe trade in beef and imports from Patagonia. The United States has also failed to demonstrate that it has satisfied the requirements of the chapeau of Article XX in light of the proposed alternatives.

K. THE U.S. HAS FAILED TO COMPLY WITH ARTICLE 8 AND ANNEX C

69. The U.S response to Argentina's claims of undue delay under Article 8 and Annex C is to repeat its flawed textual interpretation of Annex C as being very narrow in scope. The United States claims that the procedures at 9 C.F.R. §92.2 to determine the sanitary health status of a region are not within the scope of Article 8 and Annex C because they are not enumerated along with "control, inspection and approval procedures." However, Annex C(1) is very clear that the obligation to act without undue delay applies with respect to "*any procedure*" that aims to check and ensure the fulfillment of an SPS measure. The approval procedure under §92.2 is just such a procedure to check and ensure the fulfillment of SPS measures. As the Panel in *US-Poultry* explained, Annex (C)(1) does not specify nor exclude any type of procedure, as long as it is aimed at checking and ensuring the fulfillment of SPS measures. Nor does Article 8 or Annex C(1) distinguish between procedures covering a specific product or multiple products, as the United States erroneously argues.

70. The U.S. interpretation must be rejected because it would lead to absurd results. If the Annex C provisions were to be applied exclusively to specific product requests, as the U.S. argues, then procedures related to the determinations of disease-free status (regionalization) would be neither covered by Article 8 and Annex C nor by any similar provision of the SPS Agreement. This is in conflict with Article 6 and its Guidelines, the latter of which states that "Members should proceed with a recognition process without undue delay."

71. In other words, if an exporting Member's application for FMD-free recognition would fall outside the scope of Annex C, as the U.S. argues, then the exporting Member would have no recourse in the event of undue delays in the processing of those applications. Thus, the United States would effectively control another Member's ability to seek review of the U.S.' actions. This position is simply untenable.

72. With respect to the reason for the delays of several years, affecting both the beef and the Patagonia requests, the U.S.' only response is that such delays are not undue, apparently based on the events of 2001. However, the United States remains silent with respect to APHIS' reasons for inaction during the many years prior to the establishment of the Panel.

V. CONCLUSIONS AND REQUESTS TO THE PANEL

73. Argentina has demonstrated that the U.S. measures are inconsistent with Articles 1.1; 2.2; 2.3; 3.1; 3.3; 5.1; 5.2; 5.4; 5.6; 6.1; 6.2 and 10.1 of the SPS Agreement, as well as with Articles I:1 and XI:1 of the GATT 1994. Argentina respectfully requests that the Panel find the U.S. measures inconsistent with the U.S. obligations under the SPS Agreement and GATT 1994.

ANNEX B-3

FIRST PART OF THE INTEGRATED EXECUTIVE SUMMARY
OF THE ARGUMENTS OF THE UNITED STATES

OPENING STATEMENT

A. KEY FACTS AND CIRCUMSTANCES UNDERLYING THIS DISPUTE

1. FMD is considered widely to be one of the most infectious and economically devastating livestock diseases. Argentina is no stranger to FMD. FMD has been present in Argentina since the 19th century. And Argentina has struggled for decades to control the disease. The United States has not had a single case of FMD for over 80 years. Today, livestock in the United States is not vaccinated against FMD. The record shows that the APHIS review of Argentina's applications is active and, while the pace may not be to Argentina's liking, it is fully justified.

2. There has been no denial of any of Argentina's pending applications. Rather, the regulatory process is moving forward, and the time involved is reasonable in light of unstable FMD conditions in Argentina, the changes in Argentina's applications, and its history with respect to transparency and ability to control FMD.

B. THE CORE LEGAL ISSUE IN THIS DISPUTE RELATES TO THE TIME TAKEN TO CONSIDER ARGENTINA'S APPLICATIONS

3. The core legal issue in this dispute relates to the time taken to consider Argentina's two pending applications. This conclusion is supported by the Argentina's own arguments, by the factual record, and the relationship between the relevant provisions of the SPS Agreement.

4. Although there is no prescribed way for analyzing a number of inter-related SPS provisions, in this instance, the most helpful approach is to start with the language of Article 6. Given that this dispute involves Argentina's pending applications for disease free status, Article 6 is most directly relevant. Articles 6.1 and 6.2 set out the general principles that measures must be adapted to regional conditions, and that Members must recognize the concept of disease-free areas. Article 6.3 sets out the process for making determinations under Article 6.

5. Although Article 6.3 does not say that the evaluation must be completed in any particular time period, the United States does agree with the general proposition – as presented by Argentina – that an importing Member cannot take unlimited time to review an application. The SPS Agreement does contain disciplines on timeliness of decision-making, most notably in Article 5.7 and in Annex C. The United States and Argentina, while agreeing that timeliness is addressed by the SPS Agreement, disagree on which provision applies.

C. U.S. MEASURES ARE JUSTIFIED UNDER ARTICLE 5.7

6. The actions of the United States to verify and to ensure that FMD from Argentina is not introduced and established in the United States are envisioned by Articles 5.2 and 5.3, and are fully justified under Article 5.7 as a provisional measure.

7. The United States, in seeking to make a scientific determination of the present FMD threat from Argentina, is in the process of obtaining and analyzing scientific information related, to factors including: (1) the FMD situation in the country; (2) the capacity of the country's regulatory structure to prevent and control FMD outbreaks; and (3) the reliability of those responsible agencies to implement oversight and reporting obligations, including disclosure.

8. At the time of Argentina's 2002 request, it was clear that: (1) FMD was highly contagious and dangerous; (2) Argentina's systems had recently failed to control FMD on a massive scale; and (3) it was not known whether Argentina had FMD and whether its internal systems could control FMD such that exports to the United States would not pose a threat.

9. The Appellate Body recognized in *Japan – Agricultural Products II* that what is a "reasonable period of time" to review a provisional measure "depends on the specific circumstances of each case." In this case, the Panel should look to what is reasonable given the total circumstances of the record, particularly (1) Argentina's delays in responding to requests by the United States for site visits and answers to questions, (2) Argentina's three relatively recent FMD outbreaks, and (3) the country's history of intentional concealment and delayed reporting of outbreaks. Based on this record, the pace of APHIS review and analysis is reasonable.

D. APHIS' REGULATORY APPROVAL PROCESS IS BASED ON INTERNATIONAL STANDARD AND CONSISTENT WITH ARTICLE 3

10. With regard to Argentina's claim under Article 3.1, Argentina has failed to provide any legal or factual basis. The record shows that APHIS has created and implemented a system to control FMD based on the OIE's framework, consistent with Article 3.1. Argentina has the burden to demonstrate that the APHIS system is inconsistent with Article 3.1, a burden that Argentina has failed to satisfy.

11. The Appellate Body stated that a measure under Article 3.1 may embody some but not necessarily all of the elements of an international standard. Unlike Article 3.2, a measure that is based on an international standard does not need to conform to or embody the standard completely.

12. The record shows that the U.S. system for controlling FMD is built upon the relevant international standard established by the OIE. Three core principles common to both the OIE and the APHIS approach are the following: (1) Unless a country can show it does not have FMD, it is to be treated as an FMD-infected zone; (2) No decision is made about a country's FMD situation until an application is made by a country. In that application, both APHIS and the OIE consider the ability of the country in question to control and eradicate FMD as critical to the determination; and (3) An outbreak can result in the removal of FMD freedom.

13. The United States has acted consistently with Article 3.

E. APHIS ACTIONS WITH RESPECT TO PATAGONIA ARE CONSISTENT WITH ARTICLE 6.1 AND ARTICLE 6.2

14. 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 region from which products originate. 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.

15. APHIS regulations at 9 C.F.R. Section 92.2 direct it to consider applications from foreign countries to determine regions to be free of FMD. Section 92.2 sets forth the factors that it will consider in its determination and for which it requires documentation from the applicant country. These factors closely match those listed in Article 6, including geography, status of the disease in the country, extent of the country's disease control program, and structure and effectiveness of veterinary services. Thus, APHIS's regulations demonstrate that the United States recognizes the concepts of disease-free areas, consistent with Article 6.2.

16. The application process described in Section 92.2 is also consistent with reading Article 6.3 together with Article 6.1 and Article 6.2. As discussed earlier, Article 6.3 requires Members claiming that a region is free of a disease to provide necessary evidence. Section 92.2 is consistent with this understanding.

17. Further evidence that the United States recognizes the concept of disease-free areas is evident in relation to Argentina's applications. On January 23, 2014, APHIS promulgated a regulatory notice advising the public that it has determined that the Patagonia region is free of FMD, consistent with Section 94.1 of APHIS's regulations.

18. The risk analysis addresses the factors that the SPS Agreement asks members to "take into account" under Article 6.1—namely, the level of prevalence of FMD, the control program in Patagonia, and appropriate criteria of guidelines from the OIE. The risk analysis also considers the

factors identified in Article 6.2, such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary controls.

19. For these reasons, the United States has acted consistently with Articles 6.1 and 6.2.

F. ARGENTINA INTRODUCES NO SCIENTIFIC EVIDENCE TO SUPPORT A CLAIM UNDER ARTICLE 5.6

20. With regard to Argentina's claim under Article 5.6, Argentina fails to meet its evidentiary burden or otherwise to explain the basis for its claim. Rather, Argentina's claim is based on hypothetical factual scenario unsupported by the record in this dispute.

21. 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 in the record that establishes that the scientific analysis that applies to Uruguay is applicable to Argentina and that therefore the measure is scientifically appropriate. As the Appellate Body also 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."

G. ARGENTINA CANNOT MEET ITS BURDEN TO SUPPORT A CLAIM UNDER ARTICLE 2.3

22. Because Argentina fails to show how its FMD circumstances and FMD control systems are similar to that of Uruguay, Santa Catarina (Brazil), Japan, and the United Kingdom, Argentina's claim under Article 2.3 too must fail.

23. Just as with Argentina's claim under Article 5.6, Argentina makes broad conclusions about the similarity between it and other countries. But nowhere does Argentina rely on specific evidence that shows that its regulatory infrastructure, disease history, geographical position, and any other host of factors compel the same conclusion as reached by APHIS with respect to those countries. And in none of those countries was there shown to be a systematic failure to disclose FMD and to limit information as to its spread.

FIRST WRITTEN SUBMISSION

24. Argentina's first written submission starts with the assertion that "This is a simple dispute." But after reviewing Argentina's submission, the natural question is whether Argentina's assertion was made with a sense of irony. Argentina presents approximately 40 separate claims. Its submission is well over 160 pages, accompanied by over 90 exhibits. And the dispute addresses issues involving the appropriate reaction to Argentina's failure to control outbreaks of the world's most infectious and economically devastating livestock disease – FMD. One wonders what, exactly, is "simple" in this dispute.

25. The United States believes that an appropriate starting point for evaluating this dispute is to consider issues of time and timeliness. Indeed, such issues underlay the scientific, technical, and legal questions raised by the dispute.

26. First, Argentina does not dispute, and cannot dispute, that at the time the United States revoked Argentina's FMD status in 2001 in response to an Argentine FMD outbreak, the U.S. action was completely justified and fully consistent with U.S. obligations under the WTO Agreement. Indeed, Argentina itself stopped its exporters from shipping affected products. Instead, Argentina's complaint is based on the contention that the United States has not acted promptly enough to review and modify the U.S. 2001 action in light of what Argentina asserts are changed circumstances involving Argentina's FMD status and Argentina's control measures. Thus, the core legal and factual issues in this dispute revolve around the timeliness of a regulatory response to alleged changes in conditions in an exporting country.

27. Second, the United States has not had an FMD outbreak in approximately 80 years. The long-term U.S. success in the prevention of FMD outbreaks is the result of the very types of prudent regulatory action that Argentina now challenges. In contrast, Argentina has had a long history of FMD outbreaks, including three separate FMD outbreaks since 2000. In light of these

radically different experiences in controlling FMD, Argentina has no basis for arguing that U.S. regulators should cut corners and rush to conclusions about Argentina's current FMD status.

28. Third, the record will show that time is of the essence in preventing and controlling FMD outbreaks. As the United States has not had an FMD outbreak in 80 years, U.S. livestock are not vaccinated for FMD. As a result, even a single shipment of an FMD-infected product could cause massive economic damage. In these circumstances, it is not sufficient to learn after the fact that an exporting country has had an FMD outbreak. Rather, a prudent regulator has to consider whether the exporting country has adequate controls in place so as to prevent outbreaks, and – should an outbreak nonetheless occur – to report any outbreak immediately.

29. Fourth, while Argentina argues that its FMD status is radically different than when it had outbreaks in 2000-2002, 2003, or 2006, Argentina presents the U.S. regulatory situation as static. The record shows, however, that Argentina's depiction of the U.S. regulatory process is misleading. In fact, the United States is actively considering Argentina's two outstanding applications for changes to Argentina's FMD status

30. Finally, given that U.S. regulatory procedures are continuing and may be completed in about the same amount of time as involved in the completion of a complex SPS dispute, the question arises as to why Argentina has initiated this dispute at this time. Only Argentina knows the answer to this question. The United States would note, however, the following publicly available information: On May 25, 2012, the EU requested consultations with Argentina regarding Argentina's wide-ranging non-automatic import licensing measures. Within several weeks, Argentina requested consultations with the EU regarding the importation of biodiesel products. On August 21, the United States joined the EU dispute by presenting its own request for consultations addressed to Argentina's non-automatic import licensing measures. Within 9 days, Argentina initiated this dispute by requesting consultations on the U.S. 2001 regulatory action. This sequence of events may shed light on why Argentina has decided to launch a dispute at this time concerning an ongoing regulatory process.

31. At core, Argentina's legal complaints are about the length of time taken by the United States to decide whether or not Argentina has sufficiently established any credibility over its claims to have controlled FMD. The United States believes that this is the question that this Panel should tackle first under Annex C(1) and Article 5.7 of the SPS Agreement.

A. RELEVANT DISCIPLINES AND ORDER OF ANALYSIS

32. The nucleus of Argentina's complaint is this: Argentina applied for import authorization and "no decision on the matter has been made by the United States authorities to date." At base, Argentina's allegations are related to measures that govern the timeliness of the U.S. process for reviewing and amending a measure that Argentina itself recognizes was warranted at the time of adoption. Argentina is arguing that the process provided for receiving and processing applications for import authorization and designations of FMD status was not concluded in a time consistent with obligations under the SPS Agreement.

33. The SPS Agreement has two relevant disciplines on the timeliness of decisionmaking: the Annex C(1)(a) requirement "that procedures are undertaken and completed without undue delay," and the Article 5.7 requirement that "Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the [SPS] measure within a reasonable period of time." Argentina addresses both Annex C(1)(a) and Article 5.7, and these are the provisions that fit Argentina's stated concerns with the U.S. measure. Accordingly, those are the provisions that the Panel should examine to resolve this dispute.

B. ARGENTINA HAS NOT SHOWN THAT THE UNITED STATES BREACHED SPS ARTICLE 8 AND ANNEX C(1) WITH RESPECT TO ARGENTINA'S REQUESTS FOR THE RECOGNITION OF ARGENTINA AND PATAGONIA AS INDEPENDENT FMD-FREE REGIONS

34. Argentina asserts, but does not show, that the type of determination at issue in this dispute falls within the scope of SPS Article 8. Argentina cannot support this assertion. To the contrary, an examination of the text of the SPS Agreement shows that this type of determination – involving disease-free areas of potential exporters –does not fall within the scope of Article 8

35. The approval procedures serve to "check and ensure the fulfillment of SPS measures", and a Member must have reasonable time to complete the procedure. In *EC – Biotech*, the panel acknowledged the importance of the process, and of the fact that "Members applying such procedures must in principle be allowed to take the time that is reasonably needed to determine with adequate confidence whether their relevant SPS requirements are fulfilled, if these requirements are WTO-consistent." As an example, the panel stated that additional information becoming available at a late stage of the approval procedure, which may impact a determination, could justify a delay.

36. Argentina asserts that its application process suffered "undue delay" because the United States has not concluded the evaluation of Argentina's request to be recognized as a region free of FMD. In fact, the record shows that any interruptions in Argentina's application process were due to changing FMD conditions in Argentina, such as additional FMD outbreaks, regulatory changes that altered sanitary boundaries, and time attributable to Argentina's preparation of responses to questions by the United States.

37. Argentina relies on the overall length of time (11 years) that have been involved in the evaluation process But this type of argument – involving a total period of time – represents exactly the wrong type of analysis under Annex C(1)(a). It completely avoids any discussion of the specific facts and circumstances. In short, the total period of time involved in a regulatory process – standing alone – is not determinative of undue delay.

38. The United States would like to highlight in particular Argentina's failure to mention its own impact on the time period involved in the regulatory process. In this regard, the United States recalls the finding in *EC – Biotech* that delays caused by an applicant cannot be legally attributed to a Member. In other words, any interruption caused by the applicant is not the responsibility of the Member, and any consequential delays are justified. During the evaluation process, Argentina has caused numerous delays. Here, the delay between the receipt of application and the submission of additional information is attributable to Argentina. Argentina's initial request lacked adequate information necessary for the United States to perform and complete the evaluation process.

39. Argentina also has failed to demonstrate that the United States acted with "undue delay" in the evaluation of Argentina's application for the recognition of Patagonia as region free of FMD. Argentina has no basis for claiming that the United States has engaged in undue delay.

40. Argentina has failed to demonstrate that legislation, which has expired years ago and was never enacted into law, results in undue delay in the evaluation process. Neither Section 737 of the 2009 Omnibus Appropriations Act nor the Foot and Mouth Disease Prevention Act of 2008 resulted in any delay, and therefore did not cause an undue delay under Annex C (1)(a), first clause, and Article 8.

C. U.S. MEASURES WITH RESPECT TO ARGENTINA ARE JUSTIFIED UNDER ARTICLE 5.7

41. SPS Article 5.7 provides that "[i]n cases where relevant scientific evidence is insufficient," Members may take provisional measures based on "available pertinent information." In those instances, 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."

42. Argentina's complaints concern the alleged failure of the United States to complete a regulatory process based on an application submitted by Argentina for (1) authorization to import fresh, chilled and frozen beef and (2) designation of Patagonia South as an FMD-free region under APHIS regulation. In short, Argentina seeks the completion of the rulemaking phase and issuance of the authorization.

43. In *Japan – Agricultural Products II*, the Appellate Body articulated four prongs to determine whether a measure was properly deemed provisional: (1) the measure was imposed in a situation where relevant scientific information is insufficient to conduct a risk assessment; (2) the measure was adopted on the basis of available pertinent information; (3) the Member imposing the measure seeks additional information necessary for a more objective assessment of risk; and (4) the Member reviews the measure within a reasonable period of time.

44. The application of the APHIS system and the 2001 Regulations were clearly justified when adopted as Argentina implicitly concedes. Subsequent to their adoption, Argentina submitted applications in which it claimed to have regained disease-free status for parts of its territory. While the U.S. review of Argentina's requests for recognition as disease-free is ongoing, the regulations are justified under Article 5.7 and fully conform to the procedural obligations of that article.

45. First, the APHIS system and 2001 Regulations were effective during a period in which Argentina had been experiencing FMD outbreaks for months. Second, the measures were based on available information – the reports and acknowledgment by Argentina of serious FMD outbreaks. Third, upon Argentina's request for re-authorization to import in November 2002, the United States, through the provisions of 9 C.F.R. § 92.2, sought and requested additional information to ascertain the FMD status of Argentina. Fourth, considering the ongoing attempt of the United States to seek information from Argentina, and the latter's response time, the period for review has been reasonable. The United States is committed to completing the review process, of which a necessary step is the site visit which it will conduct in November 2013.

46. Similary, the continuing review of Argentina's request to consider Patagonia South as disease-free also fulfills the Article 5.7 criteria discussed above. First, at the time of Argentina's application to APHIS to consider that the region of Patagonia South as disease-free, the United States had insufficient data to make any judgment on the status of Patagonia South. Until the time of Argentina's application, Patagonia South had been considered to be part of the larger sanitary region of Argentina. In fact, Argentina's application for authorization to import fresh, chilled, and frozen beef was to cover the whole country, including Patagonia South.

47. Second, the U.S. review of Argentina's application is clearly designed to obtain the additional information from Argentina necessary to conclude whether Patagonia South is FMD free and review the 2001 Regulations accordingly within a reasonable period of time.

48. Third, APHIS sought information from Argentina through its review of Argentina's application. It continued to seek information after the draft rule on Patagonia South because of the changing sanitary conditions in Patagonia South and Patagonia North B.

49. Fourth, given the complex procedural process and historical timeline, the period for review has been reasonable. The facts and issues raised claims under Article 8 and Annex C(1) are similar in nature to the ones discussed under Article 5.7. For the same reasons, there is no basis for the panel to find that APHIS violated the "reasonable period of time" standard. The United States is committed to completing the review process, of which a necessary step is the site visit which it conducted in November 2013.

50. For the foregoing reasons, the U.S. measures fulfill the requirements of Article 5.7.

D. U.S. ACTIONS WITH RESPECT TO ARGENTINA'S IMPORTATION OF BEEF ARE CONSISTENT WITH ARTICLES 5.1 AND 5.2 OF THE SPS AGREEMENT

51. The core concern articulated by Argentina is that the United States has not completed its review of Argentina's requests for import authorization due to an alleged change in disease status. That procedural concern is one that may be examined in the light the procedural obligations in SPS Article 5.7. Because it is justified under Article 5.7, the U.S. 2001 Regulations currently under review are consistent with Articles 5.1 and 5.2.

52. Article 5.1 states that "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations." In *Australia – Apples*, the Appellate Body clarified that compliance with Article 5.1 requires an evaluation of whether there is a "rational or objective relationship between the SPS measures and the scientific evidence and between the SPS measures and the risk assessment." The U.S. measures are rationally and objectively connected to both the scientific evidence and the risk assessment.

53. Elaborating upon Article 5.1's assessment of risks, Article 5.2 provides that "Members shall take into account available 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 other treatment."

54. In removing the import authorization, the United States was not permanently prohibiting Argentina from regaining its import authorization. Instead, the removal returned Argentina to the status quo ante that if Argentina sought to export to the United States, it would have to demonstrate that it had reduced the risk of FMD to a level that would not allow the introduction and dissemination of FMD into the United States. This is the very same process – loss of designation followed by reapplication – that the OIE employed.

55. The 2001 Regulations were justified as a response to the massive FMD outbreak from 2000-2002. They continue to be justified by the assessment made at the time as APHIS is in the process of reviewing and evaluating Argentina's application. This current review and evaluation by APHIS is the basis for the position of the United States that claims under Article 5 are more appropriately addressed by Article 5.7

56. As in the case of Argentina's application for authorization to import certain beef products, the application for Patagonia was not a simple situation. There were a number of moving parts in a rather complex FMD sanitary situation. Argentina points out multiple times that South Patagonia had not had an FMD outbreak since 1976 – that fact alone is not dispositive of the inquiry. The fact is that an inquiry into the risks posed by a particular region is one into the sanitary controls and the changes in that landscape.

57. All this points to the fact that APHIS requested permission from Argentina to conduct a site visit to review the system and situation in Argentina in 2012. Argentina did not respond until July 2013, and requested that the site visit occur in November 2013. Argentina insists on pursuing litigation, when the United States is moving forward with its regulatory process.

E. U.S. MEASURES WITH RESPECT TO ARGENTINA'S IMPORTATION OF BEEF ARE CONSISTENT WITH ARTICLE 2.2 OF THE SPS AGREEMENT

58. The United States maintains that its measures are consistent with Article 2.2 because they are consistent with Article 5.7. As set out in Article 2.2, the obligation not to maintain a measure without sufficient scientific evidence expressly sets out an exception: "except as provided for in paragraph 7 of Article 5." Therefore, a measure that is consistent with Article 5.7 will not be inconsistent with Article 2.2.

59. Article 2.2 contains three separate requirements: "(i) the requirement that SPS measures be applied only to the extent necessary to protect human, animal or plant life or health; (ii) the requirement that SPS measures be based on scientific principles; and (iii) the requirement that SPS measures not be maintained without sufficient scientific evidence."

60. Argentina's only argument for satisfying the first requirement of Article 2.2 is this: "The circumstances that motivated the withdrawal of the authorization of imports of fresh beef from Argentina … are outdated by several years." This is mere assertion, without any relevant scientific evidence for support. Argentina states that its last outbreak was in 2006—yet this is not dispositive of the matter. The FMD risk of a country is not only determined by when was its last outbreak, but also by a series of other factors including the quality of the country's internal controls and its credibility in disease surveillance and reporting.

61. The 2001 Regulations and the requirement that Argentina obtain re-authorization for importation has a "rational or objective relationship" to the scientific evidence because all parties, including Argentina, agree with the OIE that FMD is an extremely dangerous, contagious and debilitating animal disease. As the OIE Code itself provides: "Before trade in animals or their products may occur, an importing country must be satisfied that its animal health status will be appropriately protected" Maintaining the 2001 Regulations in the meantime is based on scientific principles related to transmissibility and consequences of the disease.

62. In relation to the adoption of the 2001 regulations and the requirement that Argentina obtain import re-authorization, the record is replete with sufficient scientific evidence to support those measures. After submitting its application for import authorization in late 2002, months after

the devastating outbreaks of 2000-2002, which were exacerbated by cover ups, Argentina had an outbreak in 2003. This was then followed by another outbreak in 2006. It is fully consistent with the scientific record for APHIS to maintain the 2001 Regulation while APHIS conducts a review of Argentina's FMD situation and the credibility of its internal controls.

63. Argentina has provided no scientific evidence to meet its burden of proof. Argentina returns to the point that there were favorable risk assessments in 1997 and 2000 – and obliquely acknowledges the massive outbreaks in 2001 with the nuanced phrase "events in 2001.

64. With respect to Patagonia, not only are the above considerations relevant because Argentina's SENASA exercises regulatory authority over the whole country, but also the record provides an additional basis for support of the U.S. measures.

65. It is well established that "it rests upon the complaining party to establish a prima facie case of inconsistency with a particular provision of the SPS Agreement. Argentina simply has not met its burden.

F. MEASURES TAKEN BY THE UNITED STATES ARE CONSISTENT WITH ARTICLE 5.4

66. Article 5.4 states that a Member "should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects." Argentina simply does not read this text according to its plain meaning. The provision, by its terms, does not impose affirmative obligations on Members.

67. Minimizing negative trade effects in the context of FMD threats means that appropriate regulatory pathways should be in place to ensure that the importation of animals and animal products does not lead to the spread of FMD. The review of Argentina's requests for import reauthorization in relation to the 2001 Regulation is not only consistent with the OIE's own approach, but also consistent with the OIE's own larger strategy to support economic and human development.

G. MEASURES TAKEN BY THE UNITED STATES ARE CONSISTENT WITH ARTICLE 5.6

68. Article 5.6 provides that "when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility."

69. A breach of Article 5.6 can only be found once "there is a measure, other than the contested measure," that satisfies these three conditions: (1) the alternative measure is "reasonably available taking into account technical and economic feasibility"; (2) the alternative measure "achieves the Member's appropriate level of sanitary or phytosanitary protection"; and (3) the alternative measure is "significantly less restrictive to trade than the SPS measure contested."

70. The U.S. review of Argentina's requests to revise the 2001 regulations is a process that is consistent with the international standard for handling trade in animals and animal products that can spread FMD. The OIE Code outlines a number of different approaches for importation of product depending upon a determination of the FMD situation in an applicant country – the point here is that the importing country must ascertain the situation in the applicant country through a systematic review.

71. This systematic review starts with an application by an exporting country that provides information about the status of FMD and the country's internal controls. APHIS reviews this and must also conduct its own independent due diligence in order to ascertain the situation in the exporting country. These decisions are very sensitive, because inaccurate judgments can lead to an epidemic. Argentina's own FMD situation with respect to its border is a cautionary tale about how easily FMD can be spread, and how difficult it is to eradicate.

72. Whether there are appropriate alternative measures for safe importation of beef from Argentina depends on what the factual situation on the ground in Argentina is with respect to not simply its geography and disease status but the credibility of its regulatory and control system.

While the U.S. review of Argentina's requests is ongoing to permit a more objective assessment of risk, maintaining the 2001 regulations is not more trade-restrictive than required to achieve the U.S. appropriate level of protection.

73. Argentina asserts that measures applied to Uruguay's exports to the United States are appropriate and readily available to be applied to Argentina. However, Argentina has not established the premise of the argument—that Uruguay is a proper basis of comparison for Argentina. In fact, Argentina asserts that Uruguay's measures are applicable to it since "the sanitary situations are essentially similar." The above argument applies as well to Santa Catarina and Patagonia. The difference here is the fact that Argentina first applied for recognition of Patagonia South, which had a separate sanitary status from Patagonia North B.

H. MEASURES TAKEN BY THE UNITED STATES ARE NOT INCONSISTENT WITH ARTICLE 2.3 BECAUSE ARGENTINA IS NOT BEING ARBITRARILY OR UNJUSTIFIABLY DISCRIMINATED AGAINST

74. Argentina fails to show that its situation is identical or similar to that of Uruguay, Japan or the United Kingdom, and thus it cannot sustain its challenge under Article 2.3. As the discussion below illustrates, Argentina's record on issues such as geography and history are distinct from those of Uruguay, Japan, or the United Kingdom for purposes of Article 2.3.

75. To find a breach of Article 2.3's provision against arbitrary or unjustifiable discrimination, Argentina must show: (1) "the measure discriminates between the territories of Members other than the Member imposing the measure[;] (2) the discrimination is arbitrary or unjustifiable; and (3) identical or similar conditions prevail in the territory of the Members compared."

76. Argentina's complaint is that it has not completed the APHIS regulatory process in the same time that other countries have completed it. However, in the first instance, the review by of Argentina's requests is not a "sanitary or phytosanitary measure" subject to Article 2.3. An SPS measure (in pertinent part) is "applied" to "protect animal … life or health" and may include "provisions on … methods of risk assessment" (Annex A, para. 1). But Argentina is not challenging a method of risk assessment that discriminates against it, and there is nothing in U.S. law or regulations on risk assessment that discriminates.

77. In substance, Argentina's claim of discrimination based simply on alleged differences in time to review its requests is not a sufficient basis to establish discrimination. A determination of a country's FMD situation is not the same as inspecting automobiles on a factory assembly line. The process for reaching conclusion on an application for FMD status depends upon a variety of factors, not all of which are in the control of the United States.

78. Review of an application is dependent on many factors, and is a particularized review of the animal health status of a country or region with very specific characteristics. Argentina devotes substantial space to describing the conditions under which Uruguay is permitted to import animal products into the United States. It merely asserts, however, that "the physical situation and the institutional structures are similar in Uruguay and Argentina." Argentina's Article 2.3 claim cannot be sustained on the basis of its selective and meager facts.

79. Uruguay and Argentina are not similarly situated in terms of geography and risks of cross-border FMD introduction, populations of livestock susceptible to FMD, and volume of veterinary resources. Another key difference between the two countries is each one's recent FMD history. In fact, difference between the two countries can be encapsulated by the fact that since the 2001 outbreak, there has not been a reported outbreak in Uruguay. On the other hand, Argentina suffered two more outbreaks in the same period after 2000-2001.

80. Argentina's claim with respect to Japan should fail based on its own admission that "[t]he point here is not that the substantive situation of Argentina, on the one hand … and Japan, on the other, are identical." In fact, that is the point: one key prong of the Article 2.3 analysis is "that identical or similar conditions prevail in the territory of the Members compared." A notable difference between Argentina and Japan is the fact that Japan is an island chain comprised of 6,852 islands. Because of its island geography, land crossings of infected FMD animals over a long border (such as that which occurred in Argentina during the decade of the 2000s) is not possible. Japan's situation is so different from Argentina's such that Argentina's claim against the application process must fail.

81. Argentina's claim with respect to the United Kingdom should fail based on its own admission that "[t]he point here is not that the substantive situation of Argentina, on the one hand and the United Kingdom … , on the other, are identical." Similar to Japan, the United Kingdom is an island, and thus land crossings of FMD animals over a long border (such as that which occurred in Argentina) is not possible. The United Kingdom's FMD history includes an outbreak in 2000- 2001, and an outbreak in 2008. While the 2000 outbreak was significant, it differed in a number of respects from the one in Argentina. Other than that, the OIE database records the last outbreak as 1981. The source of the smaller 2008 outbreak was an official laboratory conducting research into the FMD virus. The United Kingdom's situation is so different from Argentina's such that Argentina's claim against the application process must fail.

82. The key differentiation between Santa Catarina's situation and that of Patagonia was the fact that Argentina had introduced new changes to the sanitary boundaries between Patagonia South and Patagonia North B in 2008. This factor added a new confounding element because Argentina's application in 2003 was for the region defined as Patagonia South, which was premised on certain controls with Patagonia North B. Santa Catarina, by contrast, had no sanitary boundary changes during the period of consideration, simplifying the process. It is reasonable, based on these facts, to understand how such changes could result in a difference in review periods and to see why Argentina's claim on this point must fail.

83. Article 2.3 provides that SPS measures not be "applied in a manner which would constitute a disguised restriction on international trade." As this phrase calls upon the chapeau of Article XX of the GATT, it is worth noting that no "single test might uniformly apply in all cases to determine the existence of a 'disguised restriction on international trade.'"

84. A "disguised" restriction on international trade may mean "hidden" or "dissimulated." This is not the case with respect to Argentina's applications. The record is clear as to Argentina's FMD history, the series of outbreaks since 2000, the deliberate cover-up of outbreaks, and shifting sanitary boundaries within the country. The process of reviewing the conditions in Argentina to determine under what terms that country can safely export to the United States must be thorough based on that record. It is a process that the United States undertook in "the principle of good faith" consistent with its SPS obligations.

I. U.S. APPLICATION SYSTEM TO PREVENT FMD IS CONSISTENT WITH ARTICLE 3 OF THE AGREEMENT ON SANITARY AND PHYTOSANITARY MEASURES

85. Argentina identifies the application of 9 C.F.R. § 94.1 and the 2001 Regulations to it as inconsistent with Article 3 because they are allegedly not measures based on international standard. However, 9 C.F.R. § 94.1 (together with 9 C.F.R. § 92.2) represent an approach that is entirely consistent with the OIE. Because the APHIS application system and the OIE approach reflected in the Code and in its internal process are so similar, it is clear that the former is "based on" the latter. Argentina's claim under Article 3.1 must fail.

86. Under the APHIS application system, the same principled framework applies:

87. First, just as in the OIE approach, 9 C.F.R. § 94.1(a) establishes that a country or region is to be considered the equivalent of an "FMD infected zone" unless it has been determined to be free of FMD after an examination of an application provided under 9 C.F.R. § 92.2. This is consistent with the OIE's approach and the underlying science that FMD is a dangerous, highly contagious animal disease.

88. Second, just as in the OIE approach, no decision is made about a country's FMD situation until an application is made by a country. APHIS does not take action in the abstract, in the absence of an application. The process outlined in 9 C.F.R. § 92.2 permits APHIS to authorize the importation of animals and animal products after the submission by an applicant country is received, reviewed, and a conclusion is reached. The topics that APHIS asks applicants to respond to include: Geographic description, disease history, veterinary system, history and situation related to FMD surveillance, prevention, and control measures. The topics requested mirror those asked by the OIE.

89. Third, just as in the OIE approach, an outbreak can result in the removal of authorization under 9 C.F.R. § 94.1(a)(2). A region can be reauthorized by resubmitting its information under 9 C.F.R. § 92.2 or § 92.4 as appropriate. The OIE also has a process for re-application.

90. It may be the case (and, in fact, it may often be the case) that the timeframe upon which OIE makes its designation might not be synchronized with the timeframes of the appropriate regulatory authorities in Member countries. There could be many reasons for this: for example, the OIE generally does not conduct site visits to countries that are applying for an FMD designation. Moreover, some countries might seek OIE designation but not seek particular import authorization from a specific Member state. These are procedural and policy issues that, at least in this context, cannot be swept into the ambit of an Article 3.3 legal analysis.

91. Argentina is a good example of the problem in synchronized designations. Argentina's designation status has fluctuated significantly because of its unstable FMD situation. The OIE suspended Argentina's status once Argentina ceased concealing the 2000-2002 outbreaks and finally notified the OIE. It regained its OIE status in 2003 for only a month before losing it again due to another outbreak. It then regained its OIE status in 2005, but lost it again 2006 due to another outbreak. This OIE status was regained in 2007.

92. Even if this Panel were to find that Article 3.3 applies to the U.S. measures despite the fact that the United States has not rejected the specific OIE designation, Article 3.3 provides that such measures are consistent with Article 3 "if there is a scientific justification." Based on the facts of this dispute, the U.S. measures at issue in fact are fully justified.

J. THE APHIS APPLICATION SYSTEM PERMITS ADAPTATION OF MEASURES TO THE SANITARY OR PHYTOSANITARY CHARACTERISTICS OF AN AREA CONSISTENT WITH ARTICLE 6.1

93. The United States, in adopting the 2001 regulations, ensured that its measures were adapted to the SPS characteristics of Argentina in light of its FMD outbreak. Since Argentina's request to recognize a change in its disease status, particularly for Patagonia, the United States has been undertaking to ascertain, inter alia, the level of prevalence of the disease and Argentina's control procedures in light of the evidence Argentina, as the party seeking to establish that disease status, must present pursuant to Article 6.3.

The United States is currently applying the process laid out in Article 6.1 with respect to Argentina's Patagonia application. Under 9 C.F.R. § 92.2, an applicant country that seeks designation of a region as free of FMD submits documentation to address the following factors: (1) Scope of the evaluation (the region); (2) Veterinary control and oversight; (3) Disease history and vaccination practices; (4) Epidemiological separation from potential sources of infection; (5) Surveillance; (6) Diagnostic laboratory capabilities; and (7) Emergency preparedness and response. These factors track the elements listed in Article 6.1.

94. The APHIS application system takes into account appropriate criteria or guidelines developed by international organizations including the WTO and the OIE. In fact, the APHIS application system tracks closely the SPS Committee's "Guidelines to Further the Practical Implementation of Article 6 of the Agreement on the Application of Sanitary and Phytosanitary Measures".

95. A review of the record clearly demonstrates that the United States is taking into account factors consistent with Article 6 of the SPS Agreement with respect to Argentina's application for Patagonia. The United States is committed to completing the process for Patagonia, consistent with Article 6.1., and requires that Argentina provide the necessary information, including access within Argentina, pursuant to Article 6.3.

K. THE APHIS APPLICATION SYSTEM RECOGNIZES THE CONCEPTS OF PEST- OR DISEASE-FREE AREAS CONSISTENT WITH ARTICLE 6.2

96. It is clear that the United States does recognize the concept of pest- or disease-free areas in 9 C.F.R. § 94.1 and in the definition of "region" in 9 C.F.R. § 92.1. Section 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 Section 92.2." 92.1 defines a region as "[a]ny defined geographic land region identifiable by geological, political, or surveyed boundaries. A region may consist of … [a] national entity[,] [or] [p]art of a national entity … ." The

evaluation referred to in Section 92.2 is based upon an application that considers factors such as "livestock demographics and traceability," "disease history and vaccination practices," "veterinary control and oversight," "epidemiological separation from potential sources of infection," "surveillance," "diagnostic laboratory capabilities," "emergency preparedness and response." These factors cover the factors listed by Article 6, such as "geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls."

L. THE UNITED STATES SUFFICIENTLY ACCOUNTS FOR DEVELOPING COUNTRY INTERESTS UNDER SPS ARTICLE 10.1

97. The United States, to the extent possible, takes into account developing country Members' needs in meeting its SPS obligations. Many countries at or even below Argentina's income level obtain import authorization and have been designated as FMD free. Also, Article 10.1 specifically points out "special needs" to be taken into account, however, nowhere in Argentina's discussion does it assert what "special needs" related to its status it is claiming.

M. THE UNITED STATES' APPLICATION SYSTEM IS CONSISTENT WITH ARTICLE I:1 AND ARTICLE XI :1 OF THE GATT 1994

98. Argentina argues that the United States' Application System violates Article I:1 and Article XI:1 of the GATT 1994 because the system offers other Members advantages that are not accorded immediately and unconditionally to Argentina. The Application System, however, is necessary to protect animal life or health, consistent with the SPS Agreement, and the disciplines of Article XX (b). Pursuant to Article 2.4 of the SPS Agreement, if a measure conforms to the SPS Agreement, then it is presumed to comply with Article XX(b). The Application System does not constitute a means of arbitrary or unjustifiable discrimination, or a disguised restriction on international trade against Argentina. Because the United States has satisfied its obligations under the SPS Agreement and Article XX (b), it has not breached Article I:1.

ANNEX B-4

SECOND PART OF THE INTEGRATED EXECUTIVE SUMMARY
OF THE ARGUMENTS OF THE UNITED STATES

OPENING STATEMENT AT THE SECOND PANEL MEETING

1. The core factual issues involve two regulatory proceedings: one involving Patagonia, one involving Northern Argentina. Argentina's basic complaint is that the failure to complete these processes "is a straightforward restriction on international trade" without scientific justification, and constitutes "arbitrary discrimination" *vis-à-vis* other WTO Members.

2. However, the factual landscape has fundamentally shifted since this dispute was initiated. First, the United States has issued a formal determination that recognizes Patagonia as a region that is FMD free. Second, the United States has issued a proposed rule to allow imports from Northern Argentina, with appropriate control measures that Argentina acknowledges would be acceptable.

3. With respect to the legal framework of Argentina's challenge, the critical issue has been and continues to be this: what obligations apply under the SPS Agreement and how do they operate when an exporting Member claims either that its territory, in whole or in part, is free of disease, or that it is of low disease prevalence in relation to a disease of concern to an importing Member?

4. The SPS Agreement addresses this through Articles 2, 5, and 6. The provisions of these three articles must be read together, in a manner that reflects the drafters' intention of providing a coherent, workable set of obligations governing claims of disease-free or low-disease-prevalence status. Under these provisions, the process starts when the Member making the claim of a certain disease status makes a request to the importing Member. The importing Member then must begin an assessment and seek to obtain necessary information from the exporting Member. At the same time, the exporting Member is obligated to provide the necessary information to validate its claim. Pending the completion of the information collection and review process, the importing Member may maintain provisionally a measure affecting the importation of the product that is based on pertinent available information. During this period, the importing Member collects information necessary for a more objective assessment of the risk and reviews its existing SPS measure accordingly within a reasonable period of time. Once the importing Member has completed its risk assessment, it adopts a measure that is based on the assessment and achieves its ALOP.

5. According to the logic of Argentina's arguments, when an exporting Member claims it is free of disease, the importing Member must either immediately produce an assessment specific to that Member or permit the product to enter. This view is not grounded in the text of the SPS Agreement, does not make sense of the inter-relationship of the relevant provisions, and is not the approach taken by any responsible regulatory authority. As was confirmed during the meeting with the individual experts and the OIE, neither is this view reflected in the practice of other Members nor the procedure and practice of the OIE.

6. The expert consultation process further confirms the need for importing Members to make careful assessments of disease-free or low-disease-prevalence status, and the complexity of this task. For example, the individual experts stated that importing Members conducting an evaluation process must assess the effectiveness of a multitude of complex systems within a country. Further, the OIE itself stated that its country designations do not constitute an import risk assessment. The OIE also confirmed that the paper dossier – that is, the factual submission of the Member seeking an official disease status – is not shared with other OIE Members. The experts also noted that the OIE's designation process does not involve the preparation of a full risk assessment. Dr. Bonbon observed that a risk assessment is a detailed evaluation, and must take account of the particularized situation of <u>both</u> the exporting and importing Members.

7. On January 23, 2014, APHIS published a proposed notice to designate the region of Patagonia as free of FMD. APHIS also published its 87-page risk analysis, based on a careful examination of the scientific evidence related to the disease and region. In the intervening

months, APHIS received, analyzed, and answered comments provided by the public. On August 29, APHIS published its final notice, which determines that Patagonia is a region free of FMD.

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

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

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

10. When an assertion of the disease status of the exporting Member is made, the importing Member is not likely to have all the scientific information needed to review its existing measure and determine whether changes are appropriate, as was the case here. Recognizing this, Article 5.7 obligates the importing Member to "seek to obtain the additional information necessary for a more objective assessment of the risk," and to "review the SPS measures accordingly." In the context of an assessment of a claim of disease-free status, the exporting Member will need to initiate data requests and collect information from the most relevant party – the exporting Member – and use the additional information in reviewing the existing SPS measure. This process is not indefinite; it must be completed within "a reasonable period of time."

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

B. ARTICLE 5.7 APPLIES TO THIS FACTUAL SITUATION

12. Article 2.2 is crucial in understanding Article 5.7, because it is only through Article 2.2 that Article 5.7 is tied to the obligations under the SPS Agreement. Notably, Article 2.2 speaks to the "maintenance" of a measure. A measure must not be "maintained" without sufficient scientific evidence. The application of the "sufficient scientific evidence" language in Article 2.2 is particularly difficult when that evidence changes over time – and this of course is the issue presented in this dispute. The issue is this: when the evidence changes, so that past evidence (in this dispute, a regulatory failure and an ongoing FMD outbreak) may no longer support an SPS control measure, is the importing Member immediately in breach? This is not a tenable reading of the Agreement. And indeed, Article 5.7 provides both an exception, and additional disciplines on the importing Member.

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

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

on the importing Member to seek additional information and to complete its review within a reasonable period of time.

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

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

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

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

D. APHIS'S REGULATORY APPROVAL PROCESS IS BASED ON INTERNATIONAL STANDARDS

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

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

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

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

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

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

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

24. Animals and animal products that are vaccinated pose an FMD threat. The individual experts confirmed that the risk of FMD transmission still exists even with the use of vaccination. Argentina does not and cannot dispute the fact that vaccination poses a risk that, without the use of certain control measures, some Members cannot accept.

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

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

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

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

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

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

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

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

SECOND WRITTEN SUBMISSION

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

32. According to Argentina, when an exporting Member claims it is free of disease, the importing Member must either immediately produce an assessment specific to that Member or permit the product to enter. This view is not grounded in the text of the Agreement and is not reflected in the practice of other Members, which conduct investigations to assess claims made as to disease status before accepting those claims as valid. Nor is Argentina's position consistent with the OIE system. The OIE does not take a Member's claim of disease freedom at face value. A Member seeking OIE recognition must submit scientific information so that a committee within the OIE can evaluate the claim.

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

34. Argentina has asserted that the United States breached Article 5.6 and Article 2.3 because the United States did not apply the measures to Argentina that it extended to Uruguay and Brazil. However, the United States is continuing to review conditions in Argentina, and Argentina has failed to present any scientific evidence that the conditions extended to Uruguay or Brazil to meet the U.S. ALOP would meet the U.S. ALOP when extended to Argentina. With respect to Article 2.3, Argentina similarly fails to provide any evidence that comparisons with Uruguay, Brazil, Japan or the United Kingdom are relevant and appropriate.

35. Argentina provides no argument that should persuade this Panel to reject the reasoning of prior panels and the Appellate Body that Article 5.4 does not impose affirmative obligations, and that Article 10.1 does not prescribe a specific result to be achieved.

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

36. This dispute is about determining the obligations under the SPS Agreement in connection with an exporting Member's assertion that its products should be allowed to enter the territory of an importing Member because the exporting Member's territories are alleged to be disease-free or of low disease prevalence. The proper disposition of this scenario, as envisioned by Articles 5.7 and 6, is that the importing Member collects additional information needed to assess the risks of the imported product and reviews its measure accordingly, making use of the relevant information

provided by the exporting Member. While this process is underway, the importing Member can maintain provisionally its measure affecting importation of the product.

37. The SPS Agreement – through Articles 2.2 and 5.7, as informed by Articles 6 and 6.3 in particular – addresses precisely this situation. Article 2.2 states that Members shall ensure that SPS measures are not maintained without sufficient scientific evidence, except as provided in Article 5.7. Article 5.7 in turn sets out the rules that apply when "scientific evidence is insufficient" to complete an assessment of risks. When an assertion of the disease status of the exporting Member is made, the importing Member is not likely to have all the scientific information it will need to review its existing measure and determine whether changes are appropriate, as was the case here. Notably, the importing Member does not readily have access to the exporting Member's regulatory experts and the wide range of scientific technical information necessary to form a basis for an assessment.

38. Recognizing this, Article 5.7 obligates the importing Member to "seek to obtain the additional information necessary for a more objective assessment of the risk," and to "review the SPS measures accordingly." In the context of an assessment of a claim of disease-free status, the exporting Member will need to initiate data requests and collect information from the most relevant party – the exporting Member, and will use the additional information in reviewing the existing SPS measure. This process is not indefinite, but must be completed within "a reasonable period of time."

39. Article 6 complements and reinforces this understanding of how Article 5.7 applies in these situations. Article 6.1 obligates the importing Member to adapt its measures to the SPS characteristics of the exporting Member, and those characteristics include the "level of prevalence of specific diseases." In particular, when the exporting Member makes the assertion that its territories are free of disease or of low disease prevalence as described above, Article 6.3 obligates it to "provide the necessary evidence."

40. During this process of risk assessment, the importing Member is provisionally permitted to maintain and adopt measures to restrict importation of product from the exporting Member, under Article 5.7. And there is no basis to accept – as Argentina appears to argue – that importing Members must modify their measures immediately upon an exporting Member's assertion that disease freedom or low disease prevalence is sufficient to meet the importing Member's appropriate level of protection. Such an interpretation of the SPS Agreement would be contrary to the core principle of the SPS Agreement, stated in Article 2.1, which is that each Member has "the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health."

B. ARGENTINA'S ARGUMENTS FAIL TO ADDRESS THE KEY LEGAL ISSUES IN THE DISPUTE

41. Article 2.2 states that SPS measures shall not be maintained "without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5." Article 5.7 is a "qualified" right and when its requirements are satisfied, Article 2.2's obligation not to maintain a measure without sufficient scientific evidence is "not applicable to the challenged measure." Article 5.7 applies in cases in which "relevant scientific evidence is insufficient" to conduct a risk assessment, and in these instances, the panel in *EC – Approval and Marketing of Biotech Products* concluded "Article 5.7 permits Members to do, in certain circumstances, what they would not be permitted to do under Article 5.1."

42. If the Panel were to find that Article 5.7 does not apply to this case, the systemic implications for national animal health protection regulatory authorities would be significant. It would mean that any measure validly taken to stop imports because of risks raised by an animal disease could be found inconsistent with the SPS Agreement when the exporting Member merely declares that circumstances have changed.

C. ARGENTINA'S ARTICLE 6 DISTINCTION BETWEEN "COMMODITY" AND "REGIONALIZATION" IS NOT A DISTINCTION RECOGNIZED IN THE SPS AGREEMENT

43. Article 6.1 provides that the importing Member should ensure that measures relating to the import of the product are adapted to the SPS characteristics of the area in question. Article 6.3 directly relates to Article 6.1 because, when a Member seeking to export a product (or commodity)

bases its request on the assertion that its territory is an area of disease freedom or of low disease prevalence, it should provide the necessary evidence to the importing Member. These Articles do not draw any distinction articulated by Argentina between a so-called "regionalization" request and a "commodity" request. Argentina's assertion to the United States, for all intents and purposes, is that it is free of FMD, and accordingly, seeks to export fresh beef from the whole country.

44. Argentina cannot arbitrarily limit the scope of applicability of Article 6. Argentina's position requires it to disregard the relevance of Article 6, and particularly Article 6.3, which directly obligates the exporting Member to provide the necessary evidence before an importing Member makes a decision on the disease status of the exporting Member's territory.

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

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

46. Although much is known about the modes of transmission of FMD, the scientific, technical, and administrative issues involved in a successful control program are quite complex. The record demonstrates the complexity of the issue: even after Argentina claimed to have resolved its 2000-2002 FMD outbreaks, Argentina suffered FMD outbreaks in both 2003 and 2006. At the time that Argentina sought access to the United States market in November 2002, the United States did not have information regarding Argentina's current disease situation and its regulatory system's ability to "handle products that are susceptible to the disease" and its ability to impose "import protocols." That is why the United States undertook a process of obtaining that information through information requests to Argentina.

47. Argentina argues that the United States "adopted" no measures in 2002, and that the "application by Argentina to APHIS was an action by Argentina." If Argentina is arguing that the United States was required under Article 5.7 to issue some sort of legislation or statute in order for the measure to be fall within the scope of Article 5.7, this legal position is untenable from a textual and practical standpoint.

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

49. Furthermore, Argentina's argument – if adopted – would mean that the drafters intended the following unreasonable result: when new information comes to light with respect to an existing measure – whether it be a claim of disease-free status or indeed any scientific information relating to any type of SPS measure – the importing Member would immediately have to remove its existing measure an re-adopt the same measure, labeling it as provisional. Otherwise, the existing measures would be inconsistent with Article 2.2 because it was maintained without sufficient scientific evidence, and Article 5.7 could not apply because – according to Argentina – that article only applies to newly adopted measure.

50. To the extent that Argentina is arguing that some sort of "adoption" must be found to make Article 5.7 applicable, and leaving aside the fact that Argentina's interpretation is plainly untenable in light of the clear text of Article 2.2, the United States did adopt actions in response to Argentina's request. APHIS took action to receive and review the application of Argentina within a reasonable period of time while maintaining provisionally its prohibition on Argentina's beef until APHIS made a decision on that application. In evaluating Argentina's sanitary situation in order to reach "a more objective assessment of risk," the United States has been seeking to obtain additional information necessary, in accord with Article 5.7. It has sought information including that related to veterinary control and oversight, history of the disease in Argentina, surveillance information and others, consistent with 9 C.F.R. Section 92.2 for both Argentina and areas that comprise Patagonia. It sought further information from Argentina on other occasions on topics

such as veterinarian licensing, the functions performed by the National Agrifood Inspection Service of Argentina, and additional detailed information on particular issues related to the FMD outbreaks in 2001 and 2002.

51. Argentina contends that Article 5.7 requires the importing Member "to identify the specific pertinent information it is missing at the time of imposition of the provisional measure" and that the United States did not do so. However, as discussed above, it is clear that the United States was requesting information on the topics named in 9 C.F.R. Section 92.2.

52. Argentina then objects that Article 5.7 "puts the burden on the importing Member to seek such missing information," while the United States "put[s] the burden on the exporting Member to provide information." This is a mischaracterization. Argentina came forth and made a claim of changed circumstances. The United States then requested that Argentina provide information. The text of Article 5.7 obligates the Member taking the provisional measure to "seek to obtain" the additional necessary information, and that is what the United States did upon receiving the claim of changed circumstances—it sought to obtain the information from SENASA, which has jurisdiction in Argentina for animal health issues.

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

53. The United States fully agrees that when a Member provisionally adopts a measure under Article 5.7, it must seek to obtain the necessary information and review the measure within a reasonable period of time.

54. Argentina suggests in its responses to the Panel that a period of less than two years was "beyond what was reasonable" in *Japan – Agricultural Products II*. However, Argentina fails to reference the Appellate Body's guidance that the assessment of what is reasonable must be conducted on a "case-by-case" basis. At issue in *Japan – Agricultural Products II* was whether a testing method used by Japan was appropriate. It appears to have been an experimental science issue, where the data was accessible. That is quite a different set of circumstances from this dispute, in which the data is (1) not in the United States, (2) of substantial scientific scope and breadth including geographical information, internal and cross-border animal movements, quarantine processes, and veterinary infrastructure; and (3) only accessible with the permission of or provided by Argentina's regulatory authority.

55. In this dispute, collecting the necessary additional information is not easy. Exchanges of information between APHIS and SENASA need to be seen in context of the changing situations in Argentina and on Argentina's own shifting requests for import authorization. First, Argentina wanted one review of the country for import authorization for fresh beef. Then it submitted an application for Patagonia South, which initiated a separate, new review process. During this time, there were two outbreaks of FMD in Argentina. Shortly afterwards, Argentina asked that a third area, Patagonia North B be reviewed, and then combined together with Patagonia South.

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

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

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

58. Measures falling within the scope of Article 8 and Annex C do not include the determinations at issue in this dispute. The text of the SPS Agreement does not provide that determinations involving disease-free areas of potential exporters are covered by Article 8. Argentina, however, argues that Article 8 and Annex C(1) have a broad scope of coverage, suggesting that the determinations at issue in this dispute necessarily fall within that scope.

59. Article 8 and Annex C apply specifically to "control, inspection and approval procedures." Article 8 incorporates Annex C; its text must be taken into account when interpreting the scope of measures covered by Annex C. And Article 8 is clear that the types of measures covered in Annex C do not include every type of SPS procedure, but a limited class of procedures: namely, "control, inspection and approval procedures." In addition, the context provided by the substantive obligations contained in Annex C shows that the types of "control, inspection, and approval procedures" covered by Annex C pertain to the administration of such procedures with respect to products (and not with respect to all other SPS matters, such as determinations of disease-free status).

60. The panel in *US – Poultry (China)* stopped short of accepting the view that the provisions of Article 8 and Annex C apply to all types of "control, inspection, and approval procedures," deciding that it was unnecessary to define the whole universe of what falls within its scope. And indeed, the panel did not explain how such an interpretation could fit with the plain meaning of the text.

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

62. Even if the Panel finds that the disease-free status determinations fall within the scope of Article 8 and Annex C, Argentina has failed to show that the United States has engaged in undue delay. The time taken by other Members to perform evaluations of a region's FMD situation and complete its procedure is not of special relevance to and dispositive of the Panel's determination of whether the United States engaged in undue delay in violation of Annex C(1)(a). First, the processing period itself is not indicative of whether a Member acted with undue delay. Second, the assessment of undue delay requires a consideration of the facts of the given dispute, not an abstract analysis. Third, as indicated above, Argentina has merely identified the time periods associated with its applications; Argentina has failed to show that these periods have been unjustified, and, furthermore, that the U.S. review period should have been similar to those taken by Chile and the EU.

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

63. The APHIS application system is clearly based on the OIE Terrestrial Code. Argentina's argument in response is based on the conclusory allegation of "complete disharmony between the U.S. regulatory structure and the OIE." Argentina cannot support this allegation. Argentina continues to conflate Article 3.1' "based on" requirement with the Article 3.2's different "conform to" concept. At most, Argentina points to some minor differences between the APHIS process and the OIE Code, and nothing that comes near to meeting Argentina's burden to show that the APHIS system is not "based on" the OIE Code.

64. The United States notes that Argentina's argument is founded on an erroneous interpretation of what it means to be *based on* the international standards, recommendations and guidelines that is inconsistent with the guidance of the Appellate Body in *EC – Hormones*. The Appellate Body explained that the requirement for a Member to base its SPS measure on international standards does not require it to embody the international standard completely.

65. Further, an SPS measure under Article 3.1 does not benefit from the presumption of consistency with the relevant provisions of the SPS Agreement and the GATT 1994; however, the

complainant still must meet its burden – to show that the measure has not adopted some of the elements of the international standard.

66. As the United States has observed, the relevant international standards, guidelines and recommendations are contained in Chapters 1.6, 2.1 and 8.6 of the OIE Code. The United States has demonstrated that the relevant sections of the APHIS application system are based on the relevant corresponding provisions of the OIE Terrestrial Code. The application process outlined at 9 C.F.R. §92.2(b) incorporates seven of the eight criteria contained in Article 1.6.5 of the OIE Code. The United States system also permits for re-instatement. This procedure is similar to the OIE process for the recovery of FMD-free status in Article 8.6.9 of the OIE Code. Under both APHIS and the OIE systems, a region loses its FMD-free status upon experiencing an FMD outbreak, until its FMD situation is reassessed and its status reinstated.

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

68. Argentina's position on the relevance of the OIE's FMD-free where vaccination is practiced designation is somewhat confusing. On the one hand, Argentina implies that the United States is not "based on" the relevant international standard of the OIE because APHIS regulations do not contain an express designation of FMD-free where vaccination is practiced. On the other hand, Argentina "is not challenging the U.S. standards and regulatory structure as such" or "contesting here as a legal matter the U.S. standard on vaccination." The status of FMD-free where vaccination is practiced is not a legal matter before the Panel. Therefore, the FMD-free where vaccination is practiced designation is neither relevant to nor dispositive of the determination of whether the U.S approach to FMD is "based on" the OIE Code.

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

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

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

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

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

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

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

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

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

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

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

77. Simply because two items are considered "the same" for purposes of one set of criteria does not mean that they are in fact identical, or even close.

78. Argentina further argues that the OIE status "has probative value" and that "Members can and do reasonably rely" on that status. Regardless of the accuracy of these assertions, Argentina's argument does not establish that a particular OIE designation should necessarily be accepted, without any further review, by the United States or any other Member. As noted, given that the OIE designation is not useful in evaluating finer gradations of risk than that entailed by the particular OIE disease status, the OIE designation is not conclusive as to whether a measure that made use of that OIE status would meet the importing Member's appropriate level of protection.

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

80. This argument is additionally unsound because OIE Code Article 8.6.25 does not contain the same conditions under which Uruguay can export product to the United States.

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

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

82. To establish that the United States has acted inconsistent with Article 2.3, Argentina carries the burden of showing that: (1) the measure discriminates between territories of Members other than the Member imposing the measure; (2) the discrimination is arbitrary or unjustifiable; and (3) identical or similar conditions prevail in the territory of Members compared. Argentina has not met its burden of proving these elements.

83. Argentina has maintained that the United States has acted inconsistent with Article 2.3, alleging that the United States has applied its regulations in a contrary manner to Argentina as compared to other Members. However, Argentina has failed to establish that identical or similar conditions prevail. The OIE's FMD status designations reflect that (1) the OIE has accepted documentary evidence of a region's record of regular and prompt animal disease reporting, FMD surveillance and regulatory measures for early detection; (2) there have been no reported FMD outbreaks, evidence of FMDV infections or vaccination against FMD in the preceding 12 month period; and (3) the OIE is comfortable with the detailed description of the region's boundaries and protection zones, if applicable. These factors do not consider additional, important regional dynamics, including whether the region accepts imports from FMD-infected regions and the veterinary services' capacity to detect, prevent and control the spread of FMD.

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ANNEX C

ARGUMENTS OF THIRD PARTIES

Contents		Page
Annex C-1	Integrated executive summary of the arguments of Australia	C-2
Annex C-2	Integrated executive summary of the arguments of Brazil	C-6
Annex C-3	Integrated executive summary of the arguments of China	C-9
Annex C-4	Integrated executive summary of the arguments of the European Union	C-13

ANNEX C-1

INTEGRATED EXECUTIVE SUMMARY OF THE ARGUMENTS OF AUSTRALIA

I. ARTICLE 3 OF THE SPS AGREEMENT – RECOGNITION OF THE RIGHT OF WTO MEMBERS TO DETERMINE THEIR APPROPRIATE LEVEL OF PROTECTION

1. In its first written submission, Argentina argues that application of the "US Measure against Argentine Beef" is inconsistent with Article 3.1 because it is not based on international standards and is not otherwise justified by the SPS agreement.

2. The same argument is made in relation to the United States' 2001 Regulations and also in relation to the prohibitions on imports of animals, meat and other animal products from the Patagonia region.[1]

3. Article 3.1 of the SPS Agreement provides that:

> To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.

4. Australia notes that the wording of Article 3 expressly recognises the right of WTO Members to determine their own appropriate level of protection. Article 3.3 of the SPS Agreement provides that:

> Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.

5. In *US/Canada – Continued Suspension,* the Appellate Body made the following statement about Article 3:

> … one of the primary objectives of the *SPS Agreement* is to "further the use of harmonized sanitary and phytosanitary measures between Members…This objective finds reflection in Article 3 of the *SPS Agreement,* which encourages the harmonization of SPS measures on the basis of international standards, while at the same time recognizing the WTO Members' right to determine their appropriate level of protection.[2]

6. *EC – Hormones* is another case in which the Appellate Body confirmed the individual right of a WTO Member to determine their appropriate level of protection:

> It is clear to us that harmonization of SPS measures of Members on the basis of international standards is projected in the Agreement, as a *goal,* yet to be realized *in the future.* To read Article 3.1 as requiring Members to harmonize their SPS measures *by conforming those measures with international standards,* guidelines and recommendations, *in the here and now,* is, in effect, to vest such international standards, guidelines and recommendations…with *obligatory* force and effect … But, as already noted, the *SPS Agreement* itself sets out no indication of any intent on the part of the Members to do so.[3]

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[1] Argentina's first written submission, paras. 185-206 and 415-428.
[2] Appellate Body Report, *US/Canada – Continued Suspension,* para. 692.
[3] Appellate Body Report, *EC – Hormones,* para. 165.

7. The Appellate Body further stated in *EC – Hormones* that:

> The ultimate goal of the harmonization of SPS measures is to prevent the use of such measures for arbitrary or unjustifiable discrimination between Members or as a disguised restriction on international trade, without preventing Members from adopting or enforcing measures which are both "necessary to protect" human life or health and "based on scientific principles", and without requiring them to change their appropriate level of protection.[4]

8. Australia considers that these findings of the Appellate Body appropriately reflect the object and purpose of Article 3 of the SPS Agreement, particularly with regard to the role to be played by each WTO Member in determining its own appropriate level of protection.

II. ARTICLE 3 OF THE SPS AGREEMENT – THE DISTINCTION BETWEEN "BASED ON" AND "CONFORMING TO" INTERNATIONAL STANDARDS, GUIDELINES OR RECOMMENDATIONS

9. Both parties have commented in their written submissions on the wording used in Article 3.1 of the SPS Agreement, which requires Members to base their SPS measures on "international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement and in particular in paragraph 3".

10. Argentina has argued that the application of the "US Measure against Argentine Beef", the United States' 2001 Regulations and the "US Patagonia measure" are all inconsistent with Article 3.1 because they are not based on international standards and are not otherwise justified by the SPS Agreement.[5]

11. In *EC – Hormones*, the Appellate Body clarified what it means to say that Members shall *base* their measures on international standards, guidelines and recommendations:

> … the ordinary meaning of "based on" is quite different from the plain or natural import of "conform to". A thing is commonly said to be "based on" another thing when the former "stands" or is "founded" or "built" upon or "is supported by" the latter. In contrast, much more is required before one thing may be regarded as "conform[ing] to" another: the former must "comply with", "yield or show compliance" with the latter.[6]

12. Australia is also of the view that there is a distinction between the term "based on" and the term "conform to". In our view, "conform to" imposes a higher standard.

III. WHETHER ARTICLE 5.4 OF THE SPS AGREEMENT IMPOSES AN AFFIRMATIVE OBLIGATION

13. Article 5.4 of the SPS Agreement states:

> Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.

14. In its first written submission, Argentina stated:

> … Argentina respectfully disagrees with any conclusion that Article 5.4 does not impose an affirmative obligation. The drafters of the treaty would not have inserted a paragraph in the middle of Article 5 that had no operative effect.[7]

15. With respect to this issue, Australia disagrees. The panel in *EC – Hormones* stated:

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[4] Appellate Body Report, *EC – Hormones,* para. 177.
[5] Argentina's first written submission, paras. 185-206 and 415-428.
[6] Appellate Body Report, *EC – Hormones,* para. 163.
[7] Argentina's first written submission, para. 293.

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.[8]

16. As such, Australia considers that Article 5.4 does not impose an affirmative obligation.

IV. ARTICLE 5.7 AND THE INSUFFICIENCY OF "RELEVANT SCIENTIFIC EVIDENCE"

17. To be able to adopt or maintain a provisional measure under Article 5.7 of the SPS Agreement, a Member must fulfil the four cumulative criteria set out under that provision. Specifically:

(i) The measure can only be imposed when relevant scientific evidence is insufficient;

(ii) The measure must be adopted based on available pertinent information;

(iii) The measure cannot be maintained unless the Member seeks to obtain the additional information necessary for a more objective assessment of risk; and

(iv) The measure cannot be maintained unless the Member reviews the measure within a reasonable period of time.[9]

18. Existing Panel and Appellate Body reports have focused on the question of "sufficiency" rather than the "relevance" of scientific evidence.

19. The Oxford English Dictionary defines "relevant" as "bearing on, connected with, or pertinent to the matter in hand".[10] Although we are not aware of any WTO Panel or Appellate Body report having considered the meaning of "relevant" in the context of Article 5.7 of the SPS Agreement, reports considering the term in other areas of the WTO Agreement reflect the approach of adopting the ordinary meaning of the word "relevant".[11]

20. We note that Article 5.1 of the SPS Agreement provides that "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health". Similarly, Article 2.2 of the SPS Agreement provides that "Members shall ensure that any sanitary…measure … is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5." Article 5.7 therefore acts as a "qualified exception" to the obligation in Article 2.2 to not maintain SPS measures without scientific evidence.[12]

21. Article 2.2 is closely related to Articles 5.1 and 5.2. The Appellate Body has stated that "Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2".[13] The Appellate Body concluded that a violation of Articles 5.1 and 5.2 is *ipso facto* a violation of Article 2.2[14] and that the Articles should therefore be read together.[15]

22. We therefore consider that there is an important link between Article 2.2, Article 5.1 and the assessment in Article 5.7 of what is sufficient relevant scientific evidence. "Relevant scientific evidence" is information that would contribute to the assessment of risk required by Article 5.1. The question of what evidence is "relevant" to such a risk assessment would need to be answered

[8] Panel Report, *EC-Hormones,* para. 8.169.
[9] Appellate Body Report, *Japan – Agricultural Products II,* para. 89.
[10] *Shorter Oxford English Dictionary,* Oxford University Press (6th ed.), Volume 2 N-Z, 2007, p. 2521.
[11] Appellate Body Report, *European Communities – Trade Descriptions of Sardines,* para. 230; Panel Report, *United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products,* para. 7.700.
[12] Appellate Body Report, *Japan – Agricultural Products II,* para. 80.
[13] Appellate Body Report, *EC – Hormones,* para. 180.
[14] Ibid. "In the event a sanitary measure is not based on a risk assessment as required in Articles 5.1 and 5.2, this measure can be presumed, more generally, not to be based on scientific principles or to be maintained without sufficient scientific evidence. We conclude, therefore, that if we find a violation of the more specific Article 5.1 or 5.2 such finding can be presumed to imply a violation of the more general provisions of Article 2.2".
[15] Ibid.

on a case by case basis. This could depend, for instance, on the type, purpose and subject of the particular SPS measure.

23. Given that Article 5.7 only contemplates reliance on "available pertinent information" where "relevant scientific evidence" is not available, we consider that "available pertinent information" would represent a more limited range of evidence than "relevant scientific evidence". Such "available pertinent information" can include information obtained from relevant information organisations, or from the SPS measures applied by other Members.[16] We also consider that the use of the word "information" rather than the word "evidence" in the phrase "available pertinent information" is intended to suggest a concept less rigorous than that represented by the term "relevant scientific evidence".

24. The requirement for the provisional measure to be based on "available pertinent information" is supplemented by the requirement that the Member seek the "additional information necessary" for a more objective assessment of risk, and the requirement that the SPS measure be reviewed within a reasonable period of time. Based on the ordinary meaning of the text in the context of the provision as a whole, the requirement for a "more objective assessment of risk" once the Member obtains additional information suggests that the "available pertinent information" could permit a less objective assessment. The information that the Member must seek must be "germane" to conducting the objective assessment of risk.[17] Ultimately, the Member must take steps to remedy the insufficiency of the "relevant scientific evidence", in order to come to a conclusion on whether a permanent SPS measure is justified.[18]

25. Paragraph 4 of Annex A of the SPS Agreement sets out a definition of risk assessment, namely, the evaluation of the likelihood of entry, establishment or spread of a pest or disease and the associated potential biological and economic consequences, or the evaluation of the potential for adverse effects from additives, contaminants, toxins or disease-causing organisms in foods. The "relevant scientific evidence" and "available pertinent information" referred to in Article 5.7 would logically be evidence or information that would contribute to such a risk assessment, including evidence or information related to the factors set out in Article 5.2 and 5.3 for consideration in assessment of risks.

26. Article 5.7 is applicable both in situations where the insufficiency of evidence relates to the risk associated with products originating in a specific country or region, as well as in situations where the insufficiency of evidence relates to the science on the risks associated with a particular disease.

27. The Appellate Body in *Japan – Apples* noted that:

> "relevant scientific evidence" will be "insufficient" within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement. Thus, the question is not whether there is sufficient evidence of a general nature or whether there is sufficient evidence related to a specific aspect of a phytosanitary problem, or a specific risk. The question is whether the relevant evidence, be it "general" or "specific", in the Panel's parlance, is sufficient to permit the evaluation of the likelihood of entry, establishment or spread of, in this case, fire blight in Japan.[19]

28. With the Appellate Body's statement in mind, we consider that the "risk assessment" defined in paragraph 4 of Annex A of the SPS Agreement includes an implicit reference to the country or region of origin of the relevant products. Conduct of such a risk assessment may require evidence relating to the possibility that a product from a particular country or region could carry a specific disease. As such, Article 5.7 could apply both where there is insufficient evidence of the risk associated with the origin of the product, and where there is insufficient evidence of the risks associated with a particular disease.

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[16] Article 5.7, *Agreement on the Application of Sanitary and Phytosanitary Measures.* See also Appellate Body Report, *US/Canada – Continued Suspension,* para. 678.

[17] Appellate Body Report, *Japan – Agricultural Products II,* para. 92.

[18] Appellate Body Report, *US/Canada – Continued Suspension,* para. 679.

[19] *Appellate Body Report, Japan – Apples,* para. 179.

ANNEX C-2

INTEGRATED EXECUTIVE SUMMARY OF THE ARGUMENTS OF BRAZIL

I. A RISK ASSESSMENT IS NECESSARY IN SPS MEASURES WHICH RESULT IN A HIGHER LEVEL OF PROTECTION

1. Brazil does not dispute the right of any Member to promote higher levels of sanitary protection than would be achieved by measures based on the relevant international standards. Brazil believes that Article 3.3 of the SPS Agreement establishes a proper balance between the adoption of measures based on international standards and the rights of Members to determine their appropriate level of protection[1] when designing their SPS measures. However, when imposing measures resulting in a higher level of protection than the one established by the international standard, Members shall ensure that they are applied in a manner consistent with the provisions of the SPS Agreement and do not constitute a disguised restriction on international trade or an arbitrary and unjustifiable discrimination between Members where identical or similar conditions prevail.

2. The SPS Agreement establishes that Members should only adopt SPS measures which result in a higher level of protection either (i) if there is a scientific justification or (ii) if they are in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5 of the SPS Agreement. Thus, the right to adopt measures that deviate from international standards is not an "absolute or unqualified right", as stated by the Appellate Body in *EC – Hormones*.[2] The Appellate Body understood that the examination and evaluation of available scientific information referred in this provision would appear "to partake of the nature of the risk assessment required in Article 5.1."[3] Therefore, the risk assessment seems to be a necessary instrument for a Member to fulfill the requirement of providing "scientific justification" for its SPS measures in order to adopt a higher level of protection.

3. Furthermore, the adoption of the appropriate level of protection by the Member in accordance with Article 5 of the SPS Agreement also requires the measure adopted to be based upon a risk assessment,[4] since Article 5.1 establishes that "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment of the risks to human, animal or plant life or health." Therefore, Brazil understands that SPS measures adopted by a Member which result in a higher level of sanitary or phytosanitary protection than the one established by the international standard must, in any case, be based on the relevant risk assessment in order to be considered consistent with the SPS Agreement.

4. Based on Paragraph 4 of Annex A of the SPS Agreement, the risk assessment implies, in general terms, an evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied and also an evaluation of the associated potential biological and economic consequences.

5. For that, according to the panel in *Australia – Salmon,* a three-pronged test should be applicable: (i) identification of the pests or diseases whose entry, establishment or spread a Member wants to prevent, as well as the potential biological and economic consequences associated with the entry, establishment or spread of such pests/diseases; (ii) evaluation of the likelihood of entry, establishment or spread of these pests or diseases and the associated biological and economic consequences; and (iii) evaluation of the likelihood of entry, establishment or spread of these pests or diseases according to the SPS measures that might be applied.[5]

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[1] *US/Canada – Continued Suspension*, Appellate Body Reports, para. 692.
[2] *EC – Hormones*, Appellate Body Report, para. 173.
[3] *EC – Hormones*, Appellate Body Report, para. 175.
[4] As the Appellate Body stated "the distinction made in Article 3.3 between two situations [scientific justification and adoption of the appropriate level of protection in accordance with Article 5] may have very limited effects and may, to that extent, be more apparent than real." *EC-Hormones*, Appellate Body Report, para. 173.
[5] *Australia – Salmon*, Panel Report, para. 8.72.

6. As for the analysis of economic consequences, Brazil highlights that the risk assessment should take into account the elements indicated in Article 5.3 and 5.4 of the SPS Agreement: the potential damage in terms of loss of production or sales; the costs of control or eradication in the territory of the importing Member; the relative cost-effectiveness of alternative approaches to limiting risks; and the objective of minimizing negative trade effects. Brazil is of the view that addressing other types of analysis of economic impact in the risk assessment which are not specifically related to the SPS Agreement would most likely be found inconsistent with this Agreement.

II. THE RISK ASSESSMENT AND ITS RELATIONSHIP WITH THE SPS MEASURE

7. Brazil recalls the interpretation by the Appellate Body in *EC – Biotech*[6] and *EC – Hormones* on the scope of the obligation set forth in Article 5.1 of the SPS Agreement. In the latter, the Appellate Body understood that the expression "based on" – related to the assessment of the risk – should be interpreted to mean that the SPS measure should be "sufficiently warranted by", "reasonably supported by" or "rationally related to"[7] the risk assessment. This means that Members are not supposed to disregard the elements brought by the risk assessment in the designing of the SPS measure.

8. Based on this reasoning, it seems clear that the SPS measure and the risk assessment should be closely connected or, in the words of the Appellate Body, they should be "rationally related". Therefore, in case there is a risk assessment indicating the inexistence of a risk or that the risk is negligible for the importing country, then this element should be taken into account in the formulation and/or application of the relevant SPS measure.

III. THE REGIONALIZATION PRINCIPLE AND THE MAIN OBLIGATIONS ON THE SPS AGREEMENT

9. Brazil contends that Article 6 of the SPS Agreement requires Members to ensure that their SPS measures are adapted to the sanitary and phytosanitary characteristics of the area from which the product originated and to which the product is destined. More importantly, Members shall recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Regionalization is a key concept in the SPS Agreement. It helps SPS measures to be more effective and less trade restrictive. Once a Member has an area of its territory considered a "disease-free area" and has offered satisfactory evidence and given access to the importing Member for inspection and testing, under Article 6.3 of the SPS Agreement, trade restrictions diverging from the regionalization principle could be imposed only as a result of science-based risk assessment.

10. By stating that Members shall ensure that their sanitary and phytosanitary measures are adapted to the characteristics of the area which the product is originated, the SPS Agreement requires that the concepts of pest or disease-free areas and areas of low pest or disease prevalence (the principle of regionalization) be recognized and fully implemented. For this purpose, Members shall take into account, among other factors, the appropriate criteria or guidelines developed by the relevant international organizations, particularly the *Codex Alimentarius Commission* ("Codex"), the World Organization for Animal Health ("OIE"), and the International Plant Protection Convention Secretariat ("IPPC").

11. Here again, a Member is allowed to depart from these criteria and adopt a higher level of protection. However, Articles 3.2 and 3.3, together with Article 5.1 of the SPS Agreement, require that such a higher level of protection in the context of Article 6 should only be adopted based upon a scientific justification or, as already explained, a risk assessment.

12. In Brazil's view, this interpretation would allow the adoption of the appropriate level of protection by each Member, in the case of pest- or disease-free areas, and at the same time it would ensure that no arbitrary, unjustifiable or disguised restrictions on international trade are

[6] According to the panel, "[…] if we were to allow Austria effectively to ignore favourable risk assessments, we would turn these assessments into documents without any substantive importance and the conduct of these assessments into a mere formality. Yet, the requirement in Article 5.1 to 'base' an SPS measure on a risk assessment is plainly a substantive requirement, and not simply a formal requirement to accompany an SPS measure by a risk assessment." (*EC-Biotech*, Panel Report, para. 7.3067).

[7] *EC – Hormones*, Appellate Body Report, para. 193.

created. Moreover, it would reinforce the necessary respect for the principle of regionalization, which is, as already mentioned, a fundamental step toward a freer and fairer world trade, facilitating trade in agricultural products without increasing risk to the importing country.

IV. THE OIE'S ATTRIBUTION OF AN FMD STATUS TO A SPECIFIC COUNTRY IS DONE PERSUANT TO PROCEDURES APPLICABLE TO THE ADOPTION OF STANDARDS AND RECOMMENDATIONS

13. Brazil is of the view all that standards, guidelines and recommendations have equal status under the SPS Agreement. These terms are always described together, including in the definitions of Annex A, but there is no description of what is their meaning, differently from what happens in the TBT Agreement (which defines "standard" in Annex 1). Usually, it is for the respective international organization to define them as it deems appropriate.[8] In the case of the OIE, FMD-free areas are established according to the procedures applicable to the adoption of standards and recommendations ("Procedures used by the OIE to set Standards and Recommendations for international Trade, with a Focus on the Terrestrial and Aquatic Animal Health Codes").[9]

V. UNDUE DELAY

14. The SPS Agreement establishes the requirement that SPS procedures are to be undertaken and completed without undue delay. This obligation, as set out in Article 8 and Annex C(1)(a) of the SPS Agreement, aims to prevent Members from using lengthy and unjustified SPS procedures as a trade barrier to other Members' imports. However, the SPS Agreement does not define specific deadlines for the conclusion of sanitary or phytosanitary procedures undertaken under its auspices.

15. Both the preamble and Article 2.3 of the SPS Agreement, which can be considered context for the interpretation of the rest of the Agreement, indicate that SPS measures should not be applied in a manner which would constitute a disguised restriction on international trade. Thus, allowing Members to have endless periods for any procedure, especially the review of documents and applications related to SPS procedures, could lead to unjustified trade restrictions.

16. Although Brazil does not take a position on whether or not there has been undue delay under the challenged U.S. procedures in the present case, it considers that a proper consideration for a period to the conclusion of these procedures under the SPS Agreement provisions should take into account a "reasonable" timeframe for a country to review the above-mentioned applications. In order to avoid disguised restrictions on international trade, a "reasonable timeframe" should be defined in most cases as strictly as possible, affording consideration to the difficulties a Member may face in a given SPS procedure.

17. Therefore, there should be a case-by-case analysis, taking into account the specific features of the case, in order to define what would be a reasonable time for the conclusion of the procedure. This interpretation would confer the proper balance between the required period for a Member to receive and process the information received and the obligation set by the SPS Agreement to complete the procedures without undue delay.

[8] See for instance the "Clarification of References to Codex Texts" (G/SPS/W/86/Rev.1, 18 March 1998). In October 1997, with a view to seek a definition for these terms, the Secretariat of the *Codex Alimentarius Commission* (CAC) sent a letter to the Chairman of the WTO SPS Committee, requesting a clarification on the scope of these terms. After discussing this issue, the Committee understood that the decision on how to classify them should be "an internal decision of the *Codex Alimentarius Commission* regarding the type and content of the texts it develops to address issues before it."

[9] Available at "http://www.oie.int/doc/ged/D11140.PDF".

ANNEX C-3

INTEGRATED EXECUTIVE SUMMARY OF THE ARGUMENTS OF CHINA

I. Introduction

1. The People's Republic of China intervenes in this case because of its systemic interest in the correct interpretation of the SPS Agreement and the GATT 1994. As a third party, China makes certain observations in its written submission, oral statement and responses to the Panel's questions, which are summarized as follows.

II. Measures at issue

2. In the present dispute, Argentina makes two types of claims with respect to two types of measures. First, Argentina claims that the measures of import ban, adopted and maintained by the U.S. on fresh beef from Argentina and animal products from the Patagonia Region, are inconsistent with various substantive obligations of the U.S. under the SPS Agreement, e.g., Articles 2.2, 2.3, 3.1, 3.3, 5.1, 5.2, 5.6 and 10.1. Second, Argentina claims that the relevant approval procedures of the U.S. violate procedural obligations under Article 8 and Annex C(1). China considers that the Panel should evaluate these two types of claims separately. A finding that the U.S. approval procedures are consistent or inconsistent with Article 8 and Annex C(1) may not prevent the Panel from evaluating separately the claims with respect to the import ban.

III. Articles 3.1 and 3.3 of the SPS Agreement

3. First, China considers that the OIE standard itself does not support a general import ban on animal products, such as the measures applied by the U.S. This is because the OIE standard requires Members to consider the animal health situation in the countries concerned before determining the requirements for trade and one of the important purposes of the OIE standard is to avoid unjustified trade barriers. Even assuming, *arguendo*, that the U.S. measures are based on international standards, these measures are still subject to the disciplines of Articles 2.2, 5.1, 5.6 as well as other relevant provisions of the SPS Agreement, because, as found by the Appellate Body in *EC – Hormones*, measures that are "based on" but do not "conform to" international standards do not benefit from the presumption of consistency under Article 3.2.

4. Second, China notes that the U.S. acknowledges that its appropriate level of protection (ALOP) is higher than the OIE standard. Thus the U.S. measures should be examined under Article 3.3. For a measure to be consistent with Article 3.3, the Member concerned must comply with the requirements under "relevant provisions of [the SPS] Agreement" or "relevant provisions of paragraphs 1 through 8 of Article 5 [of the Agreement]", and the measure "shall not be inconsistent with any other provisions of [the SPS] Agreement". Thus before reaching a conclusion under Article 3.3, the Panel has to examine the U.S. measures under other relevant provisions of the SPS Agreement, and, in particular, Article 5.

IV. Articles 2.2, 5.1, 5.2 and 5.7 of the SPS Agreement

5. Argentina claims the U.S. measures are inconsistent with Articles 2.2, 5.1 and 5.2, and not justified under Article 5.7. The U.S. argues that its measures are justified under Article 5.7 and not inconsistent with Articles 2.2, 5.1 and 5.2.

A. Relationship between Articles 2.2, 5.1, 5.2 and 5.7

6. First, Articles 5.1 and 5.2 are specific application of the basic obligations established under Article 2.2. In the event an SPS measure is not based on a risk assessment as required under Articles 5.1 and 5.2, this measure is neither based on scientific principles nor maintained with sufficient scientific evidence within the meaning of Article 2.2. In other words, a violation of Articles 5.1 and 5.2 would be, by implication, a violation of Article 2.2. When facing simultaneous claims under Articles 2.2, 5.1 and 5.2 in a dispute like the present one, a panel is suggested to begin its analysis with the "more specific" claims under Articles 5.1 and 5.2.

7. Second, Article 2.2 does not apply in cases where an SPS measure is adopted and maintained pursuant to Article 5.7. Neither do Articles 5.1 and 5.2, which are specific application of Article 2.2. Given that the U.S. has invoked Article 5.7 to justify its measures, the Panel is anticipated to first determine whether the U.S. measures, i.e., the import ban, are justified under Article 5.7 or not.

B. Article 5.7

8. Article 5.7 allows a Member to adopt and maintain a provisional SPS measure, provided that four cumulative requirements are met. The provisional measure must be: (1) imposed in cases where "relevant scientific evidence is insufficient" to conduct an appropriate risk assessment, and (2) adopted "on the basis of available pertinent information"; and the Member concerned must: (3) "seek to obtain the additional information necessary for a more objective assessment of risk"; and (4) review the measure within a reasonable period of time.

9. At the outset, the measures permitted under Article 5.7 must be provisional measures. A provisional measure is a measure adopted temporarily before a definitive or final measure is taken. And a definitive measure adopted pursuant to Article 5.1 cannot become a provisional measure within the meaning of Article 5.7 afterwards. This is because whether a measure is provisional should be assessed by reference to the time the measure was adopted, and furthermore, whether the relevant scientific evidence was insufficient must also be assessed by reference to the time the measure was adopted.

10. When evaluating an argument that a measure is justified under Article 5.7, an adjudicator may be confronted with an underlying argument that the measure was based on a risk assessment at the time of imposition. On the one hand, a provisional measure must be based on available pertinent information, which means there must be "some evidentiary basis indicating the possible existence of a risk" and there must be a rational and objective relationship between the risk and the measure. Thus, some kind of assessment of risks is necessary under Article 5.7. On the other hand, a provisional measure is adopted in cases where relevant scientific evidence is insufficient to perform "an adequate assessment of risks as required under Article 5.1". Accordingly, the assessment of risks envisaged under Article 5.7 should be distinguished from the risk assessment under Article 5.1. A Member may not put forward an argument that its measure was based on a risk assessment under Article 5.1 and, at the same time, justified under Article 5.7.

11. During the evaluation under Article 5.7, an adjudicator may also be confronted with a counterargument by the complainant that an international standard or a completed risk assessment exists on the same matter. According to the Appellate Body, existence of an international standard or a completed risk assessment by an international organization or another Member could be offered as evidence to an argument that the relevant scientific evidence is not insufficient within the meaning of Article 5.7, but does not create a legal presumption of sufficiency.

12. As to the burden of proof under Article 5.7, China notes that the Appellate Body has not yet decided this specific issue and the views of WTO panels in this respect are not perfectly consistent with one another. Based on the general principle of allocation of burden of proof established by the Appellate Body, China considers that it is necessary for the Panel to decide whether Article 5.7 has been invoked, in this case, to assert an affirmative claim by Argentina or to assert an affirmative defence by the United States.

13. In the present case, according to its arguments under Articles 5.1 and 5.2, the U.S. seems to argue that it had possessed sufficient scientific evidence and made an appropriate risk assessment before it adopted the import ban. This appears to imply that the import ban was adopted as a definitive measure, instead of a provisional measure adopted in cases where scientific evidence is insufficient. Therefore, the import ban could not be justified under Article 5.7.

C. Articles 2.2, 5.1 and 5.2

14. An inquiry under Article 5.1 is a two-step process: (1) was an appropriate risk assessment conducted? (2) was the SPS measure based on that risk assessment? More relevantly, the

Appellate Body has found that it would be sufficient for a complainant to raise a presumption that no relevant scientific studies or reports exist.

15. In this case, it appears that Argentina does not argue that the import ban was not based on a risk assessment, but argues that these measures are maintained without valid risk assessment *at all*. China thus considers that if the Panel were to find that the presumption of "no relevant scientific studies or reports exist" is established by Argentina, it is for the U.S. to rebut such presumption. Failure of this, Argentina's claims under Articles 5.1 and 5.2 should prevail, and, as a consequence, the claims under Article 2.2 also prevail.

V. Article 5.6 of the SPS Agreement

16. To establish the inconsistency with Article 5.6 of the measures at issue, the complainant is required to identify an alternative SPS measure which: (1) is reasonably available taking into account technical and economic feasibility; (2) achieves the importing Member's ALOP; and (3) is significantly less restrictive to trade than the SPS measure contested.

17. It is also established by the Appellate Body that the role of the Panel in making an assessment under Article 5.6 is different from its role in making an assessment under Article 5.1. Under Article 5.1, a panel's task is to review the risk assessment performed by the importing Member. In contrast, a panel, under Article 5.6, is required to undertake its own analysis on the question of whether the alternative measure would achieve the importing Member' ALOP. In making its own analysis, the panel shall evaluate whether the totality of the evidence identified and/or adduced by the complainant, which should be scientific in nature, is sufficient to establish a presumption that the alternative measure would achieve the ALOP. And this evaluation is a matter of legal characterization and not a scientific assessment of risk that must conform to the first three paragraphs of Article 5.

18. In the present case, since the import ban is most trade restrictive, the U.S. measures currently applying to Uruguay and Santa Catarina of Brazil could be alternative measures which are significantly less restrictive to trade. In addition, since these measures are currently applying to Uruguay and Santa Catarina, it could be reasonably assumed that these measures properly achieve the U.S. ALOP. Thus, the key factual question to be asked by the Panel is whether the sanitary situation of Argentina is comparable to those of Uruguay and Santa Catarina, and whether these measures are reasonably available with respect to Argentinian products taking into account technique and economic feasibility.

VI. Article 2.3 of the SPS Agreement

19. Unlike the U.S., China considers that the import ban is an SPS measure which is subject to the discipline of Article 2.3. To establish the inconsistency of a measure with the first sentence of Article 2.3, three requirements must be met: (1) the measure discriminates between the territories of Members; (2) the discrimination is arbitrary or unjustifiable; and (3) identical or similar conditions prevail in the territory of the Members compared. Based on the interpretation of the Appellate Body on "arbitrary or unjustifiable discrimination" in the chapeau of Article XX of the GATT 1994, the assessment of whether discrimination is "arbitrary or unjustifiable" should be made in light of the objectives of the measure and whether the discrimination bears a rational connection to the stated objective of the measure.

20. In light of the above, it is upon the Panel to determine the factual issues whether identical or similar conditions exist between Argentina and Uruguay, Japan, United Kingdom, and Santa Caratina, whether discrimination exists and whether the discrimination is arbitrary or unjustifiable.

VII. Article 10.1 of the SPS Agreement

21. Although the term "take account of" in Article 10.1, as interpreted by panels in previous cases, does not mean to achieve a specific result, i.e. accord special and differential treatment to developing country Members, Members do have a mandatory obligation to consider the special needs of developing country Members, and such consideration must be reflected in relevant documentation. The burden of proof of developing country Members in this regard should be treated with special care. In particular, where a developed country Member simply ignores its

obligation under Article 10.1, the developing country Members should not be required to prove something that does not exist.

22. As to the question whether the terms "developing countries" in Article 10.1 means all developing countries or individual developing countries, China first recalls that the Appellate Body has found that the phrase "developing countries" in paragraph 2 of the Enabling Clause does not mean "all developing countries", and China considers this interpretation may shed light on the interpretation of the same term in Article 10.1. China also notes that Article 2 of *the Procedure to Enhance Transparency of Special and Differential Treatment in Favour of Developing Country Members* adopted by the SPS Committee appears to imply that Article 10.1 requires members to take account of the special needs of "an" individual developing country.

23. As to the meaning of the "special needs" in Article 10.1, China considers that it includes, *inter alia*, special financial, trade and development needs, according to its context. First, Article 10.3 of the SPS Agreement enables the SPS Committee to give special treatment to developing country Members by taking into account their financial, trade and development needs. Second, as the "equivalent provision" to Article 10.1 of the SPS Agreement, Article 12.3 of the TBT Agreement requires Members to take account of the special development, financial and trade needs of developing country Members. Finally, Article 10.2 also constitutes relevant context for the interpretation of Article 10.1. It requires Members to take account of special trade needs (i.e., to maintain opportunities for exports) of developing country Members by phasing introduction of a new SPS measure.

VIII. Article 8 and Annex C(1) of the SPS Agreement

24. With respect to the U.S. argument that determinations involving disease-free areas fall outside the scope of Article 8 and Annex C of the SPS Agreement, China recalls that the Appellate Body and panels have confirmed that Article 8 and Annex C(1) have a broad coverage. The provisions do not specify or exclude any type of measures from its application, but cover any measure that is aimed at checking and ensuring the fulfilment of SPS measures. In fact, the determination of disease-free areas is one prerequisite step within the relevant U.S. approval procedures and it is thus subject to Article 8 and Annex C(1).

25. According to the interpretation of previous panels, Annex C(1)(a) first clause was essentially a good faith obligation, requiring Members to not only undertake but also complete approval procedures as promptly as possible. The phrase "undue delay" as used in Annex C(1)(a) means "an unjustified loss of time", which is determined not by the length of the delay, but by whether the delay is justified. In the present case, it appears that a decade-long waiting period for the contested approval procedures yet to be completed constitutes a delay. Thus, the focus of the dispute would be whether there is justifiable reason for this delay.

26. As to Section 737 of 2009 Omnibus Appropriations Act, China anticipates that the Panel will be guided by the Panel Report in *US – Poultry (China)*. First, China concurs that Section 737 is an SPS measure which is subject to the disciplines of articles 2, 3, 5, as well as 8 and Annex C(1). Second, Section 737 imposed "undue delays" on the U.S. approval procedures to allow the importation of fresh bovine meat from Argentina and for the recognition of Patagonia Region as FMD-free Zone by precluding the U.S. authority from issuing a risk assessment and from even initiating a rulemaking procedure to allow importation from Argentina.

ANNEX C-4

INTEGRATED EXECUTIVE SUMMARY OF THE ARGUMENTS OF THE EUROPEAN UNION

1. THE MEASURES IN RELATION TO FRESH BEEF

1.1. ARGENTINA'S CLAIMS UNDER ARTICLE 1.1 OF THE SPS AGREEMENT

1. The European Union doubts that Article 1.1 of the SPS Agreement, by itself, may serve as a legal basis for a claim in WTO dispute settlement proceedings. Neither Article 1.1, nor any other paragraph of Article 1 of the SPS Agreement contains any specific obligation for WTO Members, which is independent from the obligations contained in the other provisions of the SPS Agreement. This differentiates Article 1.1 from Article 2.2 of the SPS Agreement, which enumerates a number of clearly defined and specific obligations, which may sometimes be related to the Members' other obligations, but which are independent from them. The consequence is that there can be no legal claim based *solely* on Article 1.1 of the SPS Agreement.

1.2. ARGENTINA'S CLAIMS UNDER ARTICLE 3.1 OF THE SPS AGREEMENT

2. The European Union does not consider that the "standards" relied upon by Argentina are relevant for the analysis of the challenged measure, i.e. Section 94.1(b), because they have different scope and coverage. The "standards" deal with regions and countries that are free of foot-and-mouth disease, while Section 94.1(b) deals with regions and countries that are *not* free of foot-and-mouth disease. In addition, Argentina asserts that it is "internationally recognised as FMD-free with vaccination", or "without vaccination", depending on the region. However, the two Articles of the OIE Terrestrial Code, to which Argentina refers, do not provide any recommendation as to the *conditions* that a country or region should fulfil, in order to fall within one of the relevant categories (e.g., FMD free; FMD free without vaccination; FMD free with vaccination). Argentina does not provide those Articles of the OIE Terrestrial Code which would address the procedures to be followed in relation to imports of meat from areas that are *not* considered to be free of foot-and-mouth disease, which is the situation that Section 94.1(b) is dealing with. Consequently, Argentina has failed to make a *prima facie* case for its claims under Article 3.1 of the SPS Agreement.

1.3. ARGENTINA'S CLAIMS UNDER ARTICLE 3.3 OF THE SPS AGREEMENT

3. Article 3.3 of the SPS Agreement applies only where the challenged measure is not based on the "relevant international standards". This means that, in order to make a *prima facie* case under Article 3.3 of the SPS Agreement, the complaining party should first (a) provide the "relevant international standard"; and (b) show that the challenged measure is not "based on" this international standard. In the present case, Argentina has not provided the "relevant international standard" that should have been the basis of Section 94.1(b). Consequently, Argentina has failed to show *prima facie* that the provisions of Article 3.3 of the SPS Agreement apply to Section 94.1(b).

1.4. ARGENTINA'S CLAIMS UNDER ARTICLE 5 OF THE SPS AGREEMENT

1.4.1. Argentina's claims under Article 5.1 of the SPS Agreement

4. The import ban on animals and meat from areas where foot-and-mouth disease exists would comply with Article 5.1 of the SPS Agreement, if it was supported by a risk assessment that showed (a) that foot-and-mouth disease poses risks to human or animal health or life; and (b) that preventing the introduction of infected animals or fresh meat made of infected animals is a proper response to the risks posed by foot-and-mouth disease. This risk assessment does not need to include an analysis of which specific regions in the world are actually infected with foot-and-mouth disease. Section 94.1(b) provides for a general import ban from *any* region where foot-and-mouth disease exists: it does not include the list of infected regions. The relevant time for the existence of such a risk assessment is the time at which the general import ban of Section 94.1(b) was introduced.

1.4.2. Argentina's claims under Article 5.4 of the SPS Agreement

5. The European Union considers that the Panel's conclusion in *EC – Hormones* is correct, for the reasons discussed in that Panel's Report. Therefore, Argentina's autonomous claims under Article 5.4 of the SPS Agreement should be rejected in their entirety.

1.4.3. Argentina's claims under Article 5.6 of the SPS Agreement

6. Article 8.5.4 of the OIE Terrestrial Code states that "susceptible animals in the FMD free zone should be protected from the rest of the country and from neighbouring countries if they are of a different animal health status by the application of animal health measures that effectively prevent the entry of the virus". It also states that "these measures may include a protection zone". Therefore, the "recommendations" developed by the relevant international organization include import bans. If indeed Section 94.1(b) conforms to such international recommendations, then it should be presumed to be consistent with the SPS Agreement. Argentina does not contest the fact that the territory of the United States is a region that is free of foot-and-mouth disease. Argentina also does not challenge Section 94.1(a), which provides that Argentina is *not* a region that is free of foot-and-mouth disease. Therefore, the import ban imposed by Section 94.1(b) seems to create a "protection zone", such as the one recommended by the OIE Terrestrial Code. The Panel should accept Argentina's claims under Article 5.6 of the SPS Agreement only if the facts of the case establish that a ban on imports from territories where foot-and-mouth disease exists is not an acceptable measure to prevent the introduction of foot-and-mouth disease into the protected territories, taking into consideration the guidance provided by the recommendations of the OIE Terrestrial Code.

1.4.4. Argentina's claims under Article 5.7 of the SPS Agreement

7. The European Union observes that there is a penumbra to the distinction between "definitive" and "provisional" measures. In the "provisional" context of Article 5.7 what weighs particularly heavily in the assessment are the need for urgent action and the objective of avoiding loss to the protected interest. Science and other information, whilst relevant to the extent present, carry less weight, simply because they are less complete. On the other hand, in the "definitive" context the proposition is that sufficient time has elapsed to permit a more considered and ultimately balanced consideration of the issue, based on more complete information: time carries less weight and science more weight. Where the measure is in the nature of an *omission*, a better approach may be to examine whether the available information reasonably supports the position of the complaining Member or the position of the defending Member. The European Union also observes that there are situations in which the science is uncontroversial, but in which an importing Member might receive information about a particular region, or indeed a particular product or establishment, which could justify provisional action under Article 5.7. The European Union also considers that an application in a specific case may remain pending, without a decision, positive or negative, without this necessarily meaning that there is undue delay within the meaning of Article 8 and Annex C. A panel should take into account also Article 5.7 in this analysis.

1.5. ARGENTINA'S CLAIMS UNDER ARTICLE 2.3 OF THE SPS AGREEMENT

8. Argentina's claims under Article 2.3 of the SPS Agreement are based on a comparison of its own status as a foot-and-mouth *not* free region in the US domestic rules, with the status of other countries or regions, which are considered by the US domestic rules as foot-and-mouth free. However, the domestic measures challenged by Argentina do not determine which regions are free, or not-free, of foot-and-mouth disease. They do not seem to involve any different treatment of various regions or countries. Therefore, the European Union does not see how Argentina's claims under Article 2.3 of the SPS Agreement could be successful.

1.6. ARGENTINA'S CLAIMS UNDER ARTICLE 10.1 OF THE SPS AGREEMENT

9. It is not clear whether Article 10.1 of the SPS Agreement can serve as a legal basis for claims in dispute settlement proceedings. It is framed in very general and vague terms which do not clearly spell out any specific obligation for positive action for any WTO Member. The text of Article 10.1 of the SPS Agreement has a certain resemblance with some of the provisions of Part IV of the GATT. Prior to the creation of the WTO, various GATT contracting parties sought to base

claims, or defences, on the provisions of Part IV of the GATT, but none was successful. Likewise, following the creation of the WTO, no Panel has ever entertained a claim under Article 10.1 of the SPS Agreement.

10. Even if Article 10.1 of the SPS Agreement could serve as a legal basis for claims in dispute settlement proceedings, Argentina's assertion that the United States' "preparation and application" of the SPS measure failed to "take account" of the developing countries' "special needs" is contradicted by Argentina's assertion that the United States' "application" of the SPS measure was more favourable to Uruguay and a certain region of Brazil, which are both developing countries. The fact that Argentina acknowledges that the United States' "preparation and application" of its SPS measure is favourable to other developing countries would seem to indicate that the United States does "take account" of the developing countries' "special needs" and, therefore, that there is no breach of whatever obligation is embodied in Article 10.1 of the SPS Agreement.

1.7. THE RELATION BETWEEN ARGENTINA'S CLAIMS UNDER THE SPS AGREEMENT AND ITS CLAIMS UNDER THE GATT

11. The European Union doubts that a finding of inconsistency with any provision of the SPS Agreement automatically means, mechanistically and as a matter of law, that there is no more scope for the application of Article XX(b) of the GATT in relation to claims brought under the GATT. This would imply complete identity of scope between Article XX(b) of the GATT and the SPS Agreement in relation to measures that meet the definition of "SPS measure", as set out in Article 1.1 and Annex A.1 of the SPS Agreement. However, neither the text of the GATT, nor the text of the SPS Agreement expressly provides for such identity of scope. Article 2.4 of the SPS Agreement provides that measures that conform with the provisions of the SPS Agreement shall be *presumed* to be in accordance with the GATT and, in particular, Article XX(b). However, there is no reverse presumption. Neither Article 2.4, nor any other provision of the SPS Agreement, provides that a measure that fails to conform with the SPS Agreement shall be presumed to be inconsistent with Article XX(b). The Appellate Body has implicitly confirmed that Article XX(b) can be used to defend an SPS measure from claims raised under the GATT in its report in *Brazil-Retreaded Tyres*. The Appellate Body did not state that the analysis of Article XX(b) included the measure's consistency with the SPS Agreement. The Appellate Body went on to interpret and apply Article XX(b) of the GATT without any reference to the SPS Agreement. The same conclusion is drawn from the report of the Appellate Body in *EC – Asbestos*.

12. Moreover, if the SPS Agreement is considered to contain an entire and complete set of rules relating to SPS measures, then it should also be accepted that this set of rules would pre-empt the application of all GATT provisions (including Article I and Article XI of the GATT) on SPS measures, and not only the application of Article XX(b). Therefore, one of the following interpretations must be accepted. One, the SPS Agreement constitutes a complete, self-standing elaboration of *all* GATT provisions relating to SPS measures. The logical consequence would be that the complaining party would be precluded from raising any *separate* claims against that measure under the GATT, because the entire set of GATT obligations relating to SPS measures would be "elaborated" and contained in the SPS Agreement. Two, a complaining party may be able to challenge the SPS measures under the GATT, in addition to its challenge under the SPS Agreement. However, the defending party would also have the right to defend its measure against the GATT claims raised by the complaining party, including by relying on Article XX(b) of the GATT, irrespective of whether the measure conforms with the SPS Agreement or not.

2. THE CLAIM OF UNDUE DELAY

13. The European Union considers that Article 8 and Annex C of the SPS Agreement, and specifically the rule against undue delay, apply to control, inspection and approval procedures as regard both products and regions

14. One interesting question is whether or not an importing Member that sets up framework legislation requiring prior authorisation, and that is in receipt of an application that it does not yet find complete or convincing, is necessarily required to adopt a negative decision, or may rather continue to rely on the general and provisional prohibition contained in the framework legislation establishing the requirement of prior authorisation. The European Union considers that there may be no absolute answer to this question in abstract terms. Rather, it is something that may need to be considered on a case-by-case basis. The European Union can envisage some circumstances in

which an application is complete and ripe for what will probably be a more or less final decision. In this kind of situation, once the file is complete, importing Members should issue a negative decision, which exporting Members may then contest in the WTO should they wish to do so. Failure to issue such a negative decision could amount to undue delay.

15. At the same time, the European Union can also envisage some circumstances in which the time-frames involved are such that the framework legislation requiring prior authorisation already more than adequately sketches out the types of considerations indicated in Article 5.7 of the SPS Agreement; in which there is real and genuine controversy over whether an application is complete, in the sense that it has adequately explored and allayed the concerns of the importing Member and its citizens; and in which it is reasonable to rely on the (provisional) prohibition contained in the framework legislation. In these circumstances, the absence of a negative decision would not amount to undue delay. Rather, the question of whether or not there is undue delay will need to be considered on the basis of all the facts.

16. A distinct but related question is burden of proof. There may not be a "record" of an administrative proceeding, and the set of facts and evidence potentially relevant to assessing an SPS dispute may remain open, whether or not the importing Member has acted (by adopting a negative decision, whether final or provisional) or not yet acted. In principle, the complaining Member has the burden of making its case in WTO proceedings, and the defending Member its defence. In this respect, it should be noted that Article 6 of the SPS Agreement requires importing Members to adapt their SPS measures to the region from which a product originates, but, significantly, Article 6.3 provides that exporting Members claiming disease-free status "shall provide the necessary evidence thereof in order to objectively demonstrate" that the relevant region is disease-free.

17. In the absence of a specific negative decision, one might also expect the defending Member to provide an exhaustive and duly evidenced description of any additional material relevant to the question of the passage of time, whether or not supportive of such delay. Only then could a panel make an objective assessment of whether or not the passage of time is justified.

18. To the extent that such information is not part of the record of the proceedings, a panel may need to consider why that is the case; what inferences, if any, it may draw from what it does know; whether or not such inferences might or might not be adverse to the interests of either party; and whether or not such party has had a fair opportunity to adduce the relevant information and to reasonably understand what the consequences of not doing so may be, in accordance with the principle of due process.

3. ORDER OF ANALYSIS

19. It would seem that Argentina complains mainly about the United States' failure to respond in a timely manner to Argentina's "formal request" for a change of status. Therefore, the Panel should first examine Argentina's claims on "undue delay". As a matter of logic, the Panel should first determine whether the United States is under the obligation to adopt a decision accepting, or rejecting, Argentina's "formal request" for a change of status. Logically, the compatibility of the content of such a decision with the covered agreements should be examined only after that content becomes known.

20. Moreover, Argentina does not claim that the United States should change the way it treats countries that are *not* free of foot-and-mouth disease. Argentina simply wants the United States to change the status of Argentina and afford it the treatment it offers to countries that *are* free of foot-and-mouth disease. In these circumstances, the United States' measures relating to products coming from countries that are *not* free of foot-and-mouth disease are outside the Panel's terms of reference. The Panel should avoid making any statements in relation to the compatibility with the covered agreements of the United States' measures relating to countries that are *not* free of foot-and-mouth disease.

4. THE MEASURE IN RELATION TO PATAGONIA AND ARTICLE 6 OF THE SPS AGREEMENT

21. The European Union notes that Article 6.3 of the SPS Agreement imposes a specific obligation on exporting Members wishing to show that certain parts of their territory should not be subject to SPS measures of importing Members. Exporting Members have the burden of providing

to the authorities of the importing Members the "evidence" which is "necessary" "in order to objectively demonstrate" that certain areas are free of the disease "and are likely to remain" free of the disease in the future. The combined reading of all three paragraphs of that Article shows that Article 6 of the SPS Agreement creates a balance of rights and obligations between exporting and importing Members, where the action of each Member is conditioned upon the action of the other Member.

22. This means that an exporting Member bringing a claim based on Article 6.1 or Article 6.2 will likely have to engage with Article 6.3. The three paragraphs of Article 6 constitute a single discipline which may need to be analysed in unison. Moreover, the actions required by the exporting Member under Article 6.3 are a prerequisite for the actions of the importing Member under Articles 6.1 and 6.2. This means that an exporting Member asserting the existence of a particular fact, such as that the evidence it has provided objectively establishes the current and likely future absence of the disease in a particular area, may well have the burden to adduce evidence in support of such assertion.

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