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 INDIVIDUAL EXPERTS TO THE PANEL'S QUESTIONS

July 29, 2014

TABLE OF REPORTS

SHORT CITATION	FULL CITATION
Australia – Apples (AB)	Appellate Body Report, *Australia – Measures Affecting the Importation of Apples from New Zealand*, WT/DS367/AB/R, adopted 17 December 2010
US – Continued Suspension (AB)	Appellate Body Report, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute*, WT/DS320/AB/R, adopted 14 November 2008

I. INTRODUCTION

1. The United States appreciates the opportunity to comment on the responses to the Panel's questions provided by the experts.[1] As an initial matter, the United States has comments regarding the respective roles of experts and the Panel that apply to many of the individual questions and answers. Rather than repeat those comments for each applicable question, the United States is providing these overarching comments in this introduction.

2. The United States recalls, as it stated in its letter to the Panel of April 15, 2014, that the role of expert advice in a dispute settlement proceeding is a limited one. The experts can serve a useful role in assisting a panel in evaluating the evidence on the record in the dispute. However, expert testimony cannot itself be used to make out a party's *prima facie* case, or to meet a party's burden to prove a matter asserted. Moreover, expert advice pertains only to factual issues. The legal issues in the dispute, including the application of the application of the legal standards in the covered agreements to a particular set of facts, are a matter solely for the Panel.

3. In this regard, the United States recalls that the Appellate Body has made findings on both (1) the distinction between factual issues (with respect to which experts may be helpful) and legal issues involving the application of SPS disciplines, and (2) the limited role of a panel itself in applying SPS rules. As the Appellate Body has stated, "the purpose of a panel consulting with experts is not to perform its own risk assessment."[2] While the Panel may seek advice from experts, for example, "to identify the scientific basis" of a measure or "review whether the reasoning articulated on the basis of the scientific evidence is objective and coherent," the "role of the experts must reflect the limited task of a panel."[3] Furthermore, "[t]he consultations with the experts . . . should not seek to test whether the experts would have done a risk assessment in the same way and would have reached the same conclusions as the risk assessor."[4]

4. It is also not appropriate for experts to draw legal conclusions. While an expert "may assist a panel in assessing the level of risk associated with SPS measures and potential alternative measures,"[5] the question of whether "an alternative measure's level of risk achieves a Member's appropriate level of protection is a question of legal characterization."[6] As the Appellate Body noted, "[a]nswering this question is not a task that can be delegated to scientific experts."[7]

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[1] The United States has not reproduced questions for which it has no comment at this time, including questions 3, 4, 5, 13, 16-20, 22-29, 33, 42-44, 46, 49-60, 62, 63 66. The absence of a comment does not indicate concurrence with the responses of the experts. In addition, it appears that the paragraph labeled Question 67 is part of Dr. Batho's response to Question 66, and not a question to the experts or the parties.

[2] *US – Continued Suspension (AB)*, at para. 592.

[3] *Id.*

[4] *Id.*

[5] *Australia – Apples (AB)*, at para. 384.

[6] *Id.*

[7] *Id.*

5. The United States expresses this concern because, in response to some of the questions, the experts appear to be either performing an assessment of risk,[8] or drawing legal conclusions regarding whether the measures meet a Member's appropriate level of protection,[9] or otherwise overstepping their defined role.

II. COMMENTS ON THE RESPONSES OF THE INDIVIDUAL EXPERTS

2.1 FMD Transmission

Question 1: What are potential pathways for introduction and spread of FMD?

6. *Comment on Responses of the Experts to Question 1*: The United States takes note of the experts' statements that foot and mouth disease ("FMD") is one of the most contagious animal diseases and the experts' description of the potential pathways for the introduction and spread of FMD as described in their answers. These factual matters are fully supported by the exhibits cited in Part III.A of the U.S. First Written Submission.[10]

Question 2: Can FMD be transmitted through food waste?

a. Is there a general scientific understanding of the likelihood of transmission of FMD via food waste?

b. What measures are available in order to effectively prevent or mitigate the introduction of FMD through food waste?

c. Is there evidence on the record to indicate the likelihood that Argentine exports of fresh (chilled or frozen) beef to the United States would include infected food waste could come from exports of fresh (chilled or frozen beef) from Argentina to the United States?[11]

7. The United States takes note of the experts' statements that the FMD virus can be transmitted through food waste. This fact is fully supported by the exhibits cited in Part III.A and Part III.C of the U.S. First Written Submission.[12]

8. *Comment on Responses of the Experts to Question 2(a)*: Dr. Cupit's response highlights an important, known risk of FMDV transmission associated with food waste. He explains that the level of virus in food waste depends on the amount of virus in the tissues (in the food) and

[8] *See, e.g.*, the responses of the experts to Panel Question No. 46.

[9] *See, e.g.*, the responses of the experts to Panel Questions Nos. 62, 63, 64, 65, and 66.

[10] *See, e.g.*, Exhibit USA-2.

[11] United States' response to Panel question No. 8, para. 16.

[12] *See, e.g.*, Exhibit USA-3.

that the virus can be present in a large range of organs and can remain in some tissues "for several weeks after the appearance of neutralizing antibodies."

9. *Comment on Responses of the Experts to Question 2(b):* The United States takes note of the experts' explanations of the methods by which the risk of introducing FMD through food waste can be reduced. These facts are fully supported by the exhibits cited in Part III.C of the U.S. First Written Submission.

10. *Comment on Responses of the Experts to Question 2(c)*: The United States notes that the experts' answers to Question 2(c) and Question 3 support that a likely scenario by which FMD could be introduced into the United States from Argentine imports of fresh beef is by feeding FMD contaminated products in pigs (garbage feeding).

Question 6: Is there any evidence of the transmission of FMD via the meat of vaccinated cattle?

11. *Comment on Responses of the Experts to Question 6*: The United States notes that the experts have interpreted this question as asking whether there have been verified cases where meat that was derived from a vaccinated cow has been shown to be the source of an FMD infection. Although no verified cases have been submitted on the record in this dispute, the United States notes that Dr. Cupit's answer suggests that there is indeed a risk under certain circumstances that imported beef derived from vaccinated cattle could transmit FMD if the vaccinated animal was infected by FMD.[13]

Question 7: Is there any evidence that deboned and matured fresh beef can result in transmission of FMD?

12. *Comment on Responses of the Experts to Question 7*: The United States notes that the response of Dr. Cupit supports that deboning and maturation must be performed properly in order to result in the inactivation of FMDV and the reduction of the risk of transmission.[14] As the United States discussed previously, "if meat is not properly deboned and matured, and visible clots and lymph nodes are not removed, [the] FMD virus will remain[.]"[15]

13. The United States notes that the experts have interpreted this question as asking whether there have been verified cases where deboned and matured fresh beef has been shown to be the source of an FMD infection. Although no such cases have been submitted on the record in this dispute, the more pertinent issue is whether there is a risk of FMD transmission from deboned and matured fresh beef derived from an animal that has been infected with FMD. On this issue, Dr. Cupit's answer explains that "[t]he deboning and maturation of the carcase of infected cattle will greatly reduce the risk of viable FMDV being present in fresh (chilled or frozen) beef if

[13] Dr. Cupit's response to Panel Question No. 6, at para. 51.

[14] Dr. Cupit's response to Panel Question No. 7, at para. 65.

[15] U.S. response to Panel Question No. 8, at para. 21.

undertaken effectively. However it may not eliminate all FMDV if not conducted effectively and/or if the animal is heavily infected and/or febrile at the time of slaughter." [16]

Question 8: If an FMD-free without vaccination region (zone or compartment) borders or is wholly within a territory that is FMD-free with vaccination or FMD-infected what are the appropriate sanitary measures available to effectively prevent the introduction of FMD into the FMD-free without vaccination region?

14. *Comment on Responses of the Experts to Question 8*: The United States notes that the effectiveness of the measures identified by the experts depends largely on the capacity of the veterinary services implementing them.

Question 9: Please inform the Panel of the controls, if any, which may be performed on FMD suspected cattle prior to slaughter for export. In your answer, please clarify the underlying justification for the control(s).

15. *Comment on Responses of the Experts to Question 9*: The United States notes that the effectiveness of the measures identified by the experts depends largely on the capacity of the veterinary services implementing them, as well as the operating procedures and controls within slaughterhouses.

2.2 Vaccination

Question 10: What is the likelihood of an individual animal having a limited immunological response to the vaccine resulting in partial or no immunity?

16. *Comment on Responses of the Experts to Question 10*: The United States notes that the responses of the experts support that an individual animal may have a limited immunological response to FMD vaccination, which could result in partial or no immunity. The United States discussed this in its First Written Submission at paragraph 299 and provided record evidence. As Dr. Cupit and Dr. Bonbon explain, the likelihood of an individual animal having such a response is influenced by the way the vaccination is done. Dr. Batho also recognizes that an animal could have conditions that would impair its ability to develop immunity after vaccination.

Question 11: Is there any evidence that such partially immune animals may have longer incubation times and may not show normal disease symptoms, and that consequently, FMD in these animals (or their carcasses) may not be detected? [17]

17. *Comment on Responses of the Experts to Question 11*: The United States notes that all the experts agree that partially immune animals could have FMD and yet not be detected.[18] The

[16] Dr. Cupit's response to Panel Question No. 7, at para. 65.

[17] See Exhibit ARG-65, p. 14.

[18] Dr. Cupit's response to Panel Question No. 11, at para. 82; Dr. Batho's response to Panel Question No. 11, at para. 84; Dr. Bonbon's response to Panel Question No. 11, at para. 85.

United States discussed this in its First Written Submission at paragraph 299 and provided record evidence.

Question 12: With reference to Exhibit ARG-65, the US risk assessment of Uruguay, what is the likelihood that FMD can exist in a vaccinated population and remain undetected for some time? What mitigating measures could be put in place to ensure that infected meat from infected but asymptomatic cattle is not exported?

18. *Comment on Responses of the Experts to Question 12*: The United States observes that the experts agreed in their responses to Question 10 and Question 11 that a vaccinated animal could become infected with FMD. The United States notes that Dr. Cupit and Dr. Bonbon both state that vaccinated animals with FMD could be undetected.[19] This is consistent with the discussion in the First Written Submission of the United States at paragraph 299 and the accompanying record evidence. The United States notes that maturation and deboning can mitigate the risk that FMD infected meat is exported, if implemented correctly, as discussed in paragraph 21 of the Responses of the United States to the Panel's Questions Following the First Panel Meeting. In addition, the United States notes that no mitigation can ensure with 100 percent certainty that infected meat is not exported (zero risk).

Question 14: Are there any measures able to ensure that all animals being vaccinated develop the proper immunity to FMD?

19. *Comment on Responses of the Experts to Question 14*: The United States notes that Dr. Cupit and Dr. Batho both state that it is impossible to ensure that all animals being vaccinated develop the proper immunity to FMD.[20]

Question 15: Where an animal is administered the vaccine, is it possible that immunity to FMD may not develop for several weeks, during which time the animal could become infected?

20. *Comment on Responses of the Experts to Question 15:* The United States notes that the responses of the experts support the fact – as the United States stated in its First Written Submission at paragraphs 31 and 299 and in paragraphs 27 through 29 of its Responses to the Panel's Questions Following the First Panel Meeting – that immunity to FMD may not develop for several weeks after an animal is administered the vaccine and may not develop a sufficient immune response at all, and that "the animal can be infected at any time after vaccination."[21] Dr. Cupit explained that "[v]accinated animals may become infected, but clinical signs are generally

[19] Dr. Cupit's response to Panel Question No. 12, at para. 86; Dr. Batho's response to Panel Question No. 11, at para. 84; Dr. Bonbon's response to Panel Question No. 12, at para. 93.

[20] Dr. Cupit's response to Panel Question No. 14, at para. 124; Dr. Batho's response to Panel Question No. 14, at para. 125.

[21] Dr. Bonbon's response to Panel Question No. 15, at para. 132.

masked. Because they can still become infected, vaccinated animals should be subject to biosecurity and movement controls."[22]

Question 21: Based on the evidence on the record before the Panel, can one reasonably conclude that the vaccines used by Argentina and Uruguay comply with the standards set forth in the OIE Terrestrial Manual, including, but not limited to, those in Chapter 2.1.5?

21. *Comment on Responses of the Experts to Question 21:* The United States notes Dr. Cupit's conclusion that evidence in the record is insufficient to reach the conclusion suggested in Question 21. Dr. Batho refers to record evidence that does not appear to address the question posed. Dr. Bonbon's response appears to refer to documents not in the record.

Question 25: Is there any evidence that products derived from vaccinated cattle present a higher risk of transmission than those from un-vaccinated cattle?

a. If so, are there different mitigating measures available to apply to fresh (chilled or frozen) beef from regions where vaccination is practiced?

b. Would the mitigating measures adopted in 9 CFR 92.22 (Exhibit ARG-71) reduce the risk of transmission of fresh (chilled or frozen) beef originating in a country that vaccinates against FMD?

22. *Comment on Responses of the Experts to Question 25(b)*:[23] The United States agrees with the responses of the experts to the extent that the responses state that mitigation measures reflected in 9 C.F.R. § 92.22 can reduce the likelihood of transmission of the FMD virus when applied correctly. That is indeed the intent of this provision. The United States notes, however, that one of Dr. Bonbon's characterizations – that the measures in 9 C.F.R. § 92.22 avoid "any possibility of virus being present in the exported beef"[24] – is an overstatement, given that no control measure can reduce risk to zero.

2.3. Veterinary services, surveillance, and control measures

Question 30: What is the relevance, if any, of a system of external or internal audits of veterinary practices (including surveillance and control measures) to an assessment of the ability of a national authority to detect and control FMD?

23. *Comment on Responses of the Experts to Question 30*: The United States notes that all the experts agree that a system of external or internal audits of veterinary practices (including

[22] Dr. Cupit's response to Panel Question No. 15, at para. 129.

[23] The United States has no comment at this time to the experts' responses to Question 25 before the subparts and to Question 25(a).

[24] Dr. Bonbon's response to Panel Question No. 25(b), at para. 204.

surveillance and control measures) is relevant to an assessment of the ability of a national authority to detect and control FMD.

Question 31: Is there any reason to believe that conclusions with respect to SENASA's capability in Patagonia in USA-133 would be any different for the Argentine territory as a whole? Are the conclusions with respect to SENASA's capabilities in Exhibit USA-133 similar to those reached by the European Union in Exhibits ARG-110 and ARG-111?

24. *Comment on Responses of the Experts to Question 31*: The United States notes that Exhibit USA-133 was a risk assessment that focused specifically on the Patagonia region, which Argentina asserts is FMD free without vaccination. The risk assessment thus addressed SENASA's capabilities in Patagonia and with respect to a claim of disease free status. There was no reason for the document to address SENASA's capabilities in the rest of the Argentine territory, or with respect to a vaccination program. Indeed, the rest of the Argentine territory is alleged to be FMD free with vaccination. And as such, the demands on SENASA, including implementation of the FMD program including vaccination and surveillance activities, in that region go beyond what is required for Patagonia. Thus, while the Patagonia risk assessment perhaps could serve as a starting point for a further assessment, a separate assessment would nevertheless be required to determine SENASA's capabilities with respect to the rest of the Argentine territory.

25. The United States also notes Dr. Bonbon's statement that the U.S. and EU documents identified by the Panel only draw conclusions about SENASA compliance with respect to their respective requirements.[25]

Question 32: With reference to Exhibits USA-62 and USA-109 (SENASA Resolutions Nos. 148 and 1282, respectively) please describe whether and how the measures would improve SENASA's capacity with respect to FMD surveillance and control from that discussed in Exhibit ARG-28?

26. *Comment on Responses of the Experts to Question 32:* The responses of the experts support the fact that SENASA Resolutions 148 and 1282 were changes to measures that existed prior to those resolutions. The United States also notes the responses of the experts as to whether and how the measures improved SENASA's capacity is based upon the premise that the measure's effectiveness would require an assessment.

When answering the following questions please refer to the evidence on the record regarding the FMD situation in Uruguay, Japan and Argentina (Exhibits ARG-9, ARG-27/USA-35, ARG-28, ARG-65, ARG-88/USA-127, ARG-110, ARG-111, and USA-133):

Question 34: What are the differences and similarities between the active surveillance on the national level in Argentina and Uruguay, and Argentina and Japan? Based on the information on the record, is it possible to determine whether the FMD surveillance

[25] Dr. Bonbon's response to Panel Question No. 31, at para. 256.

programme in Argentina is similar to those in Uruguay and Japan in both design and efficacy?

27. *Comment on Responses of the Experts to Question 34:* The United States has several concerns with Dr. Bonbon's conclusory statement that, based merely upon OIE recognition, "one can assume that . . . surveillance programmes had comparable efficacy."[26] First, Dr. Bonbon's response is an assumption, without factual support. Second, the assumption goes not to any scientific issue, but rather goes to the issue of what types of considerations underlie the OIE recognition. Third, and perhaps most importantly, as the United States explained at length in its comments on the responses of the OIE staff,[27] the OIE process currently suffers from a lack of transparency. Neither OIE Members, nor outside scientific experts, are allowed to see the work product of the OIE teams that prepare the country assessments. Without such information, no comparisons may properly be drawn between different territories simply based on their OIE disease status. Rather, OIE recognition is a determination by the OIE that a country's (or region's) surveillance program has met some minimum level of efficacy as required by the OIE to achieve a certain disease status. That reference point by itself does not provide sufficient information to compare countries'/region' surveillance programs to each other to determine if they meet an importing country's required level of efficacy.

Question 35: What are the differences and similarities between the animal identification and census information taken in connection with FMD vaccination between Argentina and Uruguay, and Argentina and Japan? Based on the information on the record, is it possible to determine whether the animal identification and census information taken in connection with FMD vaccination in Argentina is similar to those in Uruguay and Japan in both design and efficacy?

28. *Comment on Responses of the Experts to Question 35:* With respect to Dr. Bonbon's statement that the same OIE recognition for countries means that measures in all countries with that recognition "should be deemed equivalent in terms of result,"[28] the United States' refers to the U.S. comment to question 34.

Question 36: What are the differences and similarities between the movement controls (traceability, control of animal movement – internal and international) on the national level in Argentina and Uruguay, Argentina and Japan? Based on the information on the record, is it possible to determine whether the movement controls in Argentina is similar to those in Uruguay and Japan in both design and efficacy?

29. *Comment on Responses of the Experts to Question 36:* With respect to Dr. Bonbon's discussion of efficacy, the United States refers the Panel to its comment on the responses of the experts to question 34.

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[26] Dr. Bonbon's response to Panel Question No. 34, at para. 280.

[27] *See* U.S. Comments on the OIE staff's response to Question 13.

[28] Dr. Bonbon's response to Panel Question No. 35, para. 286.

Question 37: Based on your reading of the exhibits on the record, do you consider that, as of today, SENASA has similar or identical capacity to prevent and control FMD outbreaks in Argentina as the veterinary authorities in Uruguay or Japan do for their own territory?

30. *Comment on Responses of the Experts to Question 37:* To the extent that Dr. Bonbon's response to this question is based on a premise that equivalent OIE FMD status recognitions imply equivalent capacity to prevent and control FMD outbreaks, the United States refers to its comments in question 34.

When answering the following questions, please refer to the evidence on the record for Patagonia and Santa Catarina (Brazil) (Exhibits ARG-9, USA-133, ARG-7):

Question 38: What are the differences and similarities between the active surveillance in Patagonia and Santa Catarina (Brazil)? Based on the information on the record, is it possible to determine whether the FMD surveillance programme in Patagonia is similar to that in Santa Catarina (Brazil) in both design and efficacy?

31. *Comment on Responses of the Experts to Question 38:* To the extent that Dr. Bonbon's response to this question is based on a premise that equivalent OIE FMD status recognitions imply equivalent efficacy, the United States does not agree, and refers to its comment in question 34.

Question 39: What are the differences and similarities between the animal identification and census information taken in connection with FMD vaccination between Patagonia and Santa Catarina (Brazil)? Based on the information on the record, is it possible to determine whether the animal identification and census information taken in connection with FMD vaccination in Patagonia is similar to that in Santa Catarina (Brazil) in both design and efficacy?

32. *Comment on Responses of the Experts to Question 39:* To the extent that Dr. Bonbon's response to this question is based on a premise that equivalent OIE FMD status recognitions imply equivalent efficacy, the United States refers to its comment in questions 34.

Question 40: What are the differences and similarities between the movement controls (traceability, control of animal movement – internal and international) in Patagonia and Santa Catarina (Brazil)? Based on the information on the record, is it possible to determine whether the movement controls in Patagonia is similar to that in Santa Catarina (Brazil) in both design and efficacy?

33. *Comment on Responses of the Experts to Question 40:* To the extent that Dr. Bonbon's response to this question is based on a premise that equivalent OIE FMD status recognitions imply equivalent efficacy, the United States refers to its comments in question 34.

2.4. Slaughterhouse Procedures

Question 41: With respect to maturation and deboning of beef:

a. How effective is the technique of maturing and deboning of beef in reducing or eliminating the risk that the beef may transmit FMD.[29] In particular, how effective is the technique of deboning and maturation in removing the FMD virus from meat?

34. *Comment on Responses of the Experts to Question 41(a):* The responses of the experts reflect a general understanding that deboning and maturation, when properly performed, can mitigate the risk of FMDV transmission. The United States notes Dr. Bonbon's statement that the effectiveness of maturation and deboning is dependent on the effectiveness of the "relevant technical, legal and organisational environment[.]" He states: "That is why it is not used as a single risk mitigation measure and should be applied by competent people, in conjunction with farm status certification, vaccination, ante- and post-mortem inspection, etc. . . ."[30]

35. In response to Dr. Bonbon's statement regarding the U.S. understanding of the OIE Code,[31] the United States notes that its response to Panel question no. 8, paragraph 22 stated that deboning and maturation are not available approaches under Article 8.6.26 for countries or zones that are FMD infected. This article is titled: "Recommendations for importation from FMD infected countries or zones." The United States observes that deboning and maturation are permitted for FMD-infected countries and zones "where an official control program for FMD, involving compulsory systematic vaccination of cattle, exists" in Article 8.6.25, which the United States noted at paragraph 190 in its Responses to the Panel's Question Following the First Panel Meeting.

b. Would your answer to (a) be different depending on the following scenarios, and if so how:

i. The beef was matured and deboned according to Article 8.5.25 of the Terrestrial Code;

ii. The beef was deboned and matured at a temperature above +2˚C for 24 hours after slaughter, in which the pH level reaches a value below

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[29] United States' response to Panel question No. 8, para. 21.

[30] Dr. Bonbon's response to Panel Question No. 41(a), at para. 340.

[31] "Contrary to the United States' response to Panel question No. 8, para. 22, the OIE Code does use this technique as an available option for export when a country or zone is FMD infected, together with other conditions." Dr. Bonbon's response to Panel Question No. 41(a), at para. 340.

6.0, measured in the centre of the muscle *Longissimus* dorsi, without lymphatic nodules, bones or clots;

iii. The beef was deboned and matured at a temperature above 40 to 50˚F (4 to 10˚C), for a minimum of 36 hours after slaughter, that reached a pH level of 5.8 or less in the loin muscle at the end of the maturation period, without lymphatic nodules, bones or clots.

36. *Comment on Responses of the Experts to Question 41(b)(i) – (iii)*: The United States notes that the responses of the experts support that the that the mitigation measures proposed in sub-questions (b)(i) – (iii) would require proper application in order to reduce the risk that beef would transmit FMD. The United States also takes note of Dr. Cupit's and Dr. Bonbon's statements that these mitigations should not be taken alone and should be used in combination with other risk control measures for FMD.[32]

c. Is it possible that maturation and deboning may fail to remove the virus from exported meat that may be derived from infected asymptomatic animals? What is the likelihood of there being infected asymptomatic animals in a vaccinated herd? Are there other mitigating measures that could be put into place to address this possibility?[33]

37. *Comment on Responses of the Experts to Question 41(c):* The United States notes the statements by Dr. Cupit that "the likelihood of there being infected asymptomatic animals in a vaccinated herd" depends on various factors, including the epidemiological situation in the environment in question.[34] This further reinforces the importance of and the need to perform site visits to assess the epidemiological situations of countries and regions that vaccinate for FMD.

Question 45: With reference to Exhibits USA-133, ARG-28, ARG-110 and ARG-111, is there any reason to believe that the slaughterhouse procedures used in the entire Argentine territory are different from those used in Patagonia?

38. *Comment on Responses of the Experts to Question 45*: The United States notes Dr. Cupit's response that Exhibit USA-133 did not discuss specific FMD control procedures used in slaughterhouses in Patagonia,[35] which Argentina contends is FMD free without vaccination. The United States observes that Exhibits ARG-110 and ARG-111 refer to FMD controls in slaughterhouses in Argentina, but those documents do not appear to indicate the location of those slaughterhouses. Given that Argentina vaccinates in areas outside of Patagonia, it cannot be

[32] Dr. Bonbon's response to Panel Question No. 41(a), at para. 340; Dr. Cupit's response to Panel Question No. 41(b)(i), at para. 342; Dr. Cupit's response to Panel Question No. 41(b)(ii), at para. 347; Dr. Cupit's response to Panel Question No. 41(c), at para. 350.

[33] *See, e.g.*, Exhibit ARG-65.

[34] Dr. Cupit's response to Panel Question No. 41(c), at para. 354.

[35] Dr. Cupit's response to Panel Question No. 45, at para. 379.

assumed that the procedures used in the entire Argentine territory are the same as and limited to those used in Patagonia.

2.5. Risk Assessment

Question 47: What is the scientifically recommended waiting period following an FMD outbreak that is sufficient to provide the minimum amount of epidemiological data for conducting a risk assessment of a country or region for the purposes of determining whether the country or region is free of FMD?

a. In your answer, please consider the distinct scenarios where a country or region was FMD-free with vaccination and FMD-free without vaccination.

b. Would the ability to conduct a risk assessment be impacted by changes in the legislative or regulatory framework in the exporting country relating to control of the disease?

c. If yes, would such legislative or regulatory changes impact on the waiting period between the outbreak and the time to conduct the risk assessment?

d. To what extent does a country or region's history of FMD outbreaks, including the size and frequency of such outbreaks, affect the recommended waiting period after an FMD outbreak before conducting a risk assessment to determine whether the country or region is free of FMD?

39. *Comment on Responses of the Experts to Question 47:* The United States notes that the waiting period for developing minimum data to initiate a risk assessment should be distinguished from the amount of time necessary for an importing country to evaluate an application for FMD-free status recognition.

Question 48: Can a risk assessment be completed using different assumptions or scenarios to take into account possible changes in the control measures in place?

40. *Comment on Responses of the Experts to Question 48*: The United States notes that this question refers to the use of assumptions in a risk assessment, not to the time it takes to complete a risk assessment. While a risk assessor may use appropriate assumptions in performing a risk assessment, the United States notes that the experts also state that changes to an input or factor that is considered in a risk assessment could make a difference in the time taken to finalize a risk assessment and therefore make a decision.[36]

2.6. Mitigating Measures

[36] *See* Dr. Batho's response to Panel Question No. 47, at para. 395; Dr. Cupit's response to Panel Question No. 47(b), at paras. 402 and 403; Dr. Cupit's response to Panel Question No. 47(c), at para. 405; Dr. Bonbon's response to Panel Question No. 47(b), at para. 404; Dr. Bonbon's response to Panel Question No. 47(c), at para. 406.

Please answer the following questions with reference to the sanitary protocols set forth in 9 CFR 9422 (Exhibit ARG-71):

Question 61: We note that this protocol establishes 11 distinct requirements (9 CFR 94.22(a)-(k)). Please explain the effect each requirement has in reducing or eliminating the risk that imports of fresh (frozen or chilled) beef may transmit FMD.

41. *Comment on Responses of Experts to Question 61*: The United States notes that each of the experts support that the requirements of 9 CFR 94.22 reduce the likelihood that imports of fresh (frozen or chilled) beef may transmit FMD.

Question 64: Given your answer to questions 62. and 63. is there any evidence on the record that would indicate that the protocols in 9 CFR 94.22 when applied to fresh (frozen or chilled) beef from the Argentine territory north of río Negro would result in those products posing the same level of risk as products from Uruguay subject to the same protocols?

42. *Comment on Responses of Experts to Question 64*: As indicated in the introduction to this submission, this question either calls for the experts to conduct a risk assessment, or asks for "any evidence." The former is not appropriate and the latter is not a useful exercise, since the differences in appropriate control measures would depend on differences between the regions, and not simply upon similarities.

Question 65: Would application of the recommendations in Articles 8.5.23 and 8.5.24 of the Terrestrial Code for importation from FMD free countries or zones where vaccination is practised to Argentina achieve the same level of protection as that achieved via the application of (i) 9 CFR 94.22 to Uruguay; or (ii) the application of the protocols applicable to for Japan? (see e.g., Exhibits ARG-20 and ARG-88/USA-127)?

43. *Comment on Responses of Experts to Question 65:* The United States notes that the experts' responses to this question, taken together with the experts' responses to Questions 61 and 66, support that the application of 9 CFR § 94.22 reduces the level of FMD risk from imported meat. In addition the United States would like to clarify that the protocol for Japan referenced in this question is connected to risk mitigations related to BSE and is set forth in 9 CFR § 94.27. This protocol is not related to FMD.