

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

(DS447)

**COMMENTS OF THE UNITED STATES ON THE RESPONSES
OF THE WORLD ANIMAL HEALTH ORGANISATION (OIE)
TO THE PANEL'S QUESTIONS**

July 17, 2014

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Exhibit	Long Citation	Short Citation
162	The Organic Statutes of the Office International Des Epizooties (OIE), Article 8	Article 8 of the Organic Statutes of the OIE
163	Final Report of the 82nd Meeting of the General Assembly of Delegates to the OIE, Paris (May 25 – 30, 2014)	Final Report of the 82nd Meeting of the General Assembly of Delegates to the OIE (May 2014)
164	9 C.F.R. § 94.21 (1998)	9 C.F.R. § 94.21
165	Resolution 19, Final Report of the 77th Meeting of the Genreal Assembly of Delegates to the OIE, Paris (May 24 – 29, 2009)	Resolution 19, Final Report of the 77th Meeting of the Genreal Assembly of Delegates to the OIE (May 2009)
166	Report of the Meeting of the OIE Scientific Commission for Animal Diseases, Paris, (February 10 – 14, 2014)	Report of the Meeting of the OIE Scientific Commission for Animal Diseases (February 2014)

I. INTRODUCTION

1. The United States appreciates the opportunity to comment on the responses to the Panel's questions provided by the staff of the World Animal Health Organization ("OIE").¹ The responses provide the parties and the Panel with the OIE staff's perspective on certain issues raised in this dispute. In particular, the OIE responses explain its procedure for attributing official disease statuses, and confirm that these designations are in fact not standards in the *Terrestrial Code* nor should they be considered such for purposes of the WTO Agreement.

2. The United States notes that the Panel should recognize the scope of the OIE staff's responses and take into consideration certain important factors when evaluating them. First, the question of how OIE documents and activities are relevant to various provisions of the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement") is a legal issue to be decided by the Panel. The staff of the OIE has no special expertise or competency on the interpretation or application of the WTO Agreement. Accordingly, any statement by the OIE staff regarding the proper application of the WTO Agreement can be given no special weight or deference. Second, the OIE staff's responses to questions posed by the Panel are the opinion of OIE staff, and not an expression of the views of the OIE organization, which, when gathered only in Assembly, is "the highest authority of the OIE."² Accordingly, the OIE staff's responses to the Panel's questions are informative, but have a lower authoritative status, than, for example, the *Terrestrial Code* itself.

3. With these considerations in mind, the United States provides its comments below.

II. COMMENTS ON THE OIE STAFF'S RESPONSES

Question 1: Does the OIE have guidelines for the interpretation of its standards and in particular for the *Terrestrial Code's* Chapter 8.5?

4. *Comment on OIE Staff's Response to Question 1:* The United States understands the response provided by the OIE staff to be that the OIE has not produced any guidelines for interpreting Chapter 8.5 of the *Terrestrial Code* specifically (other than the guidance provided within Article 8.5).³ In its answer to this question, the OIE staff identified "sources of general guidance on the interpretation of the OIE standards." These sources consist of a wide swathe of information, some that is the result of World Assembly resolution, and other, less authoritative material produced by the OIE staff. The United States agrees that the information listed in the OIE staff's answer to Question 1 is informative, but not exhaustive.

¹ The United States notes that the responses are a product of the OIE staff of which the Director General is a part. See Article 8 of the Organic Statutes of the OIE (Exhibit USA-162). Work product of the OIE staff is distinguishable from documents generated by other organs of the OIE, including the World Assembly, which is composed of OIE Member Countries.

² Article 1, General Rules of the World Organisation for Animal Health (Exhibit OIE-9).

³ Article 8.5 of the 2012 Edition of the *Terrestrial Code* is now Article 8.6 in the 2013 Edition of the *Terrestrial Code*.

Question 2: With respect to the OIE’s FMD standards:

- a. Are such regularly updated on the basis of recent scientific information and in the light of advances in veterinary science? If so, how is the updating procedure undertaken?**
- b. What is the source of the scientific information used by the OIE in this process?**
- c. What are the opportunities for OIE member governments to review and comment on the scientific information under consideration?**

5. *Comment on OIE Staff’s Response to Question 2(a):* As noted by the OIE staff, the revision of a standard such as Chapter 8.5 of the Terrestrial Code (the “FMD chapter”), would occur only upon adoption during the annual General Session of the World Assembly of the OIE. The revision or updating of such a standard is not a predictable or regular occurrence. It is dependent upon a lengthy process, described by the OIE staff as lasting two years in a “normal cycle.”⁴

6. *Comment on OIE Staff’s Response to Question 2(b):* The OIE staff lists a broad range of potential sources of information. The United States observes that the actual selection and use of any piece of scientific information is a matter decided in practice by the individuals on the commissions and other similar bodies.

7. *Comment on OIE Staff’s Response to Question 2(c):* The OIE staff’s response identifies certain aspects of the process for updating standards that are quite different than the process for designating official FMD disease status for countries.

8. In its response to Question 2(c), the OIE staff explained that during the process of setting new or revising existing standards:

The OIE places the greatest weight on submissions from OIE Members but it also considers proposals and scientific information from other sources, as outlined above, to ensure that the most comprehensive and up-to-date scientific information is taken into consideration.⁵

9. The OIE staff then states that the cycle for adopting new standards and significant revisions is **two years**.⁶ During this process, OIE Members receive any supporting document drafted by an expert at the request of the Director General.⁷ These statements are particularly notable because they highlight differences in the two procedures.

⁴ OIE Staff Responses, at p. 4.

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*, at p. 3.

10. Unlike the process for developing standards in the *Terrestrial Code*, OIE Members do not have an opportunity to make submissions to the OIE with respect to another OIE Member's application for official recognition of disease status. Indeed, OIE Members (other than the one OIE Member whose disease status is under evaluation) are not involved in the process of developing the recommendation of the *ad hoc* Group or the Scientific Commission. First, OIE Members are not informed when an application for designation of an official disease status is submitted to the *ad hoc* Group for review. Second, the dossier submitted to the OIE by the applicant country is not disclosed to the OIE Membership. Third, OIE Members' participation in the process of official disease recognition is considerably limited, as evidenced by their ability to review only the condensed reports of the *ad hoc* Group or Scientific Commission, in lieu of the complete dossiers. Fourth, OIE Members only have sixty days to consider and comment on a Member's request for FMD-free recognition – a fraction of the 2-year period allotted to review and comment on revisions to *Terrestrial Code* standards.

11. With these facts in mind, the United States notes that the OIE staff's characterization of the aforementioned processes as "directly comparable" does not shed any particular light on the matters at issue in the dispute. Rather, an examination of the facts concerning these two processes shows that there are major differences, such as between the opportunities for Members to review and comment on the scientific information under consideration. These differences help support the point that, as the United States has explained, the FMD status designations cannot be considered "standards, guidelines, or recommendations" for the purpose of the SPS Agreement.

Question 3: Kindly clarify the products covered by the *Terrestrial Code*'s recommendations relating to FMD. In particular, please confirm if the following are covered by Chapter 8.5 of the *Terrestrial Code*:

- a. **Ruminants (cattle, buffaloes, sheep, goats, deer, antelopes, camels, llamas and giraffes);**
- b. **These or any other products derived from ruminants, including: (i) fresh (chilled or frozen) meat; (ii) milk; (iii) milk products; and (iv) fresh (chilled or frozen) products other than meat, milk, and milk products.**

12. The United States has no comment at this time on the OIE staff's response to questions 3(a) and (b).

Question 4: If any of the products listed above are not covered by Chapter 8.5 of the *Terrestrial Code*:

- a. **Is there any OIE standard for FMD in relation to that product(s)?**
- b. **If not, is there a reason why there is no OIE standard that covers that product(s) with respect to FMD?**
- c. **Are products not covered by the OIE standard for FMD considered to be safe (i.e., incapable of transmitting FMD and hence subject to unrestricted trade)? If this is not the case, are such products considered to present a risk of transmission of FMD that cannot be mitigated?**

13. The United States has no comment at this time on the OIE staff's response to questions 4(a) and (b).

14. *Comment on OIE Staff's Response to Question 4(c):* The United States understands the OIE staff's response to be that products not covered by the OIE standard for FMD in Chapter 8.5 of the *Terrestrial Code* are not necessarily "incapable of transmitting FMD and hence subject to unrestricted trade." The OIE staff notes that Chapter 8.5 covers "the animal species that are susceptible to FMD and the **most commonly traded products that are derived from them**" (emphasis supplied). Accordingly, it cannot be concluded that because something is not listed in Chapter 8.5 that it is "incapable of transmitting FMD." There may be products that are not "commonly traded" that may be capable of transmitting the disease.

15. This understanding is further confirmed by the OIE staff's statement that, when there is a proposal to trade ruminant products for which there are no recommendations in Chapter 8.5, Member Countries should perform an import risk analysis according to *Terrestrial Code* Chapter 2.1 and the SPS Agreement. The United States recognizes this fact and has performed import risk analyses systematically to evaluate the risk of FMD transmission posed by all products, regardless of whether the products are commonly traded or not. Consequently, it cannot be assumed that products not covered by the OIE standard for FMD are necessarily to be considered incapable of transmitting FMD and hence subject to unrestricted trade.

16. The United States would also observe that the Panel's question assumes that the definition of "safe" is "incapable of transmitting FMD and hence subject to unrestricted trade." The United States, however, understands that there is a difference between "safe" and "incapable of transmitting FMD and hence subject to unrestricted trade."

Question 5: Are FMD status designations embodied in the *Terrestrial Code*? Does the OIE consider its official FMD status designations to constitute standards, guidelines or recommendations?

17. *Comment on OIE Staff's Response to Question 5:* In its response, the OIE staff states that "[t]he procedure for designation of an FMD status is embodied in the *Terrestrial Code*. The official recognition of a country or zone's FMD free status is an affirmation that the country or

zone meets the standards set in the *Terrestrial Code*. In other words, it is an output or result of the standard setting activities of the OIE.”⁸

18. The OIE staff’s answer helps to confirm that the disease status designation itself is **not a standard in the *Terrestrial Code***. As the United States has stated throughout this dispute,⁹ the designation is an **application of the standards** to a specific set of facts as set forth by the applicant country. An application of the standards is not the standard itself. The words chosen by the OIE staff – “an affirmation that”, “an output or result of the standard setting activities” – support the U.S. position.

19. The United States also notes with concern the assertion in the OIE staff’s response that “all resolutions adopted by the World Assembly, including those dealing with the official recognition of disease status” are “standards, guidelines and recommendations” for purposes of the SPS Agreement.¹⁰ As noted in the introduction to this submission, the matter covered in this statement is a WTO legal characterization, involving the application of the SPS Agreement to a particular set of facts, and therefore not within the competence of the OIE staff. The drafters of the OIE’s responses have no role in interpreting or applying the legal provisions of the WTO Agreement, nor do they have any special expertise in this matter.¹¹ The United States further notes that the reasoning of the statement is not persuasive.

20. In particular, the statement is based on the fact that the FMD status designations are approved by the OIE World Assembly. However, that fact alone means very little. The OIE World Assembly adopts a wide range of resolutions at every annual meeting. Recently adopted resolutions from the 2014 World Assembly of the OIE include the following: Approval of the Annual Report of the Director General on the Activities of the OIE (No. 1); Financial Contributions from OIE Members for 2015 (No. 7); Renewal of the appointment of the External Auditor (No. 9); Accession of the Republic of Liberia to the OIE (No. 12).¹² None of these various types of documents and reports are “standards, guidelines and recommendations” under the SPS Agreement.

21. The OIE staff also states that official country disease designations are similar to *Terrestrial Code* standards because “[t]he procedures used by the OIE in the official recognition of FMD status of a country or zone and those used in the development of standards in the *Terrestrial Code* are directly comparable.”¹³ “Directly comparable” does not mean they are the same procedures, and as noted above, this statement is simply a characterization, and not helpful to resolving the issues in dispute. Rather, what is relevant are the facts concerning country

⁸ *Id.*, at p. 7.

⁹ U.S. Answers to Panel Question 17, at para. 59; U.S. Second Written Submission, at para. 88.

¹⁰ OIE Staff Responses, at p. 12.

¹¹ See Agreement Between the World Trade Organization and the Office International Des Epizooties [OIE] (Exhibit OIE-10)

¹² See Final Report of the 82nd Meeting of the General Assembly of Delegates to the OIE. (Exhibit USA-163)

¹³ OIE Staff Responses, at p. 7.

designations, and those facts help to confirm that country designations are not encompassed in the term “standards, guidelines, and recommendations” as contemplated by the SPS Agreement.

22. The OIE staff states that OIE Members are afforded “[a] comment period . . . and the comments of Member Countries are considered by the Commission”¹⁴ in the case of official recognitions and in the *Terrestrial Code* standard-making process. However, in examining the facts, there are significant differences between the two processes in terms of OIE Member involvement.

23. As the OIE staff discussed in its response to Question 2, the *Terrestrial Code* standard-making process is a two-year process in which the proposals for standards, draft text, and relevant meeting reports are sent to all “Member Countries for consideration and comment.” In the *Terrestrial Code* process, draft text can be reviewed by OIE Members several times, and “[t]he reports of [Scientific] Commission meetings contain an explanation of their treatment of Member Countries’ comments.”¹⁵

24. In contrast, in the official recognition process, (1) the underlying documentation (the “dossier”) submitted to the *ad hoc* group of the Scientific Commission by the applicant country seeking recognition is not provided to Member Countries; (2) the written summaries by the *ad hoc* group and the Scientific Commission are brief, and are not comparable to full risk assessments; (3) other written work product, if any, produced in this process by the *ad hoc* group and the Scientific Commission are not available to OIE Member Countries; and (4) Member Countries are typically given no more than 60 days to review recommendations for designation (and there is typically more than one candidate under review).¹⁶

25. This stark difference between the *Terrestrial Code* process and the official recognition process in the information provided and participation in the process by OIE Members is clearest in the case of reinstatement of official recognition. Reinstatement of FMD-free country recognition is a decision made by the Scientific Commission directly and alone, “without further Assembly consultation.”¹⁷

26. The differences in transparency and participation of OIE Members in the *Terrestrial Code* and official recognition processes are significant and militate strongly towards finding that country designations are not “standards, guidelines and recommendations” for purposes of the SPS Agreement.

¹⁴ *Id.*

¹⁵ *Id.*, at p. 4.

¹⁶ See also U.S. Comment on the OIE Staff’s Responses to Question 13.

¹⁷ Resolution No. 25 of the OIE General Session, at Annex 2 to the OIE Staff’s Responses.

Question 6: What is the relevance of Article 1.6.4 of the *Terrestrial Code* in a country’s application for disease status designation?

27. *Comment on OIE Staff’s Response to Question 6:* In its response to Question 6, the OIE staff refers to its previous answer in Question 5, in which it asserted that Article 1.6.4 of the *Terrestrial Code* is a central standard regarding the procedures for official recognition of FMD status.¹⁸ Article 1.6.4 sets out the questions that the OIE asks a Member to answer in connection with that Member’s application for official recognition of FMD status.

28. The United States shares the view set out in the *Terrestrial Code* that documentation of a country’s FMD control system and disease history is an important part in evaluating a country’s animal health status. However, the procedures for eliciting information relevant for official recognition of disease status are not standards in and of themselves. Article 1.6.4 is a series of questionnaires designed to elicit factual answers from an applicant country relevant to a consideration of disease status. The United States similarly requires that each country applying for import authorization to submit an application covering the information contained in 9 C.F.R. §92.2, which addresses topics related to a country’s FMD control system and disease history.

Question 7: The position of the United States is that a country that vaccinates for FMD is not free of the disease.

Question 8: In this context, please answer the following questions:

- a. **What level(s) of health protection do the measures recommended by Chapter 8.5 of the *Terrestrial Code* aim to achieve? In your answer, please explain what the OIE means by "safe international trade in terrestrial animals (mammals, birds, and bees) and their products."¹⁹**
- b. **Does the OIE have a general statement of the level(s) of health protection achieved by the measures recommended by Chapter 8.5?**
- c. **Is this level of health protection the same for the entire Chapter 8.5, or are different product-specific recommendations intended to achieve different levels of protection?**

29. *Comment on OIE Staff’s Responses to Questions 8(a), (b) and (c):* The OIE staff recognizes that “setting the acceptable level of protection (ALOP), as defined in the SPS Agreement, is a decision for each Member Country.”²⁰ Similarly, the *Terrestrial Code* states that it is intended to provide “Member Countries considerable scope in setting import measures so as to achieve consistency with the principles of the SPS Agreement.”²¹ The OIE’s

¹⁸ OIE Staff Responses, at p. 7.

¹⁹ OIE *Terrestrial Animal Health Code*, 2012, foreword.

²⁰ OIE Staff Responses, at p. 9.

²¹ *Id.*

recommendations are meant to assist, not to supplant, the process undertaken by a Member Country in establishing its ALOP, assessing the risk from the exporting country, and adopting appropriate measures.

30. The OIE’s recommendations throughout the *Terrestrial Code*, regardless of disease, are meant to “provide for trade in animals and animal products to take place with an optimal level of animal health security.” Given that OIE Members can establish their own appropriate level of protection, as the OIE recognizes, levels other than the level contemplated by the OIE’s use of the term “optimal,” are acceptable.

31. A fundamental premise of the OIE’s recommended measures for FMD, or any other disease, is that the measures are “[c]orrectly applied.”²² The correct implementation of the recommended measures includes the accurate assessment of the conditions and controls in the exporting country. For example, Article 8.5.22 recommends that the veterinary authority of an FMD-free country provide a certificate attesting to the existence of various conditions and to include that certificate in the shipment. This recommendation should be valid only if the factual premises underlying that certificate are in fact true, and that the veterinary control system is as represented by the regulatory authorities.

Question 9: We note that the Terrestrial Code provides for different animal and product-specific recommendations from FMD-free countries where vaccination is practised and where vaccination is not practised. We understand these to be contained in Articles 8.5.12 to 8.5.33 of the Terrestrial Code.

Question 10: In this context, please answer the following questions:

- a. **What is the OIE's underlying objective for setting animal and product-specific import recommendations and therefore distinguishing between different animals and different animal products? In your answer, please clarify the criteria applied in the process.**
- b. **How are the above-mentioned product-specific recommendations to be implemented?**
- c. **In particular, when an exporting country is FMD-free with vaccination but experiences an outbreak affecting only a specific category of animals and not others, should an importing country interpret and implement the above-mentioned recommendations any differently?**
- d. **Would your answer to 10(c) above be any different if the exporting country was FMD-free without vaccination?**

32. *Comment on OIE Staff's Response to Question 10(a):* The OIE staff’s response emphasizes that its general objective is to “help Member Countries by presenting scientifically

²² *Id.*, at p. 8.

valid risk management options.”²³ The United States recognizes this, and would highlight that the OIE staff answer recognizes that the *Terrestrial Code* does not set out the only valid risk management options for Member Countries.

33. OIE staff state that the OIE’s recognition of the disease status of countries and zones is directly relevant to Article 6 of the SPS Agreement.²⁴ As discussed earlier, the OIE’s recognition of the disease status of a particular country or zone is not a “standard, guideline, or recommendation” for purposes of the SPS Agreement. As a result, it does not have direct legal relevance. Nevertheless, as a factual matter, OIE recognition is something that a WTO Member may take into account in making its Article 6 evaluation of disease free status. APHIS considers the OIE’s recognition as a relevant fact when reviewing applications for import authorization and considerations of disease free areas.

34. *Comment on OIE Staff’s Response to Question 10(b)*: The OIE staff’s response emphasizes the importance of health certificates that “attest[] that the product meets the sanitary requirements of the importing country” as a means for implementing the OIE’s product-specific recommendations. The United States recognizes that certifications can play an important role in a disease-control regime. However, all the facts and circumstances must be examined in ensuring that particular disease-control measures meet a WTO Member’s chosen ALOP.

35. Particularly with respect to FMD, what is critical to the adoption and implementation of appropriate sanitary measures is proper evaluation of the risks and animal health controls in an exporting country. The facts in this dispute bear this out: in the 2000-2001 period, every container of fresh beef that Argentina exported during its FMD outbreak, before it notified and suspended exports, contained a certificate that averred that there were no FMD outbreaks.²⁵ However, that was not true. As a result, those exports posed a risk not only to the United States, but to all of Argentina’s trading partners.

36. The United States would also highlight that the OIE acknowledges in its list of FMD status countries and zones that “Information published by the OIE is derived from declarations made by the official Veterinary Services of Members. **The OIE is not responsible for inaccurate publication of country or zonal disease free status based on inaccurate information, changes in epidemiological status or other significant events that were not promptly reported to the Central Bureau** subsequent to the time of declaration of freedom from FMD.”²⁶

37. *Comment on OIE Staff’s Response to Questions 10(c) and (d)*: The OIE staff states that it immediately suspends the official status of an FMD-free country or zone when an outbreak

²³ *Id.*, at p. 10.

²⁴ The OIE staff also references Article 4 in its response to this question; however, Article 4 is not at issue in this dispute.

²⁵ 9 C.F.R. § 94.21(e) and (j) (1998), (Exhibit USA-164)

²⁶ *See, e.g.* Resolution 15, Final Report of 82nd General Session of the OIE General Assembly (May 2014) at p. 147 (Exhibit USA-165) (emphasis supplied).

occurs, and treats the country or zone as FMD infected “until such a time as the country or zone qualifies for reinstatement of its former FMD free status.”²⁷ The United States takes the same approach in response to an outbreak. In fact, the United States, like the OIE, suspends a country or region’s FMD free status in response to an outbreak. Once a country or region loses its FMD-free status, the United States, like the OIE, treats the country or region as FMD-infected and imposes the corresponding protections until the exporting country demonstrates that its animal health status has changed.

Question 11: With respect to testing, certification and quarantine procedures regarding FMD:

- a. Does the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals set forth any FMD-specific recommendations?**
- b. As part of the process for designating the FMD status of a country or region, does the OIE take into consideration the level of compliance with the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals? If so, what were the conclusions reached with respect to the consideration of Argentina?**

38. The United States has no comment at this time on the OIE staff’s response to Questions 11(a) and (b).

Question 12: We note that official OIE recognition of country- or region-specific disease status is available for FMD.

- a. What is the difference between official OIE recognition and self-declaration of a disease status in terms of the weight to be given to such a declaration or recognition?**
- b. Can a country which complies with the OIE criteria for FMD-freedom, with or without vaccination, be considered FMD-free even if it has not requested and received formal OIE recognition of its status?**

39. *Comment on OIE Staff’s Response to Question 12(a):* In its response, the OIE staff clarifies that a self-declaration of a disease status is one in which OIE Member “may inform the OIE of its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim.” On the other hand, an OIE recognition is not a self-declaration by an OIE Member, but a designation that involves some review by some committees of the OIE. However, there are significant limits to this review, as the United States has described in its comments on Questions 2, 5, and 13. These include limitations such as not consistently making site visits to applicant countries and the inability of OIE Members to access the work papers of

²⁷ OIE Staff Responses, at p.11.

the committee.²⁸ As noted in prior comments, the OIE itself states that: “The OIE is not responsible for inaccurate publication of country or zonal disease free status based on inaccurate information, changes in epidemiological status or other significant events that were not promptly reported to the Central Bureau subsequent to the time of declaration of freedom from FMD.”²⁹

40. *Comment on OIE Staff’s Response to Question 12(b):* The OIE staff confirms that a country (or, presumably, a zone) that the OIE has not evaluated or received recognition as FMD-free “is not considered by the OIE as an FMD free country.”³⁰ That is, a country or zone not considered to be FMD free is to be treated as FMD affected. It is the responsibility of an applicant country, which possesses critical information as to disease status, control measures, surveillance, and other issues, to initiate the process for OIE evaluation.

41. The APHIS structure and approach for the evaluation of the FMD status of countries and zones is consistent with the structure and approach of the OIE process. The United States refers to the table it submitted in its first written submission at paragraph 335, which illustrates this.

Question 13: Please describe the procedure of initial designation and annual renewal that a member must undertake in order to have its FMD status (country or area) officially recognized by the OIE. In particular, please address the following questions:

- a. **When processing a request for official FMD status recognition, does the OIE’s *ad hoc* group prepare any written materials or documents to support its analysis? Are those documents shared with the OIE Members, either automatically or upon request?**
- b. **When reviewing the *ad hoc* group’s recommendations regarding a request for official FMD status recognition, does the OIE’s Scientific Commission prepare any written materials or documents responding to the analysis? Are those documents shared with the OIE Members, either automatically or upon request?**
- c. **Has there ever been a situation where the OIE’s World Assembly of Delegates rejected or delayed the recommendation of the Scientific Commission for Animal Diseases to recognize the sanitary status of a country or region for FMD purposes? If so, has Argentina’s FMD free status**

²⁸ In this OIE staff response, the OIE staff also presents the legal conclusion that “all resolutions adopted by the World Assembly” of the OIE are “standards, guidelines and recommendations” for purposes of the SPS Agreement. The United States has expressed its disagreement with this claim in its prior comment to Question 5.

²⁹ See, e.g. Resolution 19, Final Report of the 77th Meeting of the Genreal Assembly of Delegates to the OIE (May 2009) at p. 154.

³⁰ OIE Staff Responses, at p. 13.

designation been delayed and what was the OIE course of action subsequently?

- d. At the 75th General Session Argentina's application reinstatement of their disease free status with vaccination and the enlargement of the disease free area without vaccination, were reserved pending the response of the Member Country to proposals by the Scientific Commission on the control of the disease in the frontier areas of the country.³¹ What were the proposals by the Scientific Commission and what was Argentina's response? Did SENASA adopt the Scientific Commission's proposals?**
- e. Please describe the process by which an OIE Member regains its FMD-free status, including whether the process is self-initiated by the OIE or initiated at the request of an OIE Member.**
- f. What is the OIE policy regarding site visits? Is this approach different following an outbreak? Did the OIE conduct site visits to Argentina concerning FMD? If so, when? Were these visits in the context of the official status designation?**
- g. Does the OIE have guidelines regarding the timeframe required for reviewing the FMD status of a country, either for OIE internal use or for member countries to follow? If so, please specify their content.**
- h. Does the fact that Argentina's National Veterinary Authority's (SENASA) Animal Laboratory is an OIE Reference Laboratory for FMD³² have any bearing on the review of Argentina's FMD status?**

42. *Comment on OIE Staff's Response to Question 13(a):* The OIE staff's response confirms that OIE Members have no access to written materials or documents prepared by the OIE *ad hoc* Group in its evaluation of an application for FMD status, except for a short "written report of the assessments carried out at each meeting." These written reports are abbreviated and summarized, and do not provide the detail that would be required for a veterinary authority to understand the basis of the conclusion and the facts upon which the conclusion was made. The most recent set of written reports of the OIE status designations brought before the *ad hoc* Group are attached to this submission. They are brief: Paraguay (1 ¼ pages);³³ South Africa (less than

³¹ Report of the Meeting of the OIE Scientific Commission for Animal Diseases, Paris, 26-28 February 2007.

³² Argentina's Second Written Submission, at para. 45.

³³ Report of the Meeting of the OIE Scientific Commission for Animal Diseases (February 2014), at p. 50 (Exhibit USA-166).

1 page);³⁴ Botswana (3 paragraphs);³⁵ Brazil (1 ¼ pages);³⁶ Bolivia (1 ½ pages);³⁷ Argentina (2 pages).³⁸ It is not clear whether the *ad hoc* Group has any other set of working papers or analyses that underlie the brief “written reports” referenced by the OIE staff in its answer to this question. If there are, they are not provided to any Members of the OIE.

43. By way of contrast, the risk analysis produced by APHIS in its evaluation of the Patagonia region is publicly available and is substantial. At 88 pages, the risk analysis comprehensively describes and evaluates the Patagonia region’s animal health status and regulatory control system. It refers to is based on substantial material gathered by APHIS.³⁹

44. The OIE staff also confirms that the dossier – the set of material provided by the applicant country to the OIE for purposes of review – is not available to OIE Members.⁴⁰ The OIE states that an OIE Member can request information directly from the OIE Member applying for status designation. However, the applicant OIE Member is not obligated to provide the material, nor is the OIE able to compel the applicant OIE Member to supply the information, nor is there any timeframe within which the applicant OIE Member is even required to provide a reply to any request.

45. *Comment on OIE Staff’s Response to Question 13(b):* Written records of the basis for Scientific Commission decisions on status designations are even sparser than those provided by the *ad hoc* Group. For example, the most recent set of countries seeking status designation, no comment by the Scientific Commission exceeds several paragraphs. For the countries listed in the U.S. comment on the OIE staff’s answer to Question 13(a), the Scientific Commission’s decision is reduced to 3 pages total.⁴¹ From the OIE staff’s response to this question, it appears that there are no other records that provide the basis for the Scientific Commission’s recommendation. If there are other records, no OIE Members are permitted access to them.

46. *Comment on OIE Staff’s Response to Question 13(c):* The view of the United States is that FMD status designations by the OIE do not prevent an OIE Member from conducting its own review and evaluation in connection with a request for import authorization. This view has

³⁴ *Id.*, at p. 51 (Exhibit USA-166).

³⁵ *Id.*, at p. 52 (Exhibit USA-166).

³⁶ *Id.*, at pp. 57 - 58 (Exhibit USA-166).

³⁷ *Id.*, at pp. 58 - 60 (Exhibit USA-166).

³⁸ *Id.*, at pp. 60 – 62 (Exhibit USA-166).

³⁹ Exhibit USA-133.

⁴⁰ OIE Staff Responses, at p. 15.

⁴¹ Report of the Meeting of the OIE Scientific Commission for Animal Diseases (February 2014), at pp. 5-7 (Exhibit USA-166).

been previously understood by OIE Members, and was most recently reiterated by the United States at the OIE World Assembly in May 2014.⁴²

47. The OIE staff’s observation that the World Assembly has “never rejected or delayed a final resolution . . . with regard to the official status of a Member Country or zone”⁴³ is consistent with the understanding of the United States and other OIE members that importing OIE Members may choose to conduct their own examinations of claims of disease-free status. As the OIE staff itself notes, Member states are given no more than 60 days to lodge any objections or raise any questions with respect to candidates for designation before the candidates are considered by the World Assembly. Given the sparse record for most designation candidates and the fact that OIE Members typically do not have access to the dossier, OIE Members may not be in a position to review and provide an informed position regarding any particular country designation.

48. *Comment on OIE Staff’s Response to Question 13(d):* The United States does not have any comment at this time on the OIE staff’s response to this question.

49. *Comment on OIE Staff’s Response to Question 13(e):* The OIE staff confirms that reinstatement of FMD-status is only made upon application by the OIE Member seeking reinstatement. As stated in the U.S. comment to Question 16(c), reinstatement upon evaluation of an application is precisely the process that APHIS follows.

50. The United States also notes that the OIE’s process for reinstatement of status substantially differs from the one that the OIE employs when reviewing an application for OIE status in the first instance. In the latter, the OIE relies upon some sort of review by the *ad hoc* Group, the Scientific Commission, and ultimately, consideration before the World Assembly. In contrast, the Scientific Commission itself is directly authorized to reinstate an OIE Member’s status without seeking review by the *ad hoc* Group and without needing approval by the World Assembly.

51. Moreover, none of the documents reviewed by the Scientific Commission, nor any working papers underlying the Scientific Commission’s decision, are made available to the general membership of the OIE. In fact, even the letter “explaining the reasons” for a denial of reinstatement by the Scientific Commission is “not in the public domain”⁴⁴ and not shared with the membership of the OIE.

52. *Comment on OIE Staff’s Response to Question 13(f):* The OIE staff’s response to this question demonstrates that there is no clear criteria for when a site visit is necessary as part of the OIE’s review process. In contrast, the U.S. process is more rigorous in that APHIS always conducts site visits in connection with an application for import authorization.

⁴² Final Report of the 82nd Meeting of the General Assembly of Delegates to the OIE (May 2014), at p. 54 (Exhibit USA – 163).

⁴³ OIE Staff Responses, at p. 15.

⁴⁴ OIE Staff Responses, at p. 16.

53. *Comment on OIE Staff's Response to Question 13(g):* The OIE staff did not answer the Panel's question with respect to the timeframe required for it to review the FMD status of a country.

54. *Comment on OIE Staff's Response to Question 13(h):* The United States takes note of the OIE's statement that the fact that an OIE reference laboratory is located in Argentina "has no bearing on the review"⁴⁵ of whether Argentina complies with the *Terrestrial Code*. This statement supports that the Panel should not give any particular weight to this fact in Argentina's submissions.⁴⁶

Question 14: Please describe the process of suspending or removing an OIE Member/region from the lists of countries recognized by the OIE as FMD-free (with or without vaccination). Also, please describe any changes that have occurred in this process since 2002.

55. *Comment on OIE Staff's Response to Question 14(a):* The OIE staff confirmed that an official "FMD free" status of a country is "suspended immediately" after the OIE "has become aware of an FMD outbreak" in the affected country or zone.⁴⁷ As OIE staff states in its response to Question 16(c), "there is no need for a scientific evaluation because the first requirement to be FMD free is the absence of any FMD outbreak."⁴⁸ This fact that suspension is immediate recognizes the fact that FMD is a rapidly spreading disease that could quickly pose a threat to the international community and the appropriate measure is to suspend importation of potentially affected products. The OIE's process for suspension is the same as that of the United States and many other countries. Moreover, as the OIE states in its answer to Question 13(e), reinstatement from suspension "is a voluntary procedure, initiated at a Member Country's request."⁴⁹

56. In this dispute, Argentina claims that the removal of import authorization by the United States in response to FMD outbreaks in Argentina was inconsistent with the SPS Agreement for, *inter alia*, failure to provide a risk assessment. In fact, actions by the United States were entirely consistent with actions taken by the OIE because "there is no need for a scientific evaluation"⁵⁰ for treatment of Argentina as an FMD-infected country. Once a country notifies an FMD outbreak or credible reports are received, the appropriate response is to suspend importation on the basis of that disease status. The OIE only began its reassessment of Argentina's status, upon Argentina's request. As the United States has argued in this dispute, APHIS similarly began to review Argentina's status upon the submission of Argentina's application for import authorization, and that review is ongoing. The process employed by the United States is

⁴⁵ OIE Staff Responses, at p. 17.

⁴⁶ For example, Argentina refers to this fact favorably in relation to its claims against the United States in its second written submission, at paras. 45, 46, and 173.

⁴⁷ OIE Staff Responses, at p. 18.

⁴⁸ OIE Staff Responses, at p. 21.

⁴⁹ OIE Staff Response, at p. 16.

⁵⁰ OIE Staff Response, at p. 21.

consistent with the OIE’s own approach to handling FMD infection in countries with a designation, and consistent with the SPS Agreement.

57. The OIE has arrived at Argentina’s new designation in a timeframe shorter than that of APHIS, in part because of certain differences in the review procedure, as described in answers to Questions 2, 5, and 13. However, these difference in timeframes for review may in part be related to the thoroughness of review and the intensive fact gathering process reflected in site visits.

Question 15: To what extent does the OIE consider the following factors when proposing specific FMD status designations :

- a. Timely and accurate notification of diseases by the competent authorities;**
- b. Trust between veterinary authorities in OIE member countries and with the OIE;**
- c. Credibility of each country's reporting.**

58. *Comment on OIE Staff’s Response to Question 15(a):* The United States takes note of the OIE staff’s statement that “a record of regular and prompt animal disease reporting” is important. Another OIE staff document observes: “The withholding of information on a disease situation from the OIE by an OIE Member would also amount – regardless of the grounds – to a violation of the OIE Organic Statutes.”⁵¹ Indeed, timely and accurate notification of FMD by competent authorities is a critical factor in determining the risk that products from an exporting country pose to the importing country.

59. *Comment on OIE’s Staff Response to Questions 15(b) and (c):* The OIE staff states that “[t]rust and credibility are important aspects of an application for official recognition of FMD status.” Another OIE staff document observes that regaining credibility and trust because of a failure to meet international rules such as notification “is **a costly and time-consuming exercise** and can be of the highest political risk for policy-makers.”⁵² The United States agrees with the importance of the principles of trust and credibility. Regulatory authorities in an importing country cannot make an assessment of the exporting country’s situation, if it cannot rely upon the information provided. In fact, the OIE’s own disease recognition list recognizes the importance of credibility and accuracy in its FMD recognition lists, which state: “Information published by the OIE is derived from declarations made by the official Veterinary Services of Members. **The OIE is not responsible for inaccurate publication of country or zonal disease free status based on inaccurate information, changes in epidemiological status or other significant**

⁵¹ OIE, Notification of Animal and Human Diseases: Global Legal Basis, at p. 4 (Exhibit USA-20).

⁵² *Id.*, at p. 1 (emphasis supplied).

events that were not promptly reported to the Central Bureau subsequent to the time of declaration of freedom from FMD.”⁵³

60. Considerations of credibility, timeliness, and accuracy are judgments that are appropriately made by regulatory authorities in the importing country, which has “the right to take sanitary . . . measures necessary for the protection of human, animal or plant life or health” under the SPS Agreement. An importing country’s regulatory authorities cannot monitor the disease situation in an exporting country at every farm and field. Before initiating trade, the importing country must have confidence that “its animal health status will be appropriately protected.”⁵⁴

Question 16: With respect to an outbreak in a country or region:

- a. How does the OIE normally learn of an FMD outbreak?**
- b. What is considered a timely manner for notifying the OIE about any events that may affect the FMD status of a specific country or region? Is this specified in an OIE standard or other document? Is this taken into consideration in the designation of a country's FMD status?**
- c. After the OIE learns of an FMD outbreak occurring in a country with OIE recognized status, how much time lapses before the OIE suspends or removes an OIE Member/region from the list of countries that are FMD-free (with or without vaccination)?**
- d. Upon learning of an FMD outbreak, does the OIE conduct a scientific evaluation of the OIE Member/region before suspending or removing a Member from the list of FMD-free countries (with or without vaccination)?**
- e. With regard to the process of reinstating an OIE Member’s disease free status, is the information and data submitted by the OIE Member country, and/or the review and analysis documentation generated by the *ad hoc* Group and Scientific Commission, shared with OIE Member countries, either automatically or upon request?**

61. The United States has no comment on the OIE staff’s response to Question 16(a).

62. *Comment on OIE Staff’s Response to Question 16(b):* The OIE staff’s response confirms the U.S. understanding of the importance of receiving timely official notifications of FMD events discussed in its comments on the OIE staff’s response to Question 15.

⁵³ See, e.g. Resolution 19, Final Report of the 77th Meeting of the Genreal Assembly of Delegates to the OIE (May 2009) at p. 154..

⁵⁴ Article 5.3.3, OIE Terrestrial Code.

63. Timely notification is “a fundamental principle in Chapter 8.5” of the *Terrestrial Code* on FMD.⁵⁵ The OIE staff’s response states that timely notification is “*within 24 hours*” of the FMD event. Furthermore, the OIE staff’s response states that the “notification record of a Member Country is an important factor when considering the recognition of FMD freedom or the regaining of free status after an outbreak.”⁵⁶ “The withholding of information on a disease situation from the OIE by an OIE Member would also amount – regardless of the grounds – to a violation of the OIE Organic Statutes.”⁵⁷

64. In its first written submission, the United States endorsed this understanding, explaining that notification is a key element to FMD control.⁵⁸ Because the United States and the OIE alike typically learn of an FMD outbreak through official notifications from its trading partners, their respective efforts to control the disease are severely compromised when a Member Country or trading partner fails to timely notify an event. As discussed in the comment to the OIE staff’s response to Question 15, Argentina had a troubling record untimely notification, which SENASA itself has acknowledged.

65. *Comment on OIE Staff’s Response to Questions 16(c) and (d):* The United States notes that the OIE staff’s response at part (c) explains that it immediately suspends the official status of an FMD-free country or zone when it “becomes aware” of an FMD outbreak.⁵⁹ The OIE staff’s answer confirms the U.S. understanding of the OIE’s ordinary response to an FMD outbreak notification.⁶⁰ The response also shows that the approach APHIS takes is based on and consistent with the OIE approach. In its submissions, Argentina contends that the United States somehow improperly “ejected” SENASA from the “regulatory system”;⁶¹ however, the United States simply adopts a process of suspension, reapplication and reinstatement fundamentally consistent with the OIE’s approach.

66. In its answer to Question 16(d), the OIE staff states that the country or zone’s FMD status is “suspended as soon as an outbreak occurs” without the “need for a scientific evaluation because the first requirement to be FMD-free is absence of any FMD outbreak.”⁶² That is, no further evaluation is necessary when the exporting country acknowledges it has the disease of concern. As the United States noted above in its comment to the OIE staff’s response to

⁵⁵ OIE Staff Responses, at p. 20 (“The requirement for timely notification of FMD is a fundamental principle in Chapter 8.5 and in the chapters on other highly contagious diseases. The notification record of a Member Country is an important factor when considering the recognition of FMD freedom or the regaining of free status after an outbreak.”).

⁵⁶ *Id.*

⁵⁷ OIE, Notification of Animal and Human Diseases: Global Legal Basis, at p. 4 (Exhibit USA-20).

⁵⁸ U.S. First Written Submission, at para. 58 (“Trust between veterinary authorities in countries and with the OIE is critical for FMD control, and that trust is based on credibility of each country’s reporting.”).

⁵⁹ OIE Staff Responses, at p. 21.

⁶⁰ See U.S. First Written Submission, at paras. 132, 135, 235, 238, 293 and 340; U.S. Second Written Submission, at paras. 27; U.S. Answers to Panel’s Questions 33 at paras. 155 and Question 61(a), at para. 252.

⁶¹ Argentina’s Second Written Submission, at paras. 191, 249

⁶² OIE Staff Responses, at p. 21.

Question 14, this is the same general approach APHIS takes in response to an FMD outbreak notification, and the same specific approach it has taken in response to Argentina’s multiple outbreaks.⁶³

67. The United States also notes that the OIE staff’s response to Question 16(d) helps to illustrate that the United States acted consistently with Article 5.1 of the SPS Agreement when the United States prohibited the importation of beef in response to Argentina’s FMD outbreak. As the United States previously recognized, Article 5.1 requires Members to base their measures on an assessment of the risks *as appropriate to the circumstances*.⁶⁴ When the United States became aware of the FMD outbreaks in Argentina, it appropriately removed Argentina’s import authorization based on the widely known risks associated with the disease. No further evaluation was necessary. The OIE acted similarly in response to Argentina’s FMD outbreaks.

68. *Comment on OIE Staff’s Response to Question 16(e)*: The United States notes that the OIE staff’s response confirms the U.S. understanding that OIE Member Countries do not have an opportunity to review the information each applicant country submits in its dossier to the OIE.⁶⁵ This aspect of the process of reinstating an OIE Member’s disease free status is particularly concerning because Members are not able to assess the totality of the information on which the Scientific Commission relied in reaching its decision. Members may review the *ad hoc* Group’s assessment, as reflected in the Scientific Commission’s report, *only* “if the decision is positive, leading to the reinstatement of the status.”⁶⁶ These assessments merely summarize the *ad hoc* Group’s findings,⁶⁷ and lack complete information of the applicant region – information that could undoubtedly inform a Member’s evaluation and recommendation.

69. The United States also notes that the OIE reinstatement process not only limits the scope of information Member Countries may review, but also does not require the OIE to give Member Countries a 60 day consultative period.⁶⁸ By way of contrast, Member Countries are provided two years to review proposed revisions to standards of the *Terrestrial Code*. By limiting Members’ timeframes for reviewing proposals to reinstate FMD statuses, the OIE restricts Member Countries’ participation in the process.

⁶³ See U.S. First Written Submission, at para. 235.

⁶⁴ U.S. First Written Submission, at para. 248.

⁶⁵ See U.S. Second Written Submission, at para. 109.

⁶⁶ OIE Staff Responses, at p.21.

⁶⁷ Report of the Meeting of the OIE Scientific Commission for Animal Diseases (February 2014) (Exhibit USA – 166).)

⁶⁸ Resolution 25, 80th General Session of the OIE World Assembly.

Question 17: With regard to an outbreak of FMD

- a. How is an "epidemic level outbreak" defined?**
- b. What are the OIE criteria or processes for determining whether eradication of an outbreak has been successful?**
- c. In the event that the FMD virus is re-introduced, leading to a new outbreak, how is it possible to determine if this is a new outbreak or simply the extension (re-occurrence) of the existing outbreak?**
- d. To what extent and how does the cause of an outbreak, its spread or its duration affect OIE decisions regarding FMD status?**

70. The United States has no comment on the OIE staff's response to Question 17(a).

71. *Comment on OIE Staff's Response to Question 17(b):* The OIE staff's response suggests that the OIE's evaluation of a request for the recovery of an FMD-free status is not as rigorous as its assessment of Member's initial request to acquire an FMD-free status for the first time. As the response explained, the evaluation of a reinstatement request focuses on the "absence of FMD" after a certain waiting period, and not necessarily the adequacy of the control measures required to obtain an initial FMD free status and the reliability of the country's disease reporting practices.

72. The OIE staff's response refers to Article 8.5.9 of the *Terrestrial Code* as containing the relevant requirements for recovering disease-free status.⁶⁹ This provision establishes the waiting periods required to regain an FMD free status following an outbreak. The provision, however, does not call for an evaluation of the country or zone's control measures and prevention capabilities. These requirements outline an approach notably different than the requirements for acquiring an FMD status contained at Article 1.6.5 of the *Terrestrial Code*. Among other factors, Article 1.6.5 requires Member Countries requesting FMD-free status to address the following five factors concerning FMD eradication: (1) FMD history; (2) the strategy for control and eradication; (3) vaccines and vaccination; (4) legislation, organization and implementation of an FMD eradication campaign; and (5) animal identification and movement control.⁷⁰ Compared to the process of **regaining** an FMD-free status, where Members must merely show the absence of the disease for a particular period of time, Members must demonstrate their past, present and future capacity to eradicate FMD in order to **obtain** a disease-free status.

73. The United States has no comment on the OIE staff's response to Question 17(c).

74. *Comment on OIE Staff's Response to Question 17(d):* The United States notes that the OIE staff's response identifies the requirements of Article 8.5.9 as being concerned primarily

⁶⁹ OIE Staff Responses, at p. 22.

⁷⁰ Article 1.6.5, OIE Terrestrial Code (2013).

with “the control measures applied and the time taken to bring the disease under control.”⁷¹ The OIE staff’s response, however, does not address whether or to what extent the cause or handling of an outbreak affects its decisions regarding FMD status, such as whether internal controls, including but not limited to surveillance, were deficient.

75. By way of contrast, in evaluating a reinstatement request, APHIS takes into consideration the spread and duration of an FMD outbreak; APHIS also takes into account the cause of the outbreak as the reason for the cause of an outbreak may bring into question whether the country has maintained proper control, detection and eradication capabilities to prevent outbreaks.

76. As reflected in SENASA’s application and APHIS’s risk assessment, the cause and handling of Argentina’s multiple FMD outbreaks has informed the evaluation process. APHIS has utilized the information to understand the potential FMD risks posed to beef from Patagonia South and North B, and to assess whether Argentina has demonstrated the sufficient capacity to control that risk. Thus, the United States considers the cause and handling of an outbreak to have an identifiable effect on its decisions regarding FMD status.

Question 18: With respect to the significance of the official disease status recognition, does the OIE aver that products from two countries or regions that have the same designation (i.e., FMD-free with vaccination) pose the same level of sanitary risk such that application of the same mitigating measures to those products would achieve the same level of protection?

77. *Comment on OIE Staff’s Response to Question 18:* The United States notes that the OIE staff’s response offers a conclusory affirmation and cites to the response to Question 19 as explanatory support. This response and cited explanation, however, fail to acknowledge the limitations of the OIE FMD status determinations. As the United States has previously discussed, these limitations reveal problems with drawing a blanket conclusion that products from countries or regions attributed the same OIE FMD status designation necessarily pose the *same level of sanitary risk* and the application of the same mitigation measures achieve the same level of protection.

78. The United States previously explained that there are three specific observations reflected by the OIE’s FMD status designations: (1) the OIE has accepted documentary evidence of a country or zone’s record of adequate disease reporting; (2) the country or zone has not reported FMD outbreaks, FMDV infections or vaccinations against the disease in the preceding 12 months; and (3) the OIE is satisfied with a country or zone’s geographic boundaries and protections.⁷² These observations provide relevant information regarding a country or zone’s unique FMD situation, but fall short of considering other important elements.

79. The OIE’s FMD status designations alone do not allow for comparisons for the purposes of the SPS Agreement. The information obtained by the OIE pursuant to Article 1.6.5 and Article 8.5.9 provide for the assessment of a country or zone’s unique conditions, not for

⁷¹ OIE Staff Responses, at p. 22.

⁷² See U.S. Second Written Submission, at paras. 120-123.

conclusions about the comparability of different countries or zones. At the same time, the provisions indicate that the OIE may not collect the information for the purpose of comparing countries or zones. The OIE evaluates a country or zone’s FMD situation to determine whether it satisfies the criteria to be assigned an FMD status, not to determine whether uniquely situated countries or regions are identical or similar for the purposes of (1) the SPS Agreement, and (2) meeting the U.S. appropriate level of protection. The FMD status designations in themselves do not establish these equivalencies.

Question 19: (a) Is it possible that animals or animal products from two countries or regions having the same OIE official disease status recognition for FMD present different levels of risk with respect to that disease? (b) Under the Terrestrial Code would countries or regions that have the same official disease status recognition for FMD have distinct risk mitigation requirements applied to them? If so, please explain the underlying rationale for this approach and how such requirements should be applied.

80. *Comment on OIE Staff’s Response to Question 19(a):* The United States first notes that the OIE staff’s response draws the distinction that “official disease status is granted to a country or zone but not to a region.”⁷³ This apparent clarification suggests that, for the purposes of recognizing official disease status, the OIE does not acknowledge “regions”. This distinction is somewhat confusing and does not appear to harmonize with the understanding of zone and region articulated in various provisions of the *Terrestrial Code*.

81. In the Glossary to the *Terrestrial Code*, the terms “zone” and “region” are assigned the same definition. These terms are separated by a “/” but share a definition.⁷⁴ Additionally, the introduction to Article 4.3.1 of the *Terrestrial Code* chapter titled “Zoning and Compartmentalisation” sets out that “[f]or the purposes of the *Terrestrial Code*, ‘zoning’ and ‘regionalisation’ have the same meaning.”⁷⁵ The OIE itself makes this observation in its response to Question 21.⁷⁶ The similar treatment of and meaning attached to zone and region for the purposes of the *Terrestrial Code* suggest that the terms are the same for recognizing official disease status.

82. Second, the OIE staff’s response asserts that it considers animals and animal products from countries or zones with the same official disease status to present an equivalent level of risk of FMD.⁷⁷ However, the OIE staff in the same answer also states that the OIE recognizes two types of FMD status, free without vaccination and free with vaccination, and that the measures in the Code “provide an equivalent level of risk mitigation” such that countries should apply the

⁷³ OIE Staff Responses, at p. 23.

⁷⁴ *Glossary* to the *Terrestrial Code* (defining “zone/region” as “a clearly defined part of a territory containing an animal subpopulation with a distinct health status with respect to a specific disease for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade.”).

⁷⁵ Article 4.3.1, OIE *Terrestrial Code*.

⁷⁶ OIE Staff Responses, at p. 24.

⁷⁷ *Id.*, at p. 23.

same risk mitigations requirements to countries with the same official disease status. These two statements do not mean the same thing. The United States believes that this latter statement is more precisely stated and reflects most accurately the meaning and implication of the OIE disease recognitions and associated recommended measures. Accordingly, this would mean the application of the recommended measures applicable to each type of FMD status will mitigate risk so that an equivalent ALOP is achieved in each situation.

83. With this mind, the OIE’s statement that exports from countries with the same official disease status present an equivalent level of risk of FMD can be understood to mean presenting the equivalent acceptable level of risk as set by the OIE. However, the OIE’s acceptable level of risk is not the U.S. acceptable level of risk. The United States has a different ALOP than that achieved by the OIE’s recommended measures for FMD-free with vaccination. As the United States explained in its comment the OIE staff’s response to Question 18, the OIE’s FMD status designations do not provide for a comparison of the different levels of risk of FMD posed by two, unique countries or regions for purposes of the SPS Agreement. While the OIE Response asserts that “the conditions in the relevant articles take *full account* of the risks presented by animals and products”, this blanket statement assumes too much. The Panel should be careful to recognize and distinguish the OIE’s FMD-free status determinations from a legal conclusion that the countries or regions are necessarily identical or similar for the purposes of the SPS Agreement.

84. “Risk” is defined in the OIE *Terrestrial Code* as “the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health.”⁷⁸ There is no basis in logic or science to assume that two countries that have the same FMD status will always pose the exactly equivalent level of risk to an importing country. The OIE’s risk categorization attempts to match a broad category of risk with a specified set of measures and recommendations. However, these broad categories of risk do not set gradations to account for variations in conditions unique to particular countries or regions. In fact, countries and regions contain unique conditions and pose gradations of risk not accounted for by the OIE’s broad categories. Therefore, an importing Member’s may require a different set of control measures not accounted for by the OIE general recommendations in order to meet the Member’s appropriate level of protection.

85. *Comment on OIE Staff’s Response to Question 19(b)*: The United States refers to its comments to the OIE staff’s response to Question 19(a) above. The United States understands the OIE staff’s response to Question 19(b) to apply to countries with the same disease status and subject to the same mitigation requirements for purposes of achieving the appropriate level of protection established by the OIE’s recommendations. However, the statement should not be taken to mean that these same risk mitigation requirements applied to all countries that have the same official disease status would achieve the U.S. appropriate level of protection with regard to any particular country’s proposed exports to the U.S.

⁷⁸ *Glossary*, OIE *Terrestrial Code*.

Question 20: Article 1.1.2.4 of the Terrestrial Code states:

"Recognising that scientific knowledge concerning the relationship between diseases and their aetiological agents is constantly developing and that the presence of an aetiological agent does not necessarily imply the presence of a disease, Member Countries shall ensure through their reports that they comply with the spirit and intention of *notifications*. This means that the detection of the aetiological agent of a listed disease in an animal should be reported, even in the absence of clinical disease."⁷⁹

Please explain the relevance of this statement to the notification procedures set forth in the Terrestrial Code in general, and in particular with respect to FMD.

86. *Comment on OIE Staff's Response to Question 20:* The United States agrees with the OIE staff's response regarding the assertion that a country's Veterinary Services, such as SENASA or APHIS, must achieve early detection and notification of infection to effectively control and prevent the spread of the listed disease.⁸⁰ As the United States explained above in its comment to the OIE staff's responses to Questions 16(a) and (b), the notification process is a key element to the prevention of the spread of FMD. APHIS has devoted considerable attention to evaluating this element of Argentina's FMD situation, as reflected in the risk analysis of Patagonia.⁸¹

Question 21: Article 6.1 of the SPS Agreement refers to Members adapting their SPS measures to the characteristics of an area and to assessing the SPS characteristics of a "region". Please explain whether and where such concepts are embodied in the Terrestrial Code or other OIE texts. In your answer, please also explain the relevance, if any, of the concepts of pest or disease-free areas or areas of low pest or disease prevalence⁸² and where these concepts appear in the Terrestrial Code or other OIE documents.

87. *Comment on OIE Staff's Response to Question 21:* The United States notes that the OIE staff's response confirms the importance of "zoning", which is an understanding the United States shares as evidenced by APHIS's approach to regionalization outlined at 9 C.F.R. §92.2. The OIE staff's response also acknowledges that ultimate efficacy of a zoning or regionalization approach "depends on the ability of the Veterinary Authority [of the exporting country] to maintain the separation between the infected and free sub-populations."⁸³

⁷⁹ Chapter 1.1., Article 1.1.2.4, OIE Terrestrial Animal Health Code (2012).

⁸⁰ OIE Staff Responses, at p. 24.

⁸¹ See Exhibit USA-133.

⁸² See Annex A(6) and Annex A(7) of the SPS Agreement for the definition of these concepts used for the purposes of that agreement.

⁸³ OIE Staff Responses, at p. 24.

Question 22: Please consider a scenario where there is an outbreak of FMD in an otherwise FMD-free (with or without vaccination) exporting country.

- a. Are the concepts of zoning and compartmentalization applicable in such a situation? If so, how would they be applied?**
- b. What import requirements, if any, would be indicated by the Terrestrial Code in such a situation? Should the same requirements be applied to products originating from the zone where the outbreak occurred as to products from other parts of the exporting country?**

88. *Comment on OIE Staff's Response to Question 22(a):* The United States agrees with the OIE staff's response that, following an FMD outbreak in an FMD-free exporting country or zone, the proper response is to immediately suspend the status of the country or zone. The FMD status of a country or zone remains suspended until the OIE has been convinced that either reinstatement or the establishment of a containment zone is appropriate. As addressed in the U.S. comment to the OIE staff's responses to Questions 10, 14, and 16, APHIS adopts the same approach, which protects the United States from the risk of the disease, while affording an opportunity for reapplication and potential reinstatement of an FMD-free status.

89. The OIE staff's response also noted that Resolution XXV affords the Scientific Commission the mandate to recognize the establishment of a containment zone following the suspension of an FMD status, without consulting the World Assembly. The United States notes that the Scientific Commission has the mandate to exercise this authority "when a country submits an application for establishment of a containment zone", and not pursuant to its own initiative. The United States also notes that Argentina did not establish a containment zone during the events at issue in this dispute.

90. *Comment on OIE Staff's Response to Question 22(b):* The United States notes that the OIE staff's response indicates that a country or zone experiencing an FMD outbreak should have its free status suspended, and be subject to the *Terrestrial Code* requirements applicable to an FMD infected country or zone.⁸⁴ As mention above, APHIS takes a similar approach in response to an FMD outbreak, removing a country or region's FMD-free status and adjusting the applicable import requirements.

**Question 23: The chapeau of Article 4.3.1 of the Terrestrial Code reads as follows:
"Subpopulations may be separated by natural or artificial geographical barriers or, in certain situations, by the application of appropriate management practices."**

- a. What consideration does the OIE attribute to natural or artificial geographical barriers in the context of establishing and maintaining a subpopulation with a distinct FMD health status within a country's**

⁸⁴ *Id.*, at p. 26.

territory? In your answer, please explain how these factors were applied in the OIE's designation of Patagonia.

91. *Comment on OIE Staff's Response to Question 23(a):* The OIE staff's response explained that it assesses geographic barriers and regulatory measures when considering the establishment of an FMD-free zone, which requires the separation of the subpopulation in the zone from the other animals in the national population.⁸⁵ Indeed, the evaluation of barriers and regulatory measures is essential to ensuring the integrity of FMD-free zones. The United States notes that APHIS likewise evaluates the geographic barriers and regulatory measures utilized by a country requesting FMD-free status of a region.

92. In its evaluation of Patagonia's request for FMD-free status, APHIS has taken into consideration the geographic barriers and regulatory measures SENASA set in place. As an example, during its February 2009 site visit, APHIS attempted to verify the implementation of SENASA Resolution No. 1282, which amended the requirements for the movement of FMD-susceptible animals in Patagonia.⁸⁶ APHIS considers these factors when evaluating a country or region's FMD situation.

Question 24: With respect to Article 4.3.1 of the Terrestrial Code, please answer the following questions:

- a. What are the criteria for effective barriers to FMD?**
- b. What are the criteria used to measure the effectiveness of geographical features vs. effective management and husbandry practices related to biosecurity?**
- c. Is there a difference between the concept of "containment zone" as used in Chapter 8.5 and that of "zoning" as defined in Chapter 4.3? If so, please detail the requirements of each concept and clarify if both are subject to the principles contained in Chapter 1.1 of the Terrestrial Code.**

93. *Comment on OIE Staff's Response to Question 24(a):* The United States agrees with the OIE staff's response that relevant legislation, manuals of procedures, resources available to the Veterinary Services and access to an adequate framework for legal enforcement are among the factors to be considered to determine the effectiveness of barriers to FMD.

94. The United States has no comment on the OIE staff's response to Questions 24(b) and (c).

⁸⁵ *Id.*

⁸⁶ *See* U.S. First Written Submission, at para. 161.

Question 25: Does the OIE use any criteria other than the recommendations set forth in Articles 8.5.2 and 8.5.3 when it determines a country's FMD status?

95. *Comment on OIE Staff's Response to Question 25:* The United States notes that the criteria mentioned in the OIE staff's response is similar to that used by APHIS in its determination of a country's FMD status. The table contained submitted by the United States in its first written submission at paragraph 335 reflects the similarity of the two approaches.

Question 26: In the context of Articles 8.5.23 and 8.5.25, please explain why feet, head and viscera are excluded from the scope of the provision, and indicate whether these products are covered by any OIE product-specific recommendations. In your answer, please explain the logic behind the difference in requirements between the two provisions and the relevance of the concept of "OIE endorsed official control programme for FMD" as defined in Article 8.5.48.

96. *Comment on OIE Staff's Response to Question 26:* The OIE staff's response explains that the prohibition on exporting the feet, head and viscera of animals from countries or zones that vaccinate is due to the fact clinical disease may not be detected in these tissues of vaccinated cattle or buffalo after an FMD outbreak. Such countries and zones, therefore, present a greater risk that a carrier animal might be slaughtered without detection and its infected meat inappropriately exported. Accordingly, since the feet, head, and viscera are sites of localization of the FMD virus in carrier animals, excluding their export reduces the risk that FMD infected products will be exported.

97. Articles 8.5.23 and 8.5.25 provide recommendations for the importation of fresh meat of cattle and buffaloes when vaccination is practiced or exists, but exclude the aforementioned tissues. In contrast, the recommendations at Article 8.5.22 for countries and zones that do not practice vaccination make no exclusion for feet, head, and viscera because, as the OIE staff stated, "meat derived from feet, head and viscera may be exported from countries or zones that are officially recognized as FMD free without vaccination."⁸⁷

98. For these reasons, the OIE staff's response supports the fact that exports from countries vaccinating against FMD pose a different and higher of risk of FMD transmission to importing countries than the risk posed by countries that do not practice vaccination. As the United States explained above in its comment to the OIE staff's response to Question 7, vaccination introduces risks related to herd immunity and undetected infection.⁸⁸ Thus, the United States requires the application of its mitigation measures, which are designed to reduce the risks associated with vaccination, such as those associated with meat derived from feet, head and viscera.

⁸⁷ OIE Staff Responses, at p. 29.

⁸⁸ See U.S. First Written Submission, at para. 299.

Question 27: The term "susceptible animals" is systematically used throughout Chapter 8.5.

Question 28: In this context, please explain the following:

- a. Whether the category "susceptible animals" is determined on the basis of clinical signs of infection or if it applies to a specific category of animals;**
- b. the relationship between Articles 8.5.12, 8.5.13 and 8.5.14.**

99. *Comment on OIE Staff's Response to Question 28:* The OIE staff's response explains that the live animals from countries and zones recognizes as FMD-free where vaccination is practiced "have an increased probability of circulation of FMD virus." This assertion supports the U.S. concern that countries that vaccinate pose a different and higher level of FMD risk than countries and regions where vaccination is not practiced.

Question 29: Are the surveillance recommendations set forth in Articles 8.5.46 and 8.5.47 subsidiary in nature vis-à-vis the general conditions contained in Chapter 8.5, specifically Articles 8.5.3, 8.5.42, 8.5.43, 8.5.44, in order to achieve the OIE recommended level of protection? In your answer, please indicate also which recommendations apply specifically to FMD.

100. *Comment on OIE Staff's Response to Question 29:* The OIE staff's response identifies additional surveillance recommendations set out in the *Terrestrial Code* that are only applicable to countries and zones where FMD is practiced. In addition to the general recommendations of Article 8.6, Article 8.6.46 requires Member Countries to demonstrate the "absence of clinical disease in the country or zone for the past two years" when applying for the designation of FMD free where vaccination is practiced.⁸⁹ This additional procedure is required to achieve the OIE's recommended level of protection for that class of countries, and confirms that countries where vaccination is practiced pose an additional FMD risk in comparison to countries or zones that do not.

⁸⁹ Article 8.6.46, OIE *Terrestrial Code* (2013) (Compare with Article 8.6.45 which requires the demonstrated "absence of FMDV infection during the preceding 12 months.").

Question 30: In evaluating a country's capacity for FMD control and eradication:

- a. **Explain the meaning of "FMD Official Control Programme" as set forth in Article 8.5.48 of the Terrestrial Code.**
- b. **Explain the relationship between the recommendations prescribed under Article 8.5.48 and those in Articles 8.5.2 and 8.5.3 of the Terrestrial Code.**
- c. **Is the procedure set forth in Article 8.5.48 of the Terrestrial Code a step within the OIE process of country recognition?**
- d. **Is consideration given to a country's infrastructure capabilities in the OIE's decision-making process for FMD free designation? In your answer, please explain which criteria are taken into account.**

101. *Comment on OIE Staff's Response to Question 30(a):* The United States notes that the OIE staff's response explains that the concept of "Official Control Programme" applies only to countries which are infected. Thus, a country or zone that receives the OIE's endorsement for such a program is not an FMD-free country or zone, is not subject to the *Terrestrial Code* recommendations for FMD-free countries or zones, and is not designated on the lists adopted annually by the OIE World Assembly as FMD-free.

102. *Comment on OIE Response to Question 30(b):* The United States notes that the OIE staff's response does not demonstrate a direct relationship between Article 8.5.48 and Articles 8.5.2 and 8.5.3. In fact, the OIE Response explains that the actual connection exists between Article 1.6.4 and Articles 8.5.2 and 8.5.3. A country or zone requesting FMD-free status under Article 8.5.2 or 8.5.3 must address questions on FMD eradication contained in Article 1.6.4. Thus, it appears that a country cannot obtain FMD-free status under Articles 8.5.2 and 8.5.3 without providing the information requested under Article 1.6.4.

103. The OIE staff's response asserts that a country's official control program for FMD provides a basis for answering the questions required by Article 1.6.4. By "basis," the OIE appears to be saying that facts related to an official control program may be relevant for answering questions posed by Article 1.6.4. The information required to answer the questions outlined at Article 1.6.4 can likely be obtained from many sources, not only on the basis of an official control program. Thus, any relationship is limited to whether the facts connected to an official control program are relevant.

104. The United States has no comment on OIE staff's responses to Questions 30(c) and (d).

Question 31: What is the relationship between the OIE Handbook on Import Risk Analysis for Animals and Animal Products and Articles 8.5.22 and 8.5.23 of the Terrestrial Code?

105. *Comment on OIE Staff's Response to Question 31:* The United States takes note of the OIE staff's response that the OIE Handbook on Import Risk Analysis for Animals and Animal Products provides guidance to OIE Members on the conduct of such import risk analyses. The Handbook states that it "provide[s] valuable practical guidance to Veterinary Services needing to

analyse the risks posed by imports, to ensure that stakeholders, risk analysts and decision makers can be confident that the disease risks posed have been identified and managed effectively.”⁹⁰ While Article 8.5.22 and Article 8.5.23 of the *Terrestrial Code* provide conditions on the importation based on a particular disease status, the Handbook discusses in part the process of assessment of the disease status in a particular location.

106. To the extent the OIE staff in its response to Question 31 is stating a legal opinion with respect to how specific OIE documents are relevant to various provisions of the SPS Agreement, the United States again notes that these are legal issues concerning the interpretation and application of the WTO Agreement, and that the staff of the OIE have no special expertise or competency on such issues.

107. Nonetheless, the United States notes that APHIS, in its evaluation of claims of disease-free status, follows a similar approach to that set out in the Handbook. Upon receiving an application from an exporting country, APHIS conducts a risk analysis of that country to determine the conditions under which the relevant product can enter the United States. In reviewing this application, APHIS takes into consideration all relevant facts, including whether or not the OIE has extended official recognition.

Question 32: Article 8.5.19 of the Terrestrial Code starts with the phrase: "Irrespective of the FMD status of the exporting country, zone or compartment, Veterinary Authorities should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of cattle [...]" followed by a number of requirements. Please explain the basis for the approach set forth in the Terrestrial Code and why the FMD status of the country, zone or compartment of origin is not relevant to the recommendations for the product in question.

108. *Comment on OIE Staff's Response to Question 32:* The United States notes that the OIE staff's response describes *in vivo* derived embryos of cattle as a “safe commodity” with respect to FMD. The United States further notes that the OIE Terrestrial Code concludes that such commodities satisfy the OIE criteria for safe trade, regardless of the FMD status designation. *In vivo* derived embryos, however, are not the subject products of Argentina's applications and of this dispute. Rather, the products subject to this dispute include fresh (chilled or frozen) beef.

109. Argentina has not submitted an application to APHIS requesting authorization to import *in vivo* derived embryo products. Additionally, the OIE Terrestrial Code has not identified fresh (chilled or frozen) beef or products as “safe commodities.” Simply stated, the OIE's treatment of *in vivo* derived embryo products bears no relationship to the treatment of the subject products of this dispute - fresh (chilled or frozen) beef. Thus, the OIE's conclusion that *in vivo* derived bovine embryos can be traded safely, regardless of the country or zone's FMD status is immaterial to this dispute.

⁹⁰ OIE Handbook on Import Risk Analysis for Animals and Animal Products (“OIE Handbook”), Foreword.