Japan – Measures Affecting the Importation of Apples

(WT/DS245)

Answers of the United States of America
to Questions from the Panel

November 13, 2002

QUESTIONS TO BOTH PARTIES:

1. Are varieties of apples grown in Japan considered to be resistant cultivars?

1. Fuji apple is the most popular variety harvested in Japan (approximately 55 percent of the total harvest), followed by Tsugaru apple (approximately 13 percent), Jonagold (approximately 9 percent) and Orin (approximately 9 percent); other popular varieties include Mutsu, Hokuto, Kogyoku, and Delicious. Generally, the varieties of apple trees grown in Japan are considered to be susceptible cultivars; many were bred from at least one parent that is susceptible to fire blight. The varieties Red Delicious and Golden Delicious are less susceptible to fire blight, but production of these apples has declined in Japan.[1]

2. Can you confirm that the fruit as described in the submission by New Zealand, paragraph 4.18, is what is actually being proposed for export, e.g., "healthy looking mature fruit" or "symptomless mature fruit"?

2. As stated in response to a question by the Panel at the first substantive meeting with the parties, the United States agrees with New Zealand's description of the exported commodity as "mature fruit." Fruit are harvested when they have reached horticultural maturity (at or after the point of physiological maturity)[2] because only mature fruit will ripen and develop the characteristics desired by consumers. Harvested immature fruit will not develop into physiologically mature fruit and thus will not ripen, rendering them unsaleable. Furthermore, there is no scientific evidence that mature fruit in an orchard will be infected; fire blight infected fruit "fail to develop fully, turning brown to black, shriveling, and becoming mummified, frequently remaining attached to the limb."[3] Thus, a mature fruit harvested from an orchard will not be infected and, therefore, will be symptomless.

3. The United States further notes that the commodity as currently exported consists of mature apple fruit. Under U.S. law, exported apples must be "mature but not overripe."[4] "Mature," in turn, is defined as "the stage of development which will insure the proper completion of the ripening process."[5] Thus, the fruit being proposed for export consists of the same fruit that is exported to every U.S. export market.

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[1]Information on the most common varieties grow in Aomori prefecture (Japan's largest apple-growing area) may be found at http://www.pref.aomori.jp/nourin/ringo/rin-e02.html.

[2]For further information, please see U.S. Reply to Question 19 from the Panel.

[3]U.S. First Written Submission, para. 12; *see, e.g.*, European and Mediterranean Plant Protection Organization (EPPO), *Data Sheet on Quarantine Pests:* Erwinia amylovora, Quarantine for Europe, at 1-4 (1997) (Exhibit USA-5).

[4]United States Standards for Grades of Apples, 7 C.F.R. § 51.302. For further description of the requirements under U.S. law for exported apples, please see U.S. First Written Submission, fn. 38.

[5]United States Standards for Grades of Apples, 7 C.F.R. § 51.313; *see* U.S. First Written Submission, fn. 39.

3. What significance do the OECD Guidelines (identified in the submission by New Zealand at paragraph 4.40) regarding the maturity and ripeness of fruit have for the dispute at hand?

4. The OECD guidelines specify several methods and instruments that can be used for the determination of horticultural (or commercial) maturity of apple fruit. Of the four methods given in the OECD guidelines, three are routinely used by growers, fieldmen, and packinghouse personnel to determine correct harvest maturity: firmness, soluble solids, and starch. After apple fruit pass physiological maturity and they begin to ripen (through the effect of the plant hormone ethylene), starch within the fruit begins to be converted into sugars. Thus, as apple fruit approach optimum horticultural maturity, firmness values will be declining, starch levels will be declining, and the soluble solids values will be increasing. As reflected in the OECD guidelines, fruit samples are evaluated sequentially during the pre-harvest and harvest period to determine the point at which the fruit exhibits a combination of firmness, soluble solids, and starch index values that are optimum for the proposed use of the fruit, which can include immediate sale on the fresh market, regular atmosphere cold storage, or short- to long-term controlled atmosphere storage. Growers in the apple-producing areas of Washington State, for example, utilize such procedures for determining the horticultural (or commercial) maturity of apple fruit.[6]

4. How long does it take a fruit infected with E. amylovora to show signs of infection? To exude bacterial ooze? Could fruit that was healthy-looking when packed for shipping develop fire blight during shipment to Japan?

5. The scientific evidence demonstrates that mature apple fruit harvested from an orchard are not infected and do not, in fact, develop fire blight disease. Thus, there is no evidence that a mature fruit, which will be symptomless when harvested, could subsequently develop fire blight. It bears emphasizing as well that harvested fruit will only be packed and exported if it is "healthy-looking" when sorted, inspected, and graded.[7]

6. An infected immature apple fruit will show symptoms of infection because the interaction between the pathogen (*E. amylovora*) and the host fruit – that is, the infection – produces the symptoms that are characteristic of fire blight. The length of time from onset of infection to production of bacterial ooze in immature orchard fruit will vary with environmental conditions. We note that laboratory experiments to determine the length of time between inoculation and symptoms of infection must wound the fruit (for example, through stab inoculation) in order to introduce the bacteria, and damaged fruit are more susceptible to disease.

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[6]E. Kupferman, Washington State University, *Maturity, Storage and Handling of Washington Apples: A Primer* (2002) (Exhibit USA-25).

[7]E. Kupferman, Washington State University, *Maturity, Storage and Handling of Washington Apples: A Primer* (2002) (Exhibit USA-25).

7. More significant to this dispute, however, is the scientific evidence that mature apples are highly resistant to development of disease. As Dueck (1974) reported:

> *Mature apples are highly resistant to infection*. Only when high numbers of bacteria were *forcibly introduced into the cortex* [by means of a hypodermic syringe] was fruit infected. The long incubation period may have been partly due to the low temperature. It appeared that the bacteria could survive in storage as long as the fruit was physiologically sound. This presents an anomaly because under orchard conditions apples, particularly resistant cultivars, are not infected. Furthermore, *apples from severely infected trees of a susceptible cultivar, having been exposed to high levels of inoculum during the growing season, were free of the bacterium* [internally and externally] *at harvest time*.[8]

Similarly, in the joint U.S.-Japan study of 2000, 30,000 horticulturally mature apple fruit harvested at varying distances from severely blighted trees at two Washington sites and stored for up to 4 months did not develop any fire blight disease (or even contain the bacterium internally).[9] Another experiment (Roberts *et al.* (1989)), conducted in two years in which fire blight was severe in Washington State, also evaluated mature apple fruit for the presence of the fire blight bacterium and produced results identical to those from the joint 2000 study; no fire blight bacteria were detected inside mature fruit, and no fire blight disease developed during the period of cold storage.[10] Therefore, the scientific evidence demonstrates that harvested mature apple fruit do not develop fire blight, and the hypothetical likelihood of such "healthy-looking" fruit developing fire blight during shipment to Japan is so extremely low as to approach zero.

> *5. Please provide a description or flow-chart showing the pathway of events that would be necessary for fresh apples from the United States to result in the establishment of fire blight in Japan. The Panel notes that Exhibit JPN-14 provides an illustration of the pathway of infection following importation of infected apples into Japan. The US may wish to comment on this illustration.*

8. The United States has attached a diagram (Exhibit USA-26) showing the steps that must be completed for imported apple fruit to serve as a pathway. These steps are: (1) apple fruit must be externally or internally contaminated with fire blight bacteria; (2) the bacteria must survive harvest, commercial handling, and storage conditions; (3) the bacteria must survive transport

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[8] J. Dueck, *Survival of* Erwinia amylovora *in association with mature apple fruit*, Can. J. Plant Sci. 54: 349-51, at 351 (1974) (emphasis added); *see* U.S. First Written Submission, para. 33.

[9] R.G. Roberts, *Evaluation of buffer zone size on the incidence of* Erwinia amylovora *in mature apple fruit and associated phytosanitary risk*, Acta Horticulturae (forthcoming 2002) (Proceedings of Ninth International Fire Blight Workshop) (Exhibit USA-16); *see* U.S. First Written Submission, para. 33.

[10] R.G. Roberts *et al.*, *Evaluation of mature apple fruit from Washington State for the presence of* Erwinia amylovora, Plant Disease 73: 917-21 (1989) (Exhibit USA-28); *see* U.S. First Written Submission, para. 33.

(including cool storage), handling, and discard conditions (including consumption); (4) the apple fruit must be discarded near a host plant; (5) the host must be at a receptive stage (that is, able to be infected); (6) the bacteria must be transferred from the discarded, contaminated fruit to a susceptible host; and (7) suitable conditions must exist for infection to occur and fire blight to develop.

9. As explained in more detail in the U.S. first written submission,[11] the scientific evidence demonstrates that steps in the hypothetical pathway will either not be or are very unlikely to be completed. For example, in step (1) described above, there is no scientific evidence that endophytic (internal) fire blight bacteria have been recovered from mature apple fruit harvested from an orchard. The scientific evidence also demonstrates that epiphytic bacteria will very rarely be recovered from such fruit, even when harvested from blighted trees and orchards. The scientific evidence establishes that any surviving epiphytic bacteria are extremely unlikely to survive steps (2) and (3) above relating to harvest, commercial handling, storage, transport, retail distribution, and consumption and discard. The scientific evidence establishes that the effect of cool storage *alone* (for example, through the 55-day cold treatment Japan requires for codling moth) makes very unlikely the probability of survival of any epiphytic bacteria. In addition, for step (6), there is no scientific evidence of any vector to transfer any hypothetically surviving bacteria from a discarded fruit to a susceptible host. Thus, the scientific evidence establishes that apple fruit do not serve as a pathway because necessary steps will not be completed.

10. The United States has attached as Exhibit USA-27 its comments on the diagram provided in JPN-14; here, we provide a narrative description of how Exhibit JPN-14 is a wholly inadequate effort by Japan to assert that it has evaluated the likelihood of the pathway being completed. The inadequacy of Japan's analysis is evident even in reading the title: "*Probability* of fire blight dissemination via mature, apparently healthy apple fruit." However, Exhibit JPN-14 does not establish a probability of dissemination because it presents no evidence as to the *likelihood* that each step would be completed. The subtitle for the exhibit, "Disseminated by bacterial ooze," is a baseless assertion; there is no scientific evidence cited in support, and the steps laid out in the pathway *make no mention* of the role of bacterial ooze at any point. Finally, Japan's exhibit does not present scientific evidence establishing the likelihood of *any* of the steps it has identified, and it also omits several necessary steps.

11. Consider where Japan begins: "Mature, apparently healthy but infected fruit." Given that the next step in Japan's hypothetical pathway is "discard," one must *assume* the fruit arrives in the hands of consumer or retailer in Japan as "mature, apparently healthy but infected." That is, Japan has not identified the necessary step that harvested mature fruit be contaminated with

[11] U.S. First Written Submission, paras. 29-45 (Section IV.A.4: The Scientific Evidence Underlying the Fact That Mature, Symptomless Apples Do Not Serve As a Pathway for the Disease).

bacteria,[12] nor has Japan presented the "probability" of that step being completed. Japan has failed to identify necessary intermediate steps that bacteria on such contaminated fruit must survive, such as harvest, commercial handling, cool storage, cool storage in transport, and retail distribution within Japan.[13] Japan has also not evaluated the "probability" of those steps being completed. We also note that even for the steps Japan has identified, there is no evaluation of the likelihood that each step would be completed. Thus, Japan's exhibit falls far short of either a presentation of the steps comprising a pathway or a presentation of the probability that the pathway would be completed.

12. Even the steps Japan *has* identified are not supported by any scientific evidence. Again, consider the first step in Japan's hypothetical pathway: "Mature, apparently healthy but infected fruit." There is no scientific evidence to support the notion that "mature, apparently healthy but infected fruit" exist. The citation in the exhibit to van der Zwet *et al.* (1990) is indicative of the lack of support for Japan's assertion as this paper does *not* provide "[e]vidence of *Erwinia amylovora* infection with apple fruit" (or, more precisely, the "mature" apple fruit which constitute the hypothetical pathway). No experiment reported in this paper establishes that *E. amylovora* was the cause of fire blight infection in any mature, harvested fruit. Thus, the very first step in Japan's hypothetical pathway is not supported by any scientific evidence.

13. Japan's hypothetical pathway also contains the step that bacteria from "[i]nfected apple fruit placed in fields" would be transferred by birds, flying insects, or wind and rain to host plants. As stated above, there is no scientific evidence to support the notion that imported mature apple fruit would be infected. There is also no scientific evidence of any vector to transfer any hypothetically surviving bacteria from a discarded fruit to a susceptible host. Japan's citation to van der Zwet & Keil (1979) is inapt as the "[e]vidence of *Erwinia amylovora* dissemination by insects, birds, wind, and rain" refers to dissemination of bacteria from diseased host plants. There is no evidence that "insects, birds, wind, and rain" would transfer bacteria from epiphytically contaminated and discarded fruit; in fact, the scientific evidence establishes that there is no vectoring of epiphytic bacteria from contaminated, discarded fruit. Again, Japan's assertion is simply unsupported.

6. What is the projected volume of US exports of fresh mature apples to Japan (or Japanese imports from the United States) per year in the absence of any restrictions relating to fire blight prevention? What is the volume of US exports of fresh apples, per destination?

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[12]This would correspond to step 2 of the IPPC analysis of the probability of entry. International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests § 2.2.1.2, at 13 (2001) (Probability of the pest being associated with the pathway at origin) (Exhibit USA-15).

[13]These would correspond to the third and fourth steps of the IPPC analysis of entry. International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests §§ 2.2.1.3 - 2.2.1.4, at 14 (2001) (Probability of survival of the pest during transport or storage; Probability of the pest surviving existing pest management procedures) (Exhibit USA-15).

14. The United States does not at this time have reliable estimates of the projected volume of U.S. apple exports to Japan in the absence of Japan's fire blight measures. We note that official U.S. export data show that exports to Japan were highest in calendar year 1995, representing 6,545 metric tons (or 30,231,355 apples).[14] However, exports have dramatically fallen since that time, and for the most recent year for which data are available (Marketing Year 2001-02), the United States exported only 116 metric tons of apples to Japan, or 535,827 apples. For purposes of comparison, the United States has gathered export data for Marketing Year 2001-02 showing the volume of apples (in metric tons and number of fruit) shipped to the top-40 U.S. export markets as well as Japan.[15]

7. What is the CIF price of US apples arriving in Japan and how does this compare with the landed price for US apples into a comparable East Asian location? What is the wholesale price for Japanese apples on the Japanese market?

15. Japanese customs data show that in 2001 the average unit price for imported U.S. apples was $1.38/kg. By way of comparison, data from China Customs reveals that the unit value for U.S. apples imported into China was $0.43/kg, and data from Chinese Taipei (Directorate General of Customs) show an average unit price for U.S. apples of $0.53/kg in 2001. According to reporting by the U.S. Department of Agriculture, wholesale prices for Japanese apples on the Japanese market averaged $2.48/kg in 2001 and $2.64/kg over 1999-2001. The United States attaches a table presenting Japanese wholesale prices for Japanese apples and average unit value for U.S. and Japanese apples in 3 East Asian markets for 1999-2001.[16]

16. The United States also notes that these customs data reveal a wide discrepancy among unit values for imported Japanese apples, which could reflect differences in data collection, reporting, or calculation. Chinese customs data show that in 2001 the average unit value of Japanese apples in China averaged $7.76/kg while data from the Taiwan Directorate General of Customs shows that in 2001 the average unit value for Japanese apple prices was $1.62/kg.

8. Please provide any information available to you regarding Brazil's, Chile's and South Africa's phytosanitary regulations on imports of mature apples from countries where fire blight is endemic.

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[14] As in the calculations presented in the U.S. First Written Submission, assuming that an average apple is size 88 (that is, 88 apples per 42-lb. box), there are approximately 4,619 apple fruit in a metric ton.

[15] U.S. Apple Exports Volume, Marketing Year 2001-02 (Exhibit USA-29).

[16] Apple Prices in Selected East Asian Markets (Exhibit USA-30).

17. The phytosanitary requirements related to fire blight imposed by Brazil, Chile, and South Africa on U.S. apple fruit range from some to none.[17] Brazil requires a phytosanitary certificate with a declaration that either (1) fruit were treated with chlorine (100 parts per million for one minute) or (2) fruit were harvested in an area free from fire blight. Chile requires a phytosanitary certificate stating that fruit is free from *Erwinia amylovora*, and all fruit must be treated with chlorine (100 parts per million for one minute) or sodium orthophenyl phenate (3,400 to 4,900 parts per million for 2-4 minutes). South Africa has no fire blight restrictions for apple fruit but does not have an agreed export protocol. None of these WTO Members requires that exported fruit be harvested from fire blight-free orchards, none of these Members requires that a 500-meter fire blight-free buffer zone be maintained around such orchards, and none of these Members requires that such orchards and buffer zones be inspected 3 times yearly.

9. In its first submission, at paragraph 114, the United States claims that Japan substantially changed its SPS measure relating to fire blight since 1995 and did not notify the new measures. Please comment on this statement.

18. As stated in the U.S. submission, "Japan has substantively changed its fire blight measures since the entry into force of the SPS Agreement in 1995, and Japan has failed to notify these changes."[18] Japan has claimed that it notified the WTO "that it would designate *Erwinia amylovora* as one of the diseases that trigger import prohibition from April 1, 1997, in accordance with these provisions," and that "[t]he amendments to the Notification and the Detailed Rules in 1997 were technical re-phrasing of the regulations reflecting the designation of the bacterium."[19] However, the 1997 designation of *Erwinia amylovora* as a prohibited pest presumably would require amendment to the Annexed Table 2 of the Plant Protection Law Enforcement Regulations, not the 1994 MAFF Notification No. 1184 and related Detailed Rules. In fact, Japan does not deny that the current fire blight measures include MAFF Notification No. 354 and its accompanying Detailed Rules for U.S. Apples, promulgated in March and April 1997, respectively. Article 7 of the SPS Agreement requires that "Members shall notify changes in their sanitary and phytosanitary measures and shall provide information on their sanitary and phytosanitary measures in accordance with the provisions in Annex B." Thus, because Japan's 1994 fire blight measures were replaced with MAFF Notification No. 354 and the related Detailed Rules, these changes were required to be notified.

10. The "Report on Pest Risk Analysis on fire blight" submitted as Exhibit USA-3 and the "Report on Pest Risk Analysis concerning Fire Blight Pathogen (Erwinia amylovora) - Fresh apples produced in the United States" submitted as Exhibit JPN-32 are not

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[17]These restrictions or lack of restrictions are also presented in Exhibit USA-14 (table detailing fire blight measures on imported apples in fire blight-free areas).

[18]U.S. First Written Submission, paras. 114-17.

[19]Japanese First Written Submission, para. 224 (citation omitted).

identical. Please identify which of these is Japan's pest risk assessment and comment on any differences in the two texts.

19. The United States has compared the U.S. translation of the 1999 Japanese Pest Risk Analysis (Exhibit USA-3) and the Japanese translation of the same document (Exhibit JPN-32). There were minor difference in wording between the two translations, but these appear to be non-substantive differences as both appear to have similarly translated the Japanese original. (The U.S. translation does contain some phrases that were not used in the Japanese original document.)

11. Describe the difference between the IPPC standard on Pest Risk Analysis for Quarantine Pests of 1995 and that of 2001. Explain what significance this difference may have for the case at hand.

20. This question refers to two different standards under the International Plant Protection Convention that are, however, closely related. The 2001 standard presents guidelines for conducting a "Pest risk analysis for *quarantine* pests."[20] The 1996 standard presents "Guidelines for pest risk analysis" in general.[21] The former does not replace the latter; thus, they have been designated by the International Plant Protection Convention as *different* International Standards for Phytosanitary Measures. However, the two standards are related and present the same general framework for conducting a pest risk assessment (that is, evaluating the likelihood of entry, establishment, or spread of a pest as well as associated biological and economic consequences) and selecting appropriate pest risk management measures. Either standard helps make plain that Japan has not assessed the risk of introduction of fire blight through imported U.S. apple fruit consistent with its obligations under Article 5.1 of the SPS Agreement; therefore, any differences between the two standards are not significant to this dispute. For further explanation, please see the U.S. answer to Question 45 from the Panel.

12. In its first submission, at paragraph 220, Japan notes that the two experiments conducted in the US fail to provide scientific data for years of severe fire blight outbreaks. Does Japan however consider that the experiments DO provide relevant information with respect to years when there is NOT a severe outbreak of fire blight? How does Japan define "severe" fire blight outbreaks? To what extent do the levels of fire blight occurrence in 2000 differ from other years? Would the US please comment regarding Japan's statement in paragraph 220.

[20]International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests (2001) (International Standards for Phytosanitary Measures Publication No. 11) (Exhibit USA-15).

[21]International Plant Protection Convention, Guidelines for Pest Risk Analysis (1996) (International Standards for Phytosanitary Measures Publication No. 2) (Exhibit JPN-30).

21. In Paragraph 220 of its first submission, Japan asserts that the 2000 joint Japanese-U.S. experiments "fail[] to provide scientific data for years of severe fire blight outbreaks – or years when the occurrence of fire blight [is] substantially higher than in 2000." Japan's effort to diminish the results produced by the joint experiment undermines the credibility of its insistence that it would relax the fire blight measures if its scientists could "see the science for themselves." Japan's effort is also misguided, given that the joint experiment provided sound data that is entirely consistent with previous studies performed in Washington State and elsewhere.

22. The environmental conditions extant during the U.S.-Japan experiments of 2000 were, by and large, typical of those found in most growing seasons in Washington State.[22] Moreover, Japan's assertion in its submission that "we are unable to conclude with this evidence [from the joint 2000 experiment] that the proposed measure will be capable of preventing introduction of the bacterium during severe outbreaks of fire blight" – which implies that there is insufficient data – seeks to obscure the fact that the U.S. shared the Roberts *et al.* (1989) methods, data, and conclusions with Japan in 1988 (that is, even before publication) and discussed the data at bilateral meetings *from 1988 until 2002*. As previously noted,[23] this paper collected data on the incidence of *E. amylovora* associated with mature apple fruit from blighted orchards during two years when environmental conditions were conducive to fire blight development and severe blight occurred in the growing areas in central Washington.[24] Nonetheless, *no* fire blight bacteria were detected inside mature fruit, and *no* fire blight disease developed during the period of cold storage.[25]

23. The United States notes that paragraph 220 of Japan's first submission references paragraphs 88, 89, and 90 in the same document, which seek to characterize U.S. participation in the joint experiments of 2000 as deviating from the experimental design originally put forward by Japan. Japan asserts that the experimental data was not useful because of these "deviations by the United States." While the United States would not normally bring to the Panel's attention the details of bilateral technical discussions which have taken place, Japan's inaccurate characterizations of those discussions require that we make those details available.

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[22]*See, e.g.*, Exhibit USA-31 (graphs detailing 1997-2000 temperature, relative humidity, and precipitation).

[23]*See* U.S. Answer to Question 4 from the Panel.

[24]R.G. Roberts *et al.*, *Evaluation of mature apple fruit from Washington State for the presence of* Erwinia amylovora, Plant Disease 73: 917-21 (1989) ("Isolated outbreaks of fire blight in apples in several apple-growing regions of Washington State occurred in 1987 and 1988. The severity of the disease varied by location, cultivar, and year. Resistant cultivars (*e.g.*, Red and Golden Delicious) developed blossom and occasionally shoot blight that remained limited to the current year's growth. In contrast, susceptible cultivars (Jonathan or Jonathan parentage) grown in two locations – Prosser in 1987 and Yakima in 1988 – *developed extensive blossom and shoot blight that progressed into scaffold limbs and the trunk; some trees had to be removed*.") (emphasis added) (Exhibit USA-28).

[25]R.G. Roberts *et al.*, *Evaluation of mature apple fruit from Washington State for the presence of* Erwinia amylovora, Plant Disease 73: 917-21 (1989) (Exhibit USA-28); *see* U.S. First Written Submission, para. 33.

24. The United States would not have gone to the extraordinary efforts it did to host Japanese scientists for 4 months in Wenatchee, and to facilitate every aspect of the work requested by Japan, if Japan had not first agreed to the existing conditions. The United States warned Japan that their requirements for severely blighted, abandoned pear orchards, surrounded by susceptible apples, was an unrealistic request given the real-world fire blight situation in Washington State, and posed problems of interpretation if multiple sources of inoculum were present.[26] Japan was clearly and repeatedly informed that the conditions extant in Washington State, namely meteorological conditions and regulatory controls, would normally prevent such a situation from occurring, and that another option that utilized inoculated pear trees as a source of inoculum was necessary. At a March 13, 2000 meeting in Wenatchee, Washington, Japan agreed to perform the experiment using inoculated pear trees.[27]

25. Regarding paragraph 89 of Japan's first submission, several points require clarification and correction. For instance, after considerable time and effort, fire blight at the Wenas orchard near Selah, Washington, was located and deemed suitable for the experiment by the representatives of Japan standing in the orchard. Japan was specifically asked if the orchard was suitable for the "Option 1" (Experiment 1) experiment, in conjunction with the "Option 3" (Experiment 1) experiment conducted concurrently at the Columbia View site north of Wenatchee, Washington. Japan agreed verbally and then later in writing,[28] that it was acceptable so the United States proceeded with the experiment based upon this agreement. As a point to consider, both the Wenas Orchard and the Columbia View Experimental plots contained a level of fire blight far in excess of that required to exclude an orchard from the Japan export program.

26. In the "Option 3" experiment at Columbia View Experimental Plots (using inoculated pear trees as the source of fire blight inoculum), Japan asserts that the experiment also failed because conditions were not suitable for spread of the disease. However, during the planning phase of the experiments, Japan insisted that the inoculated pear trees be placed into the orchard

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[26]*See* Exhibit USA-32 (R. Roberts e-mail to A. Kawai, dated January 4, 2000), Exhibit USA-33 (R. Roberts e-mail to A. Kawai, dated February 3, 2000), Exhibit USA-34 (R. Roberts e-mail to A. Kawai, dated February 4, 2000), Exhibit USA-37 (R. Roberts e-mail to A. Kawai, dated March 7, 2000).

[27]U.S. meeting notes from this meeting record the following exchange between Dr. Kawai (AK) and Dr. Roberts (RR):

> AK-We reviewed option 5 with Japanese scientists and they had the same additional things and items. Five hundred-meter block with trees in the center. I want to add these priorities. It's okay to use the inoculated pear trees. I want to show the amount and quality of the trees are enough for the experiment. I want to show pictures.
> RR-Will pictures be enough?
> AK-I want photos of all the trees after they are inoculated.
> RR-No problem.

(Photographs of ooze from all inoculated trees, and general shots of the inoculated trees planted in the orchard were delivered to the Japanese on the CD report dated February 2, 2001.)

[28]Exhibit USA-35 (e-mail from A. Kawai, dated August 15, 2000).

four times, at two-week intervals, beginning before bloom.[29] The United States repeatedly asserted then, and still maintains the view now, that it would have been far more conducive for disease development had all of the inoculum (the U.S. proposed 100 blighted trees) been put into the orchard at once, at the time when the trees were at the most susceptible stage (bloom),[30] rather than putting the last blighted pear trees into the orchard when there were no blossoms available for infection.[31] Japan must bear full responsibility for any shortcomings of this aspect of the experiment as the meteorological conditions were not within the control of the United States.

27. That being said, Japanese scientists did document movement of the fire blight bacterium from the inoculated pear trees to apple fruitlets in the 0-meter row. However, Japan refused to assay any fruit from the 0-meter rows for internal fire blight bacteria as they had originally proposed,[32] so the United States conducted these assays from fruit harvested both at Wenas (naturally occurring fire blight) and at Columbia View (inoculum from blighted pear trees interplanted among the 0-meter rows of apple trees). The United States documented photographically that the blighted pear trees produced ooze and that the ooze was dispersed by a significant wetting event (nearly one inch of rain); the photos can be provided to the Panel at its discretion. Furthermore, regarding Japan's claim that the United States withheld water from the Columbia View Plot, resulting in low fire blight development, the United States responds that the experimental plot was under the same watering schedule as all other plots at the Columbia View facility, the trees were never in a water deficit situation, and the request by Japan to continuously water the plot (24/7) would have killed the orchard by suffocating the roots (Columbia View has a rather heavy soil containing clay). Finally, there is no evidence to support Japan's claim that continuous watering would have caused a severe fire blight outbreak even if such watering had occurred. In fact, as the season became warmer in early July, the watering schedule was modified from 8 to 16 hours of watering per week, doubling the amount of water put on the plots each week.

13. Please comment on the assumptions used by Yamamura, et al (2001) that (2) every consignment contains fruits that were drawn at random from the infinite population of the production area, and (3) each infected fruit causes infection. Please comment also on the statements in the same study by the authors that "Our numerical results are not conclusive, ...", and "Therefore, in order to obtain a reliable estimate of the probability of invasion, a considerable number of consignments from various locations should be examined for a sufficient number of years."

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[29] *See* Exhibit USA-36 (A. Kawai e-mail to R. Roberts, dated April 14, 2000).

[30] *See* Exhibit USA-37 (R. Roberts e-mail to A. Kawai, dated March 7, 2000).

[31] *See* Exhibit USA-38 (A. Kawai e-mail to R. Roberts, dated February 18, 2000).

[32] *See* Exhibit USA-39 (Japanese document entitled "Test/Surveys Required for Reconsideration of Quarantine Measures for Fireblight," dated November 15, 1999).

28. The Panel has asked for comment on specific statements in Yamamura *et al.* (2001), a paper that Japan has presented as evidence that using "more statistically adequate methods" than those employed in the hypothetical risk model of Roberts *et al.* (1998) results in a lower number of years until an estimated outbreak of fire blight through imported apple fruit. It bears repeating that a numerical calculation of the hypothetical risk posed by imported apple fruit does not constitute scientific evidence that mature apple fruit have ever transmitted *E. amylovora* or serve as a pathway for the disease. As stated at the first meeting of the Panel with the parties, the 1998 Roberts hypothetical risk model was an attempt to provide a numerical estimation of the likelihood of transmission given the absence of any scientific evidence that mature apple fruit have transmitted the bacterium and disease. The paper described a hypothetical pathway and estimated the overall likelihood of transmission from the probability that each sequential step in the hypothetical pathway would be completed. Thus, whether the statistical methods of Yamamura *et al.* (2001) or Roberts *et al.* (1998) are used, there remains no scientific evidence that apple fruit serve as a pathway for introduction of fire blight.

29. In response to the Panel's request for comment, and in light of Japan's citation of the results from Yamamura *et al.* (2001) to attack the hypothetical risk estimate given by Roberts *et al.* (1998), the United States has asked an expert in statistics to review the Yamamura *et al.* (2001) and Roberts *et al.* (1998) papers. The resulting report is attached as Exhibit USA-40, and the conclusions are damning. The expert concluded that, despite Japan's assertion that this paper presents "more statistically adequate methods," given the treatment of the essential data set (the epiphytic detections reported in Roberts *et al.* (1998), Table 1) by both parties, the methods used by Roberts *et al*. (1998) "are by far superior." In fact, the expert concludes that Yamamura *et al.* "inappropriately used" that data in such a way that "invalidates the results and conclusions of the [Yamamura *et al.* (2001)] paper concerning the magnitude of the risk posed by imported apples." In sum, the expert concluded: "Roberts *et al*. (1998) analyzed the available published data correctly. Yamamura *et al*. did not." The United States presents additional analysis from this statistical review of Yamamura *et al.* (2001) in response to Question 56 from the Panel to Japan and provides specific comments as requested in this question below.

30. *Comment on the assumption by Yamamura et al. (2001) that "every consignment contains fruit that were drawn at random from the infinite population of the production area."* This assumption might appear to suggest that the number of apples in a real production area is infinite, and that when a consignment is filled, apples are drawn at random from the entire production area. Rather, the assumption means that the model is intended to represent a typical consignment. Consignments are not considered to differ from one another except in those features explicitly included in the model. In all other respects each apple and each consignment is assumed to be like any other. This is a common assumption in modeling, whether explicitly or implicitly, and was made by both Yamamura *et al*. (2001) and Roberts *et al*. (1998).

31. *Comment ... on the assumption by Yamamura et al. (2001) that "each infected fruit causes infection."* This assumption does not mean that each infected fruit actually causes infection in the importing country. The remainder of the sentence in Yamamura *et al*. (2001)

reads: "…by an independent constant probability." What this means is that all infested fruits have the same probability of causing infection, whatever that probability is. It appears that Yamamura *et al*. (2001) understood this (and the preceding assumption), as the rest of their paper proceeds as if they did. Mathematically, this constant probability is given by both Yamamura *et al*. (2001) and Roberts *et al*. (1998) as p = P2 x P3 x P4 x P5. Whether or not this probability is truly constant and independent for all consignments and for all pieces of fruit within a consignment could be debated. The important point is to realize that it implies that no consignment, and no piece of fruit within a consignment, is "special," or different from any other. Any piece of infested fruit is considered to be as likely to cause infection as any other piece of infested fruit. This is a simplifying assumption and it is valid to make it, as long as all parties understand that it limits application of the model to situations where the assumption is reasonable.

32. *Comment on the statement by Yamamura et al. (2001) that "Our results are not conclusive."* Results based on sampling, statistics, and modeling are never certain and, in this sense, are not "conclusive." However, at any given level of knowledge, conclusions can be drawn. If appropriate quantitative tools are applied properly to data collected in a scientifically acceptable manner, and if the results are correctly interpreted and explained, then these results may be convincing and even difficult to dispute. The likelihood that quantitative results are within any desired distance of the true value can be estimated.

33. In the case of Yamamura *et al*. (2001), the above statement continued "… since the data used in the estimation, *i.e.*, Table 1 of Roberts *et al*. (1998) were not obtained from a random sampling." Moreover, the authors admitted the "the validity of the beta distribution itself might be suspect." As both the use of the data from Roberts *et al*. (1998) *as if* it represented a random sample and the use of the beta distribution to *represent* variation in the proportion of infected fruit were *vital* to the analysis of Yamamura *et al*. (2001), we may conclude that the authors themselves considered their results to be invalid, rather than inconclusive.

34. *Comment on the statement by Yamamura et al. (2001) that "Therefore, in order to obtain a reliable estimate of the probability of invasion, a considerable number of consignments from various locations should be examined for a sufficient number of years."* Yamamura *et al*. (2001) came to this end point because they felt that the results of their analysis were inconclusive. However, while additional data are always nice to have, valid, useful inferences can be drawn from the existing data, as shown by Roberts *et al*. (1998). It was the analysis of Yamamura *et al*. (2001), *not* the data, that had shortcomings. Roberts *et al*. (1998) managed to use the same data to obtain more valid, and therefore more reliable, estimates.

> *14. The ninth restriction identified by the United States (1st submission, paragraph 19) is that Japanese officials must also inspect both the disinfestation and packing facilities. How frequently is this undertaken? Is this common practice with regard to other plant pests/ importing markets? To Japan: Why is certification by US officials not sufficient?*

35. Japan's Detailed Rules for U.S. Apples require that Japanese officials inspect both the disinfestation and packing facilities. Disinfestation of the apple fruit is done in accordance with the work plan whenever fruit destined for export to Japan are being processed (or "run") on the packing line. The work plan requires that the sterilization with chlorine dioxide foam, or the use of other approved disinfectants, is done immediately prior to the initiation of packing for export to Japan. Japanese officials will generally monitor the disinfection of the entire production line at the beginning of each run and will monitor subsequent disinfections for the duration of the season. If domestic fruit or fruit for markets other than Japan is run, the line must be cleaned and retreated prior to running fruit for Japan.

36. The requirement of a chlorine treatment of the packing line equipment by the country of import is not required for fire blight by any other country. The direct supervision of low-value mitigation measures such as packing facilities sterilization by the country of import is not a common practice. The level of oversight needed for a particular mitigation is generally a question of the consequences of a measure not being done correctly. Generally, where there are lesser treatment mitigations or low value mitigations required, such as packing facilities sterilization, it is common practice to allow these treatments to be monitored by the national plant protection organization ("NPPO") of the exporting country. This is generally allowed because the proper application of such treatments can be effectively monitored by the exporting country NPPO. Such operations will be occasionally reviewed during periodic site visits made by representatives of the importing country. This is considered a less-trade-restrictive means to fulfilling a given phytosanitary requirement and is the predominant means of entry for products entering the United States.

15. What can be, in your view, the relevance of practices of other countries to an assessment of measures under Articles 2.2, 5.1 or 5.7 of the SPS Agreement?

37. The practices of other countries may provide some relevant information for the Panel's assessment of measures under Articles 5.1 and 5.7 of the SPS Agreement but would appear to be less relevant in the case of Article 2.2, except to the extent that the practices themselves produce evidence. Article 2.2, as applied to this dispute, requires a Member to ensure that its SPS measures are not maintained without sufficient scientific evidence. The practices of other countries would not as such constitute "scientific evidence" relating to the risks to human, animal, or plant life or health posed by a pest or disease; such practices would principally reveal what other countries had determined to be appropriate SPS measures, given their individual appropriate levels of protection and particular circumstances such as its disease or pest profile. The fact that another country has taken a particular measure is no guarantee that its measure is based on sufficient scientific evidence. The particular level of protection of such other country, moreover, may or may not be the same or similar to that of a Member whose measures are being assessed. Thus, the practices of other countries, as such, would appear to have limited utility in assessing the consistency of Japan's fire blight measures with its obligations under Article 2.2. On the other hand, the practices of other countries may have the effect of producing scientific evidence relevant under Article 2.2. For example, where fire blight-free countries having no (or

minimal) SPS measures on apple fruit import significant quantities of fruit over a number of years, and this fruit has not introduced fire blight, this can, as here, have the effect of creating scientific evidence relevant under Article 2.2.

38. Under Article 5.1 and Annex A of the SPS Agreement, a Member must "ensure" that its fire blight measures are based on an assessment of the risks to plant life or health, that is, "an evaluation of the likelihood – *i.e.*, the probability – of entry, establishment or spread of a pest or disease within the territory of [the] importing Member according to the . . . phytosanitary measures which might be applied, and of the associated potential biological and economic consequences." Again, the practices of other countries would not appear as such to be relevant to an evaluation of the likelihood of entry, establishment, or spread of fire blight or *Erwinia amylovora* within Japan but may have the effect of creating evidence relevant to that evaluation. The practices of other countries might also provide information as to "phytosanitary measures which might be applied" by demonstrating some measures that should have been part of the importing Member's evaluation of the likelihood of entry, establishment, or spread "according to the . . . phytosanitary measures *which might be applied*." The practices of other countries, in conjunction with their fire blight status and experiences, might also provide some relevant information to assess whether the importing Member has properly evaluated the "associated potential biological and economic consequences." And of course the practices of the exporting country (such as the SPS measures applied) can be very relevant to an assessment of the risk posed by those exports.

39. Under Article 5.7, the practices of other countries who are WTO Members may have more direct relevance. The first sentence of Article 5.7 states that "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations *as well as from sanitary or phytosanitary measures applied by other Members*." Thus, to the extent the other country is a WTO Member, such a country's practices may be relevant to assessing whether a provisional SPS measure under Article 5.7 is adopted "on the basis of available pertinent information." In the current dispute, however, the practices of other WTO Members are not relevant to determining whether Japan may invoke the qualified exemption under Article 5.7 because Japan has not demonstrated the requirements necessary under Article 5.7 to claim the qualified exemption from Article 2.2 for an SPS measure that is maintained without sufficient scientific evidence. For a more detailed explanation of why the Japanese fire blight measures are not justified under Article 5.7, please see the U.S. answer to Question 40 from the Panel.

> *16. In Japan - Measures Affecting Agricultural Products, the Appellate Body indicated that whether there is a rational relationship between an SPS measure and the scientific evidence is to be determined on a case-by-case basis and will depend on the particular circumstances of the case, including "the characteristics of the measure at issue and the quality and quantity of the scientific evidence". (Report of the Appellate Body,*

WT/DS76/AB/R, para. 84) Could you please elaborate on which "characteristics of the measure" are relevant in this case?

40. The Japanese fire blight measures constitute a prohibition on imported U.S. apples unless produced, treated, and imported in accordance with the requirements set out in those measures. However, there is *no* scientific evidence of *any* quality that the imported commodity – mature apple fruit – has ever transmitted the disease or is a pathway for introduction of fire blight. Thus, the first and most fundamental characteristic of the fire blight measures, their application to mature apple fruit, is not supported by any scientific evidence. Put differently, there is no rational or objective relationship between the Japanese fire blight measures and the scientific evidence because the measures are directed at a commodity for which there is no evidence of risk to plant life or health within Japan.

41. The lack of a rational or objective relationship between the Japanese fire blight measures and the scientific evidence can also be seen by examining the restrictions imposed by those measures.[33] For example, Japan prohibits the importation of any fruit from a "designated" export orchard in which fire blight is detected, no matter how far from a source of inoculum such fruit are, no matter how severe or light the fire blight occurrence is, and no matter when during the growing season the fire blight was detected. Although the restrictions imposed by the fire blight measures are cumulative (each requirement must be met for exported fruit and failure to meet any one results in prohibition of such fruit), Japan has also failed, "in any substantial way, [to] evaluate or assess their relative effectiveness in reducing the overall disease risk."[34] For example, Japan deems a 500-meter buffer zone surrounding an orchard sufficient to establish that all fruit from an export orchard, even those at the periphery, will be free of fire blight bacteria. Japan does not explain, however, why fruit that is 500 meters or more away from a source of fire blight *within* the orchard would not also be free of fire blight bacteria. How can a requirement that Japan deems effective outside of an orchard not also be effective within an orchard? Thus, the onerous and cumulative nature of all of the requirements imposed by the fire blight measures are also relevant characteristics pointing out the lack of any objective or rational relationship between the measures and the scientific evidence.

17. Should the conformity of a risk assessment under Article 5.1 of the SPS Agreement be assessed in light of information available at the time of conducting the risk assessment or at the time of assessing the measure, or both?

42. Article 5.1 imposes an ongoing obligation on Members to "ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the

[33] *See* U.S. First Written Submission, paras. 46-62 (Section IV.A.4: The Japanese Measures Impose Restrictions Unsupported by Any Scientific Evidence).

[34] *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, paras. 133-34 (quoting Panel Report, WT/DS18/R, para. 8. 90) (November 6, 1998) ("*Australia – Salmon*").

risks to human, animal, or plant life or health." The obligation that an SPS measure be "based on" a risk assessment "requires that the results of the risk assessment must sufficiently warrant – that is to say, reasonably support – the SPS measure."[35] In this dispute, as there has never been any scientific evidence that mature apple fruit are a pathway for the disease, reviewing the information available at any one particular time (at the time of conducting the risk assessment or at the time of assessing the measure) does not alter the inconsistency of Japan's assessment of risks with Article 5.1 of the SPS Agreement. Thus, the issue of the point in time for assessing a risk assessment is not posed in this dispute, and the Panel need not (indeed should not) reach it.

43. Paragraph 5 of Annex A defines a "risk assessment" as an "evaluation of the *likelihood* of entry, establishment, or spread of a pest or disease within the territory of the importing Member." The United States notes that, if evidence available at time of the formal assessment of risk and relevant to an evaluation of likelihood is not mentioned, or is mentioned but ignored, this would be relevant to determine whether an evaluation of likelihood has been made.

44. The United States notes that in its assessment of risks Japan has failed to identify the steps necessary for apple fruit to serve as a pathway for introduction of fire blight to Japan and has failed to identify and evaluate scientific evidence related to each step.[36] Japan's failure to evaluate the likelihood of each step in the pathway occurring demonstrates that it cannot have evaluated the likelihood – *i.e.*, the probability – of entry, establishment, or spread of fire blight within Japan. Japan's alleged risk assessment fails to meet the SPS Agreement requirements - nothing that occurred after the risk assessment could cure its deficiency. Thus, Japan has not made a proper assessment of risk within the meaning of Article 5.1 and Annex A of the SPS Agreement.

> *18. In Japan - Measures Affecting Agricultural Products, the Appellate Body noted that " Article 5.7 operates as a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. An overly broad and flexible interpretation of that obligation would render Article 5.7 meaningless." (Report of the Appellate Body, WT/DS76/AB/R, para. 80). In light of Japan's invocation of Article 5.7 in this instance, could you please comment on the relationship between Articles 2.2 and 5.7 of the SPS Agreement and its relevance to the panel's assessment of the sufficiency of scientific evidence in this case?*

45. The statement by the Appellate Body quoted by the Panel was made as part of the Appellate Body's reading of the term "sufficient" within the phrase "maintained without

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[35]*European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, para. 193 (February 13, 1998) ("*EC – Hormones*").

[36]*Compare* Exhibit JPN-14 (Japan's presentation of pathway consisting of 3 steps) *with* International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests §§ 2.2.1.1-2.2.1.5, at 13 (2001) (International Standards for Phytosanitary Measures Publication No. 11) (describing 5 steps comprising evaluation of probability of entry of a pest) (Exhibit USA-15).

sufficient scientific evidence" in Article 2.2. The Appellate Body noted that the context of these words included Articles 5.1, 3.3, and 5.7.[37] With respect to the context provided by Article 5.7, the Appellate Body noted that "Article 5.7 operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. An overly broad and flexible interpretation of that obligation [in Article 2.2] would render Article 5.7 meaningless."[38] In light of the text and context of Article 2.2, including its reading of Article 5.7, the Appellate Body "agree[d] with the Panel that the obligation in Article 2.2 of the SPS Agreement that an SPS measure not be maintained without sufficient scientific evidence requires that there be a rational or objective relationship between the SPS measure and the scientific evidence."[39] Only after examining Japan's claim under Article 2.2 did the Appellate Body turn to the issue of whether the qualified exemption of Article 5.7 would justify adoption of the varietal testing requirement.[40]

46. Thus, in light of the relationship between Article 2.2 and 5.7, the Panel should first determine whether Japan has maintained its prohibition on imported U.S. apples unless produced, treated, and imported in accordance with Japan's fire blight measures "without sufficient scientific evidence" – that is, without "a rational or objective relationship between the SPS measure and the scientific evidence." If the Panel concludes that Japan's fire blight measures are maintained without sufficient scientific evidence and are therefore inconsistent with Article 2.2, the Panel would then need to turn to the "alternative defense" asserted by Japan and determine whether the qualified exemption in Article 5.7 is applicable. For an explanation of the U.S. position that the qualified exemption under Article 5.7 is not available in this case, please see the U.S. answer to Question 40 from the Panel.

TO THE UNITED STATES

19. Please clarify how an assessment that an apple is "mature" and symptomless" can be performed. Is this a well-established (e.g. horticultural, commercial, scientific or phytosanitary) notion?

47. Apple fruit maturity assessments are performed routinely by tree fruit industry personnel, including growers, commercial consultants, fieldmen, and packing house personnel. These maturity assessments include determination of the starch index, soluble solids (sugar content), and flesh firmness. Titratable acidity is sometimes determined but is not routinely used as a criterion for determining horticultural maturity. Other guides could include calculation of

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[37] *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R, para. 74 (March 19, 1999) ("*Japan – Varietals*").

[38] *Japan – Varietals*, WT/DS76/AB/R, para. 80 (emphasis in original).

[39] *Japan – Varietals*, WT/DS76/AB/R, para. 84.

[40] *Japan – Varietals*, WT/DS76/AB/R, para. 86.

number of days from bloom and observation of the seed color, flesh color, and ground color of the fruit; references relative to the particular variety and local growing region may be utilized based on years of practice and experience. As noted earlier,[41] as apple fruit approach optimum horticultural maturity, firmness values will be declining, starch levels will be declining, and the soluble solids values will be increasing. Fruit samples are evaluated sequentially during the pre-harvest and harvest period to determine the point at which the fruit exhibits a combination of firmness, soluble solids, and starch index values that are optimum for the proposed use of the fruit, which can include immediate sale on the fresh market, regular atmosphere cold storage, or short- to long-term controlled atmosphere storage. Optimum harvest condition will be well past the time when immature apples could be harvested.

48. An assessment of whether or not a fruit is symptomless (that is, free of disease) is made at several points during the commercial post-harvest handling process and includes several visual examinations for decay and defects and at least one machine-based assessment carried out by computer-controlled color sorter/sizer machines, which look at every fruit for color values and weight (size) and segregate them according to grade and size. These methods are well-established post-harvest practices and conditions for market-quality apple fruit.

49. These commercial practices are founded on scientific principles developed through the study of the physiological changes that occur in plants during growth and maturation. As this has been a historically active area of research, a well-established lexicon has developed to standardize the terminology used in these studies (Watada *et al.* (1983)).[42] This lexicon distinguishes physiological maturity from horticultural maturity. Physiological maturity is defined as: "The stage of development when a plant or plant part will continue ontogeny even if detached." Horticultural maturity is defined as: "The stage of development when a plant or plant part possesses the prerequisites for utilization by consumers for a particular purpose." With regard to fruits, the paper stated that "Fruits have been separated into 2 groups: those harvested when partially developed and physiologically immature, and those harvested when fully developed and physiologically mature, or even ripe." Figure 2 of the paper indicates that apples are among the latter group that is harvested when they are "fully developed and physiologically mature, or even ripe." Thus, there is definitely a long-established scientific, commercial, and horticultural basis for the use of these concepts and methods.

20. How probable/likely is it that some immature fruit could be included in cartons of mature apples for export? What controls/inspections are in place to prevent this from occurring?

50. Given the multiple human and machine-based examinations that each fruit is subjected to,

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[41] *See* U.S. response to Question 3 from the Panel.

[42] A.E. Watada *et al.*, *Terminology for the Description of Developmental Stages of Horticultural Crops*, HortScience 19: 20-21 (1984) (Exhibit USA-41).

and the strict grade requirements that categorically exclude immature fruit, it is extremely unlikely that an immature fruit would be included in a carton of mature, export-quality apple fruit. As described in the U.S. answer to Question 19 above, the harvest process involves careful and repeated assessment of the maturity of apple fruit utilizing numerous objective criteria. Any very small apples (those most likely to be immature) are eliminated from fresh market packs for commercial reasons; *i.e.*, they are not saleable. Apples are held in cold storage for a period of several days to several months (the vast majority being held for months), during which time the apples continue to ripen, although at a greatly reduced rate. Were any fruit immature, it would likely show shriveling and might also show signs of chilling injury (depending upon storage temperature), making such a fruit more easily detectable during sorting/grading operations.

51. In Washington State, for example, commercial practices involve very stringent sorting and grading of the orchard lots of apples prior to packing/packaging. Defective fruits, which are defined to include immature apples, are removed from all commercial grades for fresh market consumption. All fresh market apples are inspected by Washington State Department of Agriculture ("WSDA") inspectors under a mandatory grading system. The individual grade specifications, whether based on the minimum U.S. Standards for Grades of Apples or Washington Standards for Apples, exclude immature fruits. In addition, particularly during the early period of the shipping season, there are additional regulations in place for the purpose of ensuring taste and quality. In certain varieties, mandatory minimum soluble solids or specified stages of starch/iodine indices (described further in the U.S. answer to Question 3 from the Panel on the OECD maturity and ripeness guidelines) are incorporated into the inspection/certification procedures for fresh market sale. These regulations further ensure that immature apples will be eliminated from a commercial pack. During inspection and when applying the grade standards, the previously-described criteria and methods used by growers and consultants preceding and during harvest are also employed by inspection personnel.

> *21. Please describe the normal process followed in the United States with regard to the harvest, treatment, packing, inspection and certification of fresh apples for export to countries other than Japan.*

52. Apples are harvested when the growers and consultants have determined that the variety within the local growing location has reached optimum level of maturity for the various marketing seasons; *i.e.*, early, mid-season, and late season. Apples are harvested into bulk bins and typically are delivered to cold storage facilities the same day as harvested, or the following day (after overnight cooling in the orchard). Upon delivery to the cold storage/packing facility, the field-run apples are placed in either regular cold storage rooms or in controlled atmosphere ("CA") rooms. Temperatures are maintained at or near 32 degrees F. In CA rooms, the oxygen is maintained between 1% and 5%. Due to the ability to preserve fruit condition for 12 months or more under CA conditions, the duration of storage is determined by the marketing plan of the growers and packing facilities and will vary from several days to several months. As the fruit is needed for the market, it is removed from storage, separated from leaves and other debris, and washed, sized, sorted, and graded by packing facility personnel. Following grading the fruit is

placed in the packages or containers that are used for shipment and the shipping cartons are properly labeled as to variety, grade, size, responsibility, origin, etc.

53. A variation of the preceding conventional practice as described is that of pre-sorting and pre-sizing. In this method the apples are sorted and sized but not packaged. The apples, segregated by grade and size, are returned to cold storage in field bins. When needed to fill an order for market, the particular variety, grade, and size of apples is taken from cold storage, given a final washing, sorting/grading, and is then placed in the shipping container and labeled.

54. Prior to export, the apples are inspected by the Federal-State inspectors (WSDA inspectors working under cooperative agreements with United States Department of Agriculture, Agricultural Marketing Service ("USDA-AMS") and Animal Plant Health Inspection Service ("USDA-APHIS")). The apples are inspected for compliance with the applicable grade standard, the requirements of the U.S. Export Apple Act, and the phytosanitary requirements of the receiving foreign country.

55. The phytosanitary inspection includes sampling of the shipment, visual inspection for pests and/or disease, and when applicable, certification of treatment. Upon completion of the inspection, an export certificate is issued as to the quality/condition of the apples. A separate phytosanitary certificate is issued as to freedom of quarantine pests/disease and a statement as to the required treatment.

56. For markets other than Japan, there are generally few differences in these practices for harvesting, storing, washing, sizing, sorting, grading, and inspecting exported apple fruit. For example, Exhibit USA-14 details the fire blight measures imposed by other fire blight-free areas on U.S. apples; none requires that exported fruit be harvested from fire blight-free orchards, none requires that a 500-meter fire blight-free buffer zone be maintained around such orchards, and none requires that such orchards and buffer zones be inspected 3 times yearly.

> *22. What is US export grade? What are the quality requirements? Is the US arguing that compliance with the US Export Apple Act (referred to in the US submission, paragraph 106 and footnote 223) would constitute the "technically feasible, less trade restrictive measure" in the context of Article 5.6? How are the measures as described in footnote 223 enforced?*

57. Under U.S. law (U.S. Export Apple Act, 7 U.S.C. § 581), exported apple fruit must be of a Federal or State grade that meets a minimum quality established by regulation. Those regulations (7 C.F.R. § 33.10) currently require exported U.S. apples to satisfy at least the requirements for the "U.S. No. 1" grade, pursuant to which apples must be:

> [M]ature but not overripe, carefully hand-picked, clean, fairly well-formed; free from decay, internal browning, internal breakdown, bitter pit, Jonathan spot, scald, freezing injury . . . and broken skin or bruises except those which are

> incident to proper handling and packing. The apples are also free from damage caused by . . . sunburn or sprayburn, limb rubs, hail, drought spots, scars, stem or calyx cracks, disease, insects, [or] damage by other means . . . .[43]

Thus, U.S. law and regulations require that exported fruit be mature (and also free from any disease symptoms). As explained in more detail in the U.S. answer to Question 21 from the Panel, apple fruit for export are inspected by Federal-State inspectors for compliance with the requirements of the U.S. Export Apple Act, the applicable grade standard, and any additional phytosanitary requirements of the export market. Upon completion of the inspection, including sampling of the shipment and visual inspection for pests and/or disease, an export certificate is issued as to the quality/condition of the apples and a separate phytosanitary certificate is issued as to freedom of quarantine pests/disease and a statement as to the required treatment.

58. The United States is not arguing that compliance with the U.S. Export Apple Act as such would constitute the alternative measure that is reasonably available, achieves Japan's appropriate level of protection, and is significantly less restrictive to trade, although compliance with U.S. law *does* achieve Japan's appropriate level of protection. Rather, consistent with Article 2.2, Japan may require that imported apple fruit be restricted to mature apple fruit. Such a measure is reasonably available, achieves Japan's appropriate level of protection, and is significantly less restrictive to trade than Japan's current fire blight measures. Thus, Japan has acted inconsistently with Article 5.6 of the SPS Agreement.

> *23. In its first submission and in paragraph 27 of its oral statement, Japan cites four instances of trans-oceanic dissemination of fire blight. Could you please comment on each of these incidents?*

59. The United States has reviewed the literature relating to each instance of trans-oceanic dissemination of fire blight cited by Japan. None of these involves apple fruit. Japan concedes that two of these instances (to New Zealand and Egypt) are attributed to movement of infected propagative material (nursery stock) and not to trade in apple fruit. For the third instance (to Great Britain), Japan believes that the introduction has been demonstrated to be linked to contaminated fruit boxes from the United States; our review of the literature does not support this assertion. Japan believes a fourth instance of fire blight transmission (to Hawaii) was caused by movement of infected fruit from the United States; our review of the literature does not support the claim, and our research reveals that *Erwinia amylovora* is not, in fact, found in Hawaii. We discuss each instance in more detail below.

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[43]United States Standards for Grades of Apples, 7 C.F.R. § 51.302 (requirements for U.S. No. 1 is the same as for "U.S. Fancy," except for "color, russeting, and invisible water core").

60. Dissemination to New Zealand from the United States in 1919. The dissemination of fire blight to New Zealand was reported by Cockayne (1921)[44] and Campbell (1920)[45] and is believed to have resulted from importation of infected nursery stock.[46] There is no scientific evidence of any kind to support a claim that fruit were responsible for spread of fire blight to New Zealand.

61. Dissemination of fire blight to England from the United States in the 1950s. The paper cited by Japan[47] in turn cites two sources: Great Britain Ministry of Agriculture, Fisheries and Food (1969)[48] and Lelliot (1959).[49] This first document, which has been cited as evidence that fire blight was spread to the United Kingdom on fruit from the United States, actually *discounts* this hypothesis when read carefully:

> Movement of infected planting material, particularly shrubs, has almost certainly been the cause of some spread. *Transport of infected fruits is unlikely to be a common means of dissemination because most of these would be rejected during grading and packing and because of the low probability that infected fruit will reach orchards*. [C]ontaminated wooden fruit boxes, which are taken into orchards for fruit picking, *could* therefore serve as a source of infection. There is good *circumstantial evidence* that infection was introduced into a new area of the country by this means on one occasion.[50]

Thus, the report considers infected (that is, symptomatic) fruit to be an "unlikely" means of dissemination, does *not* claim that infection was introduced from the United States, and does *not* specify that the spread "into a new area of the country" it attributes to fruit boxes was introduced from abroad rather than from a domestic source. The paper also describes the evidence (which it does not detail) on contaminated wooden fruit boxes as "circumstantial" because such evidence apparently did not meet the criteria that define scientific evidence, which is that gathered during

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[44] A.H. Cockayne, *Fire blight, a serious disease of fruit-trees*, New Zealand J. Agric. 20: 156-157 (1921).

[45] J.A. Campbell, *The Orchard; The outbreak of fire blight*, New Zealand J. Agric. 20: 181-182 (1920).

[46] S.V. Thomson, *Fire blight of apple and pear*, *in* Plant Diseases of International Importance, vol. 3: Diseases of Fruit Crops 32-65, at § 2-2-1 (J. Kumar *et al.*, eds.) (1992) (Exhibit USA-44).

[47] T. van der Zwet, *The various means of dissemination of the fire blight bacterium* Erwinia amylovora, EPPO Bull. 24: 209-214, tbl. 2 (1994).

[48] Great Britain Ministry of Agriculture, Fisheries and Food, *Fire Blight of Apple and Pear* (1969) (Advisory Leaflet 571).

[49] R.A. Lelliott, *Fire blight of apples and pears in England*, Agriculture 65: 564-68 (1959).

[50] Great Britain Ministry of Agriculture, Fisheries and Food, *Fire Blight of Apple and Pear* at 7 (1969) (Advisory Leaflet 571) (emphasis added).

the exercise of the scientific method. Therefore, contrary to Japan's suggestion,[51] this document provides no scientific evidence that fruit or contaminated fruit boxes were responsible for the spread of fire blight to England.

62. Lelliot (1959) is an earlier source for the claim that contaminated fruit boxes were involved in the introduction of fire blight to England. This paper also discounts the possibility that fruit were involved in spread of the disease:

> It is not known how fire blight entered this country. *The chance that it was introduced with infected fruit* or contaminated stocks of bees *is very slight, and can probably be ignored*; the bacterium might have been brought in with imported pollen, but there is no evidence to support such a suggestion. *Two* more plausible explanations are that it was introduced with young trees, stocks, or budwood, *or* on boxes contaminated with bacterial slime - in this connection a common practice has grown up recently on English orchards of using boxes in which fruit has been imported from the U.S.A., and it is known that American *or* New Zealand boxes were brought into some of the earlier affected orchards about 1956-57.[52]

Thus, Lelliott states that fruit were unlikely to be the means of introduction of fire blight into England. He posits that the origin of the outbreak was through infected propagative materials *or* through contaminated (recycled) wooden boxes, which could have been from New Zealand or the United States.

63. Recent studies by Jock *et al.* (2002),[53] which utilized molecular fingerprinting techniques to assess the distribution of different *E. amylovora* populations in Europe, also challenge the notion, repeated by Japan, that the source of transmittal of fire blight to England was the United States:

> The XbaI patterns form North American *E. amylovora* strains were often different from those *E. amylovora* strains isolated from Europe and in the Mediterranean

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[51]Japan suggests that van der Zwet *et al.* (1990) supports its contention that fruit shipments pose a risk of fire blight transmission, in part, because of the authors' recollection of "observations of fruit blight symptoms on pear shipments to Hawaii and England." Japanese First Written Submission, para. 74 (internal quotation marks deleted; footnote deleted by Japan). The footnote for the "observations" of blighted pear fruit shipments to England is a reference to the Great Britain Ministry of Agriculture, Fisheries & Food (1969) paper we have quoted above. As we have seen, the paper does *not* attribute fire blight transmission to England to shipments of fruit, and it *expressly* states that transport of fruit is "unlikely to be a common means of dissemination."

[52]R.A. Lelliott, *Fire blight of apples and pears in England*, Agriculture 65: 564-68, 564 (1959).

[53]S. Jock *et al.*, *Following spread of fire blight in Western, Central and Southern Europe by molecular differentiation of* Erwinia amylovora *strains with PFGE analysis*, Environmental Microbiology 4(2): 106-114 (2002).

> region. Consequently, the high conservation of pattern of the latter strains, together with strains from New Zealand, could result in the speculation that fire blight was not repeatedly disseminated from N. America, otherwise highly divergent pattern types should also occur in the other fire blight countries. A few strains with the same pattern type could have escaped from North America first to New Zealand and later to countries of the Northern Hemisphere.

This finding casts further doubt on the often repeated supposition that fire blight in England resulted from dissemination of the bacterium from the United States on contaminated fruit boxes.

64. From the United States to Egypt in 1962. While Japan notes that the scientific literature attributes the spread of fire blight to Egypt to export of pear budwood, Japan neglects to mention scientific literature that draws a connection not to the United States but to European countries. For example, El-Helaly (1962) states: "The occurrence of the disease (fire blight) is quite probable, because: 1) *Seedling production in Egypt depends, mostly, on imported nursery stock from certain European countries where the disease has long been established*, 2) The recent records of the occurrence of fire blight in countries known to be free of it [references omitted], and 3) the prevalence of certain symptoms on some pear trees grown in certain Egyptian localities, similar to those known for *Erwinia amylovora*."[54] The Jock *et al.* (2002) paper also provides molecular evidence that supports a European origin for the fire blight that appeared in Egypt: the PFGE pattern type in Egypt is the same as that which occurs in Belgium. Thus, the spread of fire blight to Egypt from the United States or via trade in fruit from any country has never been supported by any scientific evidence.

65. Mainland United States to Hawaii in 1965. The only reference given for Japan's assertion that fire blight was disseminated to Hawaii is a University of California Newsletter that anecdotally relates an incidence of infected pear fruit arriving in Hawaii that originated in California. Despite this anecdotal report, and in spite of the movement of other fruit to Hawaii over decades, fire blight disease has never been recorded as occurring and is not known to occur in Hawaii. Therefore, this reference in the context of transoceanic dissemination of fire blight is factually incorrect. We also note that the purported date of dissemination would not be 1965, the date of publication of the newsletter, but at least 15 years prior to publication (that is, at the time of the discovery of the fruit by a University of California scientist).

24. Can the US confirm Japan's expanded list of countries prohibiting imports of apples from countries not free of fire blight (eg, addition of Korea)?

66. The United States is not aware of Japan's citation of any countries besides Korea and Australia that allegedly prohibit imports of apples from countries not free of fire blight. We are

[54] El-Helaly *et al.*, *The occurrence of the fire blight disease of pear in Egypt*, Phytopath. Mediter. 3: 156-63 (1962) (emphasis added).

aware that Australia prohibits apple fruit imports due to fire blight. However, the United States cannot confirm that Korea prohibits the importation of apples from countries with fire blight.[55]

67. Korea does currently prohibit apple fruit from the United States. This prohibition, however, does not appear to be based on a risk of apple fruit vectoring fire blight. There has not been any official (Korean National Plant Quarantine Service) notification that *Erwinia amylovora* is a pest of concern for apple fruit. U.S. records indicate that Korea *has* explicitly prohibited importation of *host plants* of *Erwinia amylovora*, including apple, hawthorn, cotoneaster, and pyracantha, due to concerns about fire blight. Korea has also explicitly prohibited importation of U.S. apple fruit (except Hawaii) due to codling moth (*Cydia pomonella*), of Hawaiian apple fruit due to Oriental fruit fly (*Dacus dorsalis*), and of Puerto Rican and Hawaiian apple fruit due to Mediterranean fruit fly (*Ceratitis capitata*). However, Korea has not indicated that apple fruit imports are prohibited due to fire blight, even while explicitly prohibiting apple *plant* imports for that reason.

25. Please clarify why the US is seeking changes to the measures regarding fresh apples which it previously agreed with Japan? (Japan's first submission, paragraph 8 refers.)

68. After more than 20 years of U.S. efforts to resolve this dispute bilaterally, the United States seeks nothing more through this dispute than to have Japan reform its fire blight measures so as to be maintained with sufficient scientific evidence as required by the SPS Agreement. Although the United States acquiesced to the fire blight measures imposed by Japan in 1994 as preferable to an outright ban on imported apple fruit, the United States did so reluctantly and recognizing that the scientific evidence did not support the restrictions.[56] Nonetheless, the United States undertook an active, prolonged, good-faith effort to work with Japan to resolve this dispute on a technical level. The United States has never waived its rights under the SPS Agreement, and the U.S. efforts to resolve the dispute were without prejudice to those rights. These efforts included presenting and explaining through numerous bilateral meetings the scientific evidence that mature apple fruit are not a pathway for fire blight to Japan and even conducting joint research with Japan in 2000 that duplicated numerous scientific studies that evaluated the incidence of endophytic and epiphytic bacteria on or in mature apple fruit. Not surprisingly, the joint experiment found that endophytic bacteria were not recovered from mature apple fruit, even when such fruit were harvested from blighted trees.[57] When, notwithstanding the results of these experiments proposed by, jointly conducted with, and agreed to by Japan, Japan still refused to change its fire blight measures, the United States reluctantly concluded that

[55]*See* Exhibit USA-14 (table detailing fire blight measures on imported apples in fire blight-free areas).

[56]As the Panel has noted, the United States continued to communicate this position to Japan even as the 1994 fire blight measures were being imposed by Japan. *See* Exhibit USA-22.

[57]R.G. Roberts, *Evaluation of buffer zone size on the incidence of* Erwinia amylovora *in mature apple fruit and associated phytosanitary risk*, Acta Horticulturae (forthcoming 2002) (Proceedings of Ninth International Fire Blight Workshop) (Exhibit USA-16).

WTO dispute settlement proceedings would be necessary to ensure that Japan fulfilled its WTO commitments.[58]

69. The United States also notes that trade in agricultural products depends upon effective market access. In negotiating for market access a country may acquiesce to certain import measures imposed by the country of import that it believe are not supported by science merely to avoid further delays, including those inherent in resort to dispute settlement. However, that does not affect the importing Member's obligations to comply with the SPS Agreement. Here, the question for the Panel is whether Japan's measures are consistent with its WTO obligations. The United States respectfully submits that they are not.

26. In its first submission, paragraph 142, Japan states "Clearly, there is an agreement between Japan and the United States that some phytosanitary measures are needed to counter the risk of fire blight, which can be harbored in American apples in general. The difference lies in the specifics of the measure." Does the United States concur with this statement? Please elaborate.

70. There is no scientific evidence that *Erwinia amylovora* "can be harbored" in mature apple fruit, whether American, Japanese, or of any other origin. Rather, the scientific evidence establishes that mature apple fruit harvested from orchards will not contain endophytic bacteria. The scientific evidence further establishes that mature apple fruit are not a pathway for introduction of fire blight. Therefore, the U.S. position is that the only phytosanitary measure supported by scientific evidence would be to restrict importation to the exported commodity: mature apple fruit.

27. Robert, Hale et al (1998) (Exhibit JPN-5) estimates that 2.8% of US apples originate from orchards that meet current Japanese requirements, whereas 95% of apples produced in the US would meet conditions of only one pre-harvest field survey, no restriction on varieties, no buffer zone, and fire blight strikes on less than 1% of trees in orchards, but apples from infected or adjacent trees are not exported. Does the US concur with these estimates? Please comment.

71. The U.S. has not obtained any additional data since the publication of the referenced article that would suggest that the original estimations used to classify U.S. orchards according to fire blight status for the PRA need to be revised. Therefore, we concur with the estimates used by Roberts *et al.* (1998).

28. Please comment on the additional five "items" for which Japan has requested further information (Exhibit JPN.6, page 7).

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[58] Should the Panel wish an even more detailed account of U.S. efforts to resolve the dispute bilaterally, please see Exhibit USA-1.

72. Japan has raised the issue of five items of data it wished the United States to offer "to supplement the results of" the 2000 joint Japanese-U.S. experiments. However, this request for data came *two years* after Japan proposed the joint experiments and approximately *10 months* after the results of these same experiments became available; the request also was made despite the scientific evidence that mature apple fruit do not transmit fire blight. Japan has demonstrated that it is keenly aware of the literature on the subject of fire blight. As answers to all of the questions not addressed directly in our numerous bilateral meetings are found in the scientific literature, there was simply no reason to continue technical discussions under the guise of discussing more data.

73. Japan is all too aware of the data available on these five items, which may help to explain its request. In the event the Panel were further interested in these items, the United States summarizes the issues and data here. In response to items (a) and (b) of Exhibit JPN-6, the occurrences of fire blight in Oregon, Washington, and the rest of the United States are not systematically recorded because the disease is endemic and not under official control. Therefore, as was communicated verbally to Japan at several bilateral meetings, this data is unavailable.

74. For Item (c), there are no official, mandated forecasting systems for fire blight outbreak. CougarBlight and MaryBlight are two computer forecasting programs that are commonly used, and Japan is well aware of them (see Exhibit JPN-33). We note that in Exhibit JPN-33 Japan inappropriately attempts to represent the often inaccurate *predictions* of fire blight occurrence from a CougarBlight simulation as *actual data on fire blight incidence*, which they clearly are not.

75. For Item (d), the United States has not provided data on a mechanism by which *E. amylovora* can "invade inside apple fruit" because it does *not* invade inside mature apple fruit harvested from orchards as amply demonstrated by the scientific evidence. Thus, Japan's request appears to invite the United States to provide hypothetical data on a non-existent phenomenon.

76. For Item (e) regarding the spreading mechanism of fire blight inside Washington State, the United States is unaware of any means of spreading fire blight inside Washington State that has not been documented elsewhere for other areas: wind-driven rain, some insects, infected nursery stock, and contaminated pruning tools.

> *29. Do any states within the United States impose phytosanitary measures on the inter-state movement of fresh fruits for risks associated with, or comparable to those associated with, fire blight?*

77. A review of all Plant Laws and Regulations of the 50 States maintained by the United States National Plant Board reveals that no State has a quarantine requirement or regulation on fruit addressed to fire blight. On the other hand, each State maintains a Nursery Inspection Program which addresses the movement and health of nursery stock, including Malus (apple) and

other Rosaceae plants. These nursery programs prohibit the movement across state lines of Malus and other Rosaceae stock infected with any plant pathogen or pest, including *Erwinia amylovora*.

> *30. What is the USDA blight scoring system (referred to in Exhibit USA-18). Is it relevant for certification of exports of mature fruit? Is it widely accepted outside of the US?*

78. The "USDA" fire blight scoring system (in quotations because the system was never formally adopted by the U.S. Department of Agriculture) was developed, named, and initially published by Dr. van der Zwet in 1970 as a method to estimate fire blight severity in order to objectively evaluate germplasm for fire blight resistance. Although various authors have used and cited the system over the years, it is now rarely used. As noted by Lespinasse and Aldwinckle (2000) in their discussion of fire blight scoring systems:

> Scores used by van der Zwet (1970) ranked from 0 to 10, with the higher scores (10-8) indicating the least damage. This system is an overall appraisal which does not take account of the origin of the infection, usually flowers or shoots. In fact, it was demonstrated (van der Zwet, 1975) that susceptibility could vary widely depending on the organs affected. Studying a large number of pear selections in different locations (Maryland and Ohio), van der Zwet *et al.* (1984) showed inconsistencies in the comparative results (using the scoring system), especially in the moderately resistant and resistant classes and occasionally even among the fairly susceptible classes.[59]

Thus, this fire blight scoring system is not relevant for certification of exports of mature fruit.

> *31. In the US first submission, in footnote 76, reference is made to the number of strikes per tree. What is the common level of infection of US orchards (per state or region)? Does this vary widely from year-to-year?*

79. There can be no generalization made about a common level of fire blight infection in U.S. orchards as the incidence and severity of fire blight varies by year, local environmental conditions, and variety. Generally speaking, the drier the climate and the cooler springtime weather during bloom, the lower the incidence of fire blight will likely be (assuming that fire blight inoculum is present in all areas). For instance, such conditions prevail in Washington State in most years, and fire blight occurs only sporadically in the state. Occasionally, however, as in 1987 and to a slightly lesser degree in 1988, warm springtime conditions and wetting events (rainfall or heavy dew) coincide to create conditions conducive for severe fire blight outbreaks.

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[59] Y. Lespinasse & H.S. Aldwinkle, *Breeding for Resistance to Fire Blight*, *in* Fire Blight: The Disease and Its Causative Agent, *Erwinia amylovora*, 253-73, 254 (J.L Vanneste ed.) (2000) (Chapter 13).

Washington State has not experienced such a severe outbreak since 1987-88. Nevertheless, even when evaluated under these severe conditions, mature apple fruit were found to be free of the *E. amylovora*, internally and externally, even when harvested from severely blighted trees.[60]

32. Can the size of a buffer zone for another disease of fruit, eg citrus canker, have any scientific relevance with regard to the size of a buffer zone which might be appropriate to ensure the fire blight -free status of an apple orchard? Please explain.

80. We are not aware of any scientific evidence that establishes a link between the epidemiology of any other plant disease with that of fire blight such that an appropriate phytosanitary measure for the former would necessarily be appropriate for the latter. The epidemiology of fire blight is different and distinct from other bacterial plant diseases. There is no scientific evidence to support a 500-meter buffer zone (or a zone of any other width) surrounding an apple orchard to prevent the spread of the disease by mature apple fruit.

33. The US first submission, at paragraph 35, gives a citation of van der Zwet et al. (1990) stating that "Epiphytic bacteria were recovered after storage ... " This seems to contradict the statement in the penultimate sentence of paragraph 37 of the US first submission: "The scientific evidence indicates that "bacteria on the surface of [apple] fruit dies within a short time". Please explain.

81. The latter statement that "bacteria on the surface of [apple] fruit dies within a short time" (by Anderson (1952) and cited by Thomson (2000)) is not contradicted by the recovery of epiphytic bacteria from fruit in storage by van der Zwet *et al.* (1990). As the United States has previously explained, fire blight bacteria are not suited for external survival (other than on stigmas of developing flowers) in orchards, and those rare instances of epiphytic recovery from harvested mature fruit are likely due to fresh deposition of bacteria from active inoculum sources.[61] To put the data from van der Zwet (1990) in perspective, although all 175 apple fruit were harvested from trees in severely blighted orchards and were stored only 1 week before testing, *only 10 cells* of *E. amylovora* were recovered from 5 fruit. Thus, because the recovered bacterial cells were likely freshly deposited from nearby inoculum sources shortly before harvest, these findings are not inconsistent with the evidence that bacteria on fruit surfaces dies within a short time.

82. The notion that orchard conditions lead to a decline in bacterial populations is well-established. Dueck (1974) studied the survival of Erwinia amylovora in association with apple fruit, and in this work he made special reference to orchard conditions affecting the survival of E. amylovora: "Apparently orchard conditions are unfavorable for the survival of E. amylovora

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[60]R.G. Roberts *et al.*, *Evaluation of mature apple fruit from Washington State for the presence of* Erwinia amylovora, Plant Disease 73: 917-21 (1989) (Exhibit USA-28); *see* U.S. First Written Submission, paras. 33, 35.

[61]*See* U.S. First Written Submission, para. 37 (citing sources).

toward the end of the growing season. . . . . There is a natural decline in the *E. amylovora* population on vegetative plant parts of apple and pear in late August and early September. Twig cankers are inactive by September (*i.e.*, the harvest period) and have relatively low numbers of bacteria. In the present investigation the pathogen could not be detected on fruit of naturally infected trees during the normal harvest period." Dueck (1974) also found that when naturally-occurring fire blight ooze containing *E. amylovora* was swabbed onto developing apples in an orchard, the bacterium was not detectable (viable) after 18 days. Other work by Hale and Taylor (1999) reported sharp declines in number of surviving *E. amylovora* cells on inoculated apples during 25 days of cold storage. In light of these results, it is highly probable that the few live cells detected by van der Zwet *et al*., (1990) after 1 week of storage were remnants of an earlier population that was nearing extinction when the fruit were assayed.

34. Please explain the relevance of the Maas Geesteranus and de Vries (1984) study cited in footnote 91 of the US first submission.

83. Maas Geesteranus and de Vries (1984) is significant because it reports experimental data on survival of *E. amylovora* on leaf or coverslip surfaces under varying environmental conditions. The authors reported that *E. amylovora* cells died within a few hours of exposure to relative humidities greater than 75% and within 6 hours when exposed to sunlight as they would be in an orchard. *E. amylovora* cells survived slightly longer in natural ooze than as naked cells, but otherwise they responded similarly to the environmental variables studied. These data further support the explanation given in Question 33 above regarding declining numbers of surviving *E. amylovora* cells over time due to vulnerability to environmental conditions.

35. Does the US concur with the statement in Japan's first submission, footnote 51, "...that the United States admits the recovery of endophytic bacteria from inside symptomless apples as late as August - up to 21%"?

84. Japan provides no citation for its claim that "the United States admits the recovery of endophytic bacteria from inside symptomless apples as late as August – up to 21%." We presume, given the 21% figure, that Japan is referring to the distance experiment reported in Table 3 of van der Zwet *et al.* (1990). If this is correct, we do not "admit" the statement presented by Japan because Japan has, once again, misreported the data in van der Zwet *et al.* (1990).

85. A plain reading of Table 3 reveals that the "21%" figure cited by Japan does *not* relate to "endophytic bacteria from inside symptomless apples as late as August." The recovery of fire blight bacteria from 21 percent of fruit tissues tested clearly was made from Red Rome fruit *harvested in July* 0 cm from a blighted shoot. "[A]s late as August," Table 3 reports recovery of fire blight bacteria from only 3 percent of blighted fruit tissues, 5 percent of tissues from fruit 0 cm from a blighted shoot, and 2 percent of tissues from fruit 15 cm from a blighted shoot; no bacteria were recovered from any other distances. (As is evident from the July and August harvest dates and expressly stated by Dr. van der Zwet in his declaration, moreover, the fruit

harvested in *both* July and August were immature.) Thus, the United States does *not* "admit[] the recovery of endophytic bacteria from inside symptomless apples as late as August – up to 21%" because the plain data in the van der Zwet *et al.* (1990) paper do not support the statement.

36. The US submission makes reference to several studies which have not been provided to the Panel. Could you please provide copies of the following studies:
Dueck (1974)
Maas Geesteranus and de Vries (1984)
Roberts, et al (1989)
Thomson (1992)
Van der Zwet, et al (1991)

86. The United States attaches copies of Dueck (1974) as Exhibit USA-42, Maas Geesteranus and de Vries (1984) as Exhibit USA-43, Roberts *et al.* (1989) as Exhibit USA-28, Thomson (1992) as Exhibit USA-44, and Van der Zwet *et al.* (1991) as Exhibit USA-45.

37. Has the relevant scientific evidence concerning the measures at issue changed or evolved over time in a way that affects their consistency with Articles 2.2, 5.1 or 5.7 of the SPS Agreement?

87. No. The scientific evidence has always been the same: there is no scientific evidence that mature apple fruit transmit the disease. Many billions of apple fruit traded worldwide have not resulted in *any* evidence that commercially-traded apple fruit have transmitted *E. amylovora* that caused an outbreak of fire blight. To the contrary, the scientific evidence establishes that mature apple fruit are not a pathway for introduction of the disease to Japan. As a result, Japan has acted inconsistently with its obligation under Article 2.2 because there is no rational or objective relationship between the scientific evidence and Japan's fire blight measures. Where there never has been any scientific evidence that mature apple fruit are a pathway for introduction of fire blight, there never has been a probability or likelihood that mature apple fruit will introduce the disease, and there is no scientific evidence of a risk to mitigate; thus, Japan has failed to base its fire blight measures on a proper assessment of risks, inconsistently with Article 5.1. Finally, where the scientific evidence has always been that imported apple fruit have never transmitted *E. amylovora* and are not a pathway for introduction of fire blight, the qualified exemption under Article 5.7 for measures inconsistent with Article 2.2 has never been available to Japan.[62]

38. Japan indicates that "the risk posed must be assessed on the basis of available indirect evidence". Could you please comment on this notion of indirect evidence (see para. 26 and 39 of the Japanese oral statement) and more generally on (1) the nature of

[62]For a more detailed explanation of the U.S. view of Japan's Article 5.7 defense, please see the U.S. answer to Question 40 from the Panel.

the evidence available with regard to the evaluation of risks from fire blight infection and (2) how the existence of this type of risk can be established?

88. The evidence that is relevant to Japan's WTO commitments and relevant to the Panel's assessment of conformity with those commitments is "scientific evidence." Specifically, Article 2.2 of the SPS Agreement states that a Member shall ensure that an SPS measure is not maintained "without sufficient scientific evidence." Thus, in the first instance, the Panel should look not to whether evidence is direct or indirect but whether it is scientific.

89. The term "scientific evidence" is not defined in the SPS Agreement;[63] according to the customary rules of interpretation of public international law, these terms should be interpreted according to their ordinary meaning in their context, in light of the object and purpose of the Agreement. "Evidence" is defined as "something serving as a proof."[64] "Scientific" is defined as "[o]f, pertaining to, or of the nature of science; based on, regulated by, or engaged in the application of science . . . ; valid according to the objective principles of the scientific method."[65] The "scientific method" is defined as "a method of procedure that has characterized natural science since the 17th cent., consisting in systematic observation, testing, and modification of hypotheses."[66] Thus, "scientific evidence" may be understood as something serving as proof that is valid according to the objective principles of the scientific method, understood as systematic observation, testing, and modification of hypotheses. The United States does *not* assert that evidence sufficient for Japan to maintain its fire blight measures must be direct or that it may not be indirect, but under Article 2.2 such evidence *must* be scientific, that is, valid according to the objective principles of the scientific method.[67]

90. In the U.S. first written submission and closing statement to the Panel, the United States suggested that scientific evidence that apple fruit pose a risk of introduction of fire blight to Japan could consist of evidence that fruit have, in fact, introduced the disease to other areas and evidence that fruit are a pathway for introduction. On the first point, Japan does not appear to contest that there is no evidence that apple fruit have ever transmitted the disease. On the second

[63]The term is also used in Article 5.2, which states that "In the assessment of risks, Members shall take into account available scientific evidence . . . ."

[64]*The New Shorter Oxford English Dictionary*, vol. 1, p. 867 (Oxford Univ. Press 1993).

[65]*The New Shorter Oxford English Dictionary*, vol. 2, p. 2717 (Oxford Univ. Press 1993).

[66]*The New Shorter Oxford English Dictionary*, vol. 2, p. 2717 (Oxford Univ. Press 1993) (special collocations under definition of "scientific").

[67]We note that, in discussing the evidence to which Japan cites to support its requirement that containers for harvesting be treated with chlorine, we stated: "The evidence Japan cites is circumstantial, not direct or scientific evidence, and Japan makes no assessment of the relative effectiveness of this measure on reducing the likelihood of entry or overall disease risk." U.S. First Written Submission, para. 85 (item (6)) (footnote omitted). If the use of the word "direct" in this passage has led to the repeated invocation of "indirect" and "direct," we regret the imposition on the Panel's time and would be content to argue simply that "circumstantial" evidence is not "scientific" evidence.

point, Japan has neither identified each step necessary for imported apple fruit to serve as a hypothetical pathway (for example, the 5 steps identified by the International Plant Protection Convention)[68] nor cited to the scientific evidence on which it relies to establish that each step of the hypothetical pathway would be completed. Thus, even if examining the scientific evidence relating to each step of the hypothetical pathway to determine the likelihood of entry, establishment, or spread of *E. amylovora* and fire blight through imported apple fruit would be characterized as an assessment of "indirect" evidence, Japan has not made such an evaluation.

91. Japan's three sets of "indirect" evidence on which it bases its measures are: (1) evidence of "a serious risk of dissemination of the disease through latently infected apple fruit," (2) "published literature on the ecology, properties and survivability of *Erwinia amylovora* [that allegedly] establishes that the bacteria are evidently capable of survival inside or on the surface of apple fruit," and (3) various results allegedly reported in the 1990 paper by van der Zwet *et al.*[69] The "indirect" evidence cited by Japan does not constitute scientific evidence relating to step 3 (the probability of survival of the pest during transport or storage), step 4 (the probability of the pest surviving existing pest management procedures), or step 5 (the probability of transfer of the pest to a suitable host) of the IPPC analysis of entry.

92. First, Japan supports its assertion of "a serious risk of dissemination" by reference to four instances of trans-oceanic dissemination. However, these instances clearly do *not* "indicate[] that there is a serious risk of dissemination of the disease through latently infected apple fruit" since none of these instances *involved* apple fruit.[70] Second, the unnamed "variety of published literature on the ecology, properties and survivability of *Erwinia amylovora*" which purportedly "establishes that the bacteria are evidently capable of survival inside or on the surface of apple fruit" does not constitute an evaluation of the likelihood of survival through steps 3, 4, and 5 of the analysis of entry; in fact, the scientific evidence establishes that it is highly unlikely that fire blight bacteria would survive commercial handling, storage, and transport, existing pest management procedures, and consumption and/or discard.[71] Finally, we have corrected and will continue to correct serious errors in Japan's reading of the evidence, particularly van der Zwet *et al.* (1990). However, even accepting Japan's erroneous reading, this paper would only present scientific evidence related to step 2 (the probability of the pest being associated with the pathway at origin) of the IPPC analysis of entry.

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[68] *See* International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests §§ 2.2.1.1-2.2.1.5, at 13 (2001) (International Standards for Phytosanitary Measures Publication No. 11) (describing 5 steps comprising evaluation of probability of entry of a pest) (Exhibit USA-15).

[69] Oral Statement of Japan, paras. 27-29 (October 21, 2002).

[70] For further discussion of these four instances of dissemination as well as Japan's misreporting of the relevant literature, please see the U.S. answer to Question 23 from the Panel.

[71] *See* U.S. First Written Submission, paras. 38-41 (Section IV.A.3.C: Bacteria Are Highly Unlikely to Survive Commercial Handling, Storage, and Transport of Fruit).

93. Thus, Japan has not presented any scientific evidence, indirect or direct, relating to steps 3, 4, or 5. In fact, had Japan evaluated the likelihood that each of these steps would be completed – that is, that bacteria would survive commercial handling, storage, and transport; that the bacteria would survive the current pest management procedures Japan imposes on U.S. apples for other pests (such as the 55-day cold treatment requirement for codling moth); that bacteria would survive consumption and/or discard; and that bacteria would be vectored to a susceptible plant host, at a receptive stage, with infection occurring – it would have been plain to Japan that the scientific evidence establishes that steps in the hypothetical pathway will either not be (step 5) or are very unlikely to be (steps 3 and 4) completed.[72] Thus, no fire blight measure is justified on imported mature fruit because the scientific evidence establishes that no genuine risk arises to Japanese plant life or health from apple imports.

> *39. Could you please comment on Japan's observation in paragraph 37 of its oral statement that the United States "appears to demand that Japan, not the United States, bear the burden of proof on this point and prove with "direct" evidence the pathway of fire blight"? Please also comment on Japan's argument in the same paragraph concerning the availability of evidence to it, as an importing country.*

94. Japan's concern is misplaced; the United States recognizes that in this dispute it bears the burden of proof of establishing that Japan has acted inconsistently with its obligation to ensure that its fire blight measures are not maintained without sufficient scientific evidence, and we believe that we have met our burden of proof under Article 2.2.[73] However, Japan has an *obligation* under Article 2.2 not to maintain its measure without sufficient scientific evidence, and the assignment of a burden of proof in dispute settlement cannot alter this obligation.

95. In *Japan – Varietals*, the United States argued that it would be impossible to prove that *no* scientific evidence supporting a measure exists because it is impossible to prove a negative. The Appellate Body noted that, in the context of an argument that there is no scientific evidence supporting a measure under Article 2.2:

> [It is] sufficient . . . to raise a presumption that there are no relevant studies or reports. Raising [such] a presumption . . . is not an impossible burden. The United States could have requested Japan, pursuant to Article 5.8 of the SPS Agreement, to provide 'an explanation of the reasons' for its varietal testing requirement, in particular, as it applies to [several products]. Japan would, in that case, be obliged to provide such an explanation. The failure of Japan to bring forward scientific studies or reports in support of its [measure] would have been a strong indication that there are no such studies or reports. The United States

[72] *See* U.S. First Written Submission, paras. 29-45 (Section IV.A.3.: The Scientific Evidence Underlying the Fact That Mature, Symptomless Apples Do Not Serve As a Pathway for the Disease).

[73] *See* Opening Oral Statement of the United States, paras. 26-28 (October 21, 2002).

> could also have asked the Panel's experts specific questions as to the existence of relevant scientific studies or reports or it could have submitted to the Panel the opinion of experts consulted by it on this issue.[74]

From this, it is clear that, while the burden of presenting facts and arguments establishing a presumption of an absence of evidence lies with the United States, this burden is not, in light of the nature of the obligation, a high one.

96. The United States did, in fact, request pursuant to Article 5.8 that Japan provide an "explanation of the reasons for" its measures, including specific requests that Japan "identify the scientific evidence upon which [each fire blight] restriction is based" and "provide any scientific studies or reports that support [each such] restriction."[75] No written response was received to this request, but at the WTO dispute settlement consultations, Japan indicated that the scientific basis for its measures was provided in letters from Japan to the United States dated December 6, 1996,[76] and May 27, 1999,[77] and in the Japanese 1999 Pest Risk Analysis.[78] (Japan neither pointed to nor provided copies of any specific scientific studies or reports to support its measures.) As the scientific evidence cited in these 3 documents has been examined and discussed in this proceeding, Japan's reply raises a presumption that (1) there is *no* scientific evidence that mature apple fruit have ever transmitted *E. amylovora* and introduced the disease;[79] (2) there is *no* scientific evidence that mature apple fruit harvested from an orchard may be infected with *E. amylovora*;[80] (3) there is *no* scientific evidence that mature apple fruit harvested from an orchard may be endophytically contaminated with *E. amylovora*;[81] and (4) there is *no* scientific evidence that a vector exists to transfer any hypothetically surviving *E. amylovora* on a discarded mature apple fruit within Japan to a susceptible plant host.[82] Japan's failure to respond to requests to *identify* such scientific evidence further raises a presumption that no such evidence exists. Finally, the United States notes that it has provided substantial affirmative evidence that

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[74] *Japan – Varietals*, WT/DS76/AB/R, para. 137.

[75] Letter from David Shark, Permanent Mission of the United States, to Ambassador Koichi Haraguchi, Permanent Mission of Japan (April 4, 2002) (Question 1) (Exhibit USA-24).

[76] Letter from Ministry of Agriculture, Forestry and Fisheries, to R. Spaide, U.S. Department of Agriculture (December 6, 1996) (Exhibit USA-21).

[77] Letter from T. Kocha, Ministry of Agriculture, Forestry and Fisheries, to J. Mackley, U.S. Department of Agriculture (May 27, 1999) (Exhibit USA-46).

[78] Ministry of Agriculture, Forestry and Fisheries, Report on Pest Risk Analysis on Fireblight (1999) (Exhibit USA-3).

[79] *See* U.S. First Written Submission, paras. 24-28.

[80] *See* U.S. Answers to Questions 2 and 4 from the Panel.

[81] *See* U.S. First Written Submission, paras. 33-34.

[82] *See* U.S. First Written Submission, paras. 42-45.

mature apple fruit have not transmitted fire blight and are not a pathway for transmission of the disease,[83] including evidence that steps in the hypothetical pathway will either not be or are very unlikely to be completed.[84] The United States has more than met its burden in this dispute of establishing that Japan is maintaining its measure without scientific evidence in contravention of its obligation under Article 2.2.

97. As we have noted in response to Question 38 from the Panel, Japan need not provide "direct" evidence that apple fruit are a pathway, but it must provide "scientific" evidence establishing it. The "indirect" evidence Japan provides is not *scientific* evidence that each step necessary for an analysis of the probability of entry of fire blight via mature apple fruit will be completed. Evidence of dissemination of fire blight through infected budwood (propagative materials), for example, is not scientific evidence relevant to *any* step necessary for apple fruit to serve as a pathway. Nonetheless, such conjecture and non-scientific assertions form an integral part of the "evidence" on which Japan relies to maintain its measures. As to Japan's assertion that it "does not have easy access to crucial information," Japan has the same access to the scientific evidence as any WTO Member, and that scientific evidence establishes that imported mature apple fruit have never introduced and do not serve as a pathway for introduction of fire blight. Further, Japan cannot credibly fault the United States' creation of, and provision of, relevant scientific evidence over the course of the past 15 years. Over that time, the United States has conducted a comprehensive review of the fire blight literature and 4 experiments, even going so far as to repeat a study documenting the absence of endophytic bacteria in mature fruit, simply to obtain the evidence in the presence of Japanese scientists. That Japan continues to this day to deny the affirmative scientific evidence of a lack of risk from mature apple fruit supports a conclusion not that Japan lacks the ability to obtain evidence, but that it does not wish to obtain it.

40. Japan has invoked Article 5.7 of the SPS Agreement. Could you please comment on this defense?

98. The United States does not believe that the requirements necessary under Article 5.7 to claim the qualified exemption from Article 2.2 for an SPS measure that is maintained without sufficient scientific evidence have been established. As noted by the panel and Appellate Body in *Japan – Varietals*, Article 5.7 sets out four requirements that must be met in order to adopt a provisional SPS measure exempt from Article 2.2. Pursuant to the first sentence of Article 5.7, the provisionally adopted measure may be imposed only "[i]n cases where relevant scientific evidence is insufficient" and must be adopted "on the basis of available pertinent information." Pursuant to the second sentence of Article 5.7, the provisional measure may not be maintained unless the adopting Member "seek[s] to obtain the additional information necessary for a more objective assessment of risk" and "review[s] the . . . measure within a reasonable period of time."

[83] *See, e.g.*, U.S. First Written Submission, paras. 24-45.

[84] *See* U.S. Answer to Question 38 from the Panel.

The four requirements "are clearly cumulative in nature" and "[w]henever *one* of these four requirements is not met, the measure at issue is inconsistent with Article 5.7."[85]

99. The Panel's analysis can begin and end with the first requirement that the provisional measure be imposed only "[i]n cases where relevant scientific evidence is insufficient." This requirement has not yet been construed by a panel or the Appellate Body. "Relevant" means "[l]egally pertinent or sufficient" and "[b]earing on, connected with, or pertinent to the matter in hand."[86] The matter at hand under Article 5.7 is the assessment of risks. Article 5.7 forms part of Article 5, entitled "Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection." Important context for the word "relevant" is given by the second sentence of Article 5.7, which clarifies that, "[i]n *such* circumstances," a Member taking a provisional measure "shall seek to obtain the *additional information necessary for a more objective assessment of risk*." The negative implication is that, at the time the provisional measure is adopted, the information necessary for an objective assessment of risk is lacking.

100. This is only logical. If there were sufficient information to conduct a risk assessment and that information supported a measure, there would be no need to adopt a measure "provisionally," since it could be adopted "based on" the risk assessment pursuant to Article 5.1. Likewise, if there were sufficient information to conduct a risk assessment and that assessment indicated that a measure were not justified, a Member which would not be able to adopt a measure under Article 5.1 should not then be free to adopt a measure "provisionally" under Article 5.7. Otherwise, the obligation in Article 5.1 would become meaningless.

101. The conclusion that sufficiency in the first sentence of Article 5.7 should be understood to relate to the information available for a risk assessment is also supported by the language of the second clause of that sentence. "In cases where relevant scientific evidence is insufficient," provisional measures may be adopted "on the basis of available pertinent information including that from the relevant international organizations as well as from ... phytosanitary measures applied by other Members." It would not be necessary to adopt a measure "on the basis of" such "available pertinent information" if the measure could be "based on" a risk assessment (which presupposes that there is sufficient scientific information to conduct the risk assessment).

102. Thus, the phrase "[i]n cases where relevant scientific evidence is insufficient" indicates that a provisional measure may be taken only where some piece of scientific evidence bearing on or pertinent to a more objective assessment of risk is unavailable. Japan has not demonstrated that the relevant scientific evidence is insufficient.

103. In this case, the scientific evidence is more than sufficient to establish that imported mature apple fruit do not pose a risk to plant life or health within Japan. The scientific evidence

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[85] *Japan – Varietals*, WT/DS76/AB/R, para. 89.

[86] *The New Shorter Oxford English Dictionary*, vol. 2, p. 2536 (Oxford Univ. Press 1993).

establishes that exported fruit have not resulted in introduction of fire blight to new areas, despite billions of fruit traded. Major reviews of the scientific evidence related to the epidemiology of the disease have either not considered it necessary to describe the insignificant risk posed by trade in fruit (Schroth *et al.* (1974)[87]) or have explicitly concluded that fruit are not implicated in spread of the disease (Thomson (1992)[88], European and Mediterranean Plant Protection Organization (1997)[89], Roberts *et al.* (1998)[90], Thomson (2000)[91]). The scientific evidence also establishes that mature apple fruit are not a pathway for the disease.[92] Steps necessary to form a pathway are either very unlikely to or will not occur. For example, the scientific evidence demonstrates that endophytic fire blight bacteria are not recovered from mature apple fruit; that epiphytic fire blight bacteria are very rarely recovered from mature fruit, even when harvested from blighted trees and orchards; that even if a mature, symptomless apple were externally contaminated with bacteria, such bacteria are unlikely to survive normal commercial handling, storage, and transport of fruit; and that even if external bacteria remained on discarded imported fruit, there is no dispersal mechanism or vector to allow movement of such bacteria from the fruit to a suitable host. Thus, this is not a case where the "relevant scientific evidence is insufficient"; the evidence is more than sufficient to establish that imported apple fruit have never transmitted and are not a means of introduction of fire blight to Japan. As a result, the first requirement under Article 5.7 is not satisfied, and Japan may not adopt a provisional measure pursuant to that provision.

104. Nor has Japan met the second requirement of the first sentence of Article 5.7, that the measure was adopted "on the basis of available pertinent information." In its first written

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[87]M.N. Schroth *et al.*, *Epidemiology and control of fire blight*, Annual Review of Phytopathology 12: 389-412, 386-99 (1974) (no mention of role of trade in fruit in short- or long-distance spread) (Exhibit USA-47).

[88]S.V. Thomson, *Fire blight of apple and pear*, *in* Plant Diseases of International Importance, vol. 3: Diseases of Fruit Crops 32-65, at § 2-9-1 (J. Kumar *et al.*, eds.) (1992) ("[I]t seems very remote that contaminated fruit could be responsible for establishing new outbreaks. The presence of E. amylovora on or in healthy fruit has not been shown to be a source of inoculum in fruit orchards.") (Exhibit USA-44).

[89]European and Mediterranean Plant Protection Organization (EPPO), *Data Sheet on Quarantine Pests:* Erwinia amylovora, Quarantine for Europe, at 4 (1997) (Means of Movement and Dispersal) ("[T]he risk of [fire blight] transmission on fruit is considered insignificant in current trade practice.") (Exhibit USA-5).

[90]R.G. Roberts, *et al. The potential for spread of* Erwinia amylovora *and fire blight via commercial apple fruit: a critical review and risk assessment*, Crop Protection 17: 19-28, 25 (1998) ("We have found no evidence in the scientific literature that apple fruit in commercial shipments, whether contaminated with E. amylovora or not, have provided inoculum for an outbreak of fire blight.") (Exhibit USA-4).

[91]S.V. Thomson, *Epidemiology of Fire Blight*, *in* Fire Blight: The Disease and Its Causative Agent, *Erwinia Amylovora*, at 17 (2000) (J.L. Vanneste, ed.) ("[I]t has never been demonstrated that mature fruit are involved in dissemination of Erwinia amylovora and serve as a source of new infections in orchards. It would be extremely unlikely that contaminated fruit could be responsible for establishing new outbreaks of fire blight.") (Exhibit USA-2).

[92]*See* U.S. First Written Submission, paras. 29-45 (Section IV.A.3: The Scientific Evidence Underlying the Fact That Mature, Symptomless Apples Do Not Serve As a Pathway for the Disease).

submission, Japan cites no *specific* "available pertinent information," instead making a vague reference to "foreign SPS measures and a range of literature."[93] However, even if one were to consider that Japan is relying on all of the information raised with respect to Article 2.2 as "available pertinent information," this would not support the measure. None of this information so much as suggests that mature apple fruit can serve as a pathway for fire blight. Furthermore, foreign fire blight measures in the vast majority of cases either support the *opposite* conclusion (where they are non-existent or minimal and have nevertheless not resulted in fire blight transmission)[94] or relate to the prevention of fire blight spread on host plants (rather than on fruit), such as the buffer zone measures referred to in paragraph 237 of Japan's submission.[95]

105. Japan's "available pertinent information," like its "scientific evidence," is thus either not "pertinent" to apple fruit, or, with respect to its suggested pathway, is little more than speculative. On the latter point, the Appellate Body has already noted that such hypothetical risks may not serve as the basis for a risk assessment under Article 5.1.[96] Likewise, such speculation is not enough to justify application of a "provisional" measure under Article 5.7. If speculation were sufficient, Members would not need to conduct risk assessments, nor would they need to maintain measures with sufficient scientific evidence; Article 5.7 would simply swallow the rest of the SPS Agreement.

106. Japan also fails to meet the requirements of the second sentence of Article 5.7. Japan suggests that it met the first requirement, that it "seek to obtain the additional information necessary for a more objective assessment of risk," through its proposal of, and participation in, the 2000 joint study, and through the five questions posed to the United States ten months after completion of this study.[97] To the contrary, Japan's actions in connection with the joint study only confirm that it has *not* been seeking such additional information. Notwithstanding the clear confirmation through this study of results which had been presented to Japan over the previous twelve years, Japan waited eight months after the results became known to inform the United States of alleged flaws in a study it had proposed and previously agreed to, and asked five questions to which it knew the answers.[98] That is, Japan waited until the 2001 harvest season

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[93]First Written Submission of Japan, para. 240.

[94]*See* Exhibit USA-14 (table detailing fire blight measures imposed on imported apples in fire blight-free areas).

[95]Japan also cites "empirical evidence" from a study in Belgium isolating *E. amylovora* up to 250 meters away from a source of inoculum. As the United States has explained, this work suffers from serious limitations, such as the use of a detection method that does not distinguish dead from live bacterial cells and the failure to confirm that the bacterial cells detected were of the same strain as the inoculum source (and thus not cells from some other fire blight source in the area). *See* U.S. First Written Submission, para. 51.

[96]*EC – Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, para. 186.

[97]First Written Submission of Japan, para. 241.

[98]*See* U.S. answer to Question 28 from the Panel.

was underway to respond, at which point it was *too late* to change its measure to allow shipment of that crop, ensuring at least another year without significant U.S. apple imports. This is evidence that Japan affirmatively avoided relevant additional information.

107. Further, even if Japan's participation in the joint study could be considered an effort to obtain additional information with respect to the presence of *Erwinia amylovora* in mature apple fruit, it provides no information with respect to other elements of the pathway. Here as well, Japan's refusal to acknowledge information submitted to it over the previous twelve years supports the conclusion not that it was not seeking this information, but avoiding it. As the Appellate Body noted in *Japan – Varietals*, under the second sentence of Article 5.7, the information sought must "allow the Member to conduct 'a more objective assessment of risk'. Therefore, the information sought must be germane to conducting a risk assessment."[99] Japan has not sought, but disregarded, evidence relating to whether any epiphytic bacteria would survive commercial handling, storage, and transport; whether any epiphytic bacteria would survive Japan's mandated cold treatment for codling moth or any other existing pest management procedures; whether any epiphytic bacteria would survive consumption and/or discard; and whether any epiphytic bacteria could be vectored from a discarded apple fruit to a susceptible host.

108. Likewise, Japan has failed to meet the requirement of the final element of Article 5.7, that it "review . . the . . . measure within a reasonable period of time." In *Japan – Varietals*, the panel correctly concluded that Japan could not meet this requirement if it was not even *seeking* the relevant information.[100] Japan in its 1996 and 1999 pest risk assessments never examined, let alone sought, information and evidence on critical elements of the pathway for transmission of fire blight, nor has it since. Under these circumstances, it is clear that Japan has not reviewed the measure in the nearly eight years since 1995, notwithstanding the periodic restatements (in response to U.S. prodding) of its speculation that mature apple fruit pose a risk of transmitting fire blight.

109. Thus, the Panel should reject Japan's attempt to justify its measure as meeting the requirements of Article 5.7.

> *41. Japan has indicated, in its first submission and in paragraph 4 of its oral statement, how the US claim should, in its view, be understood. Do you agree with this description of your claim?*

110. In paragraph 4 of its oral statement, Japan suggests that the U.S. claim under Article 2.2 "should be understood to mean that there is, allegedly, *no longer* sufficient scientific evidence for Japan's phytosanitary requirements in light of the latest information available. Specifically,

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[99] *Japan – Varietals*, WT/DS76/AB/R, para. 92.

[100] *Japan – Varietals*, WT/DS76/R, para. 8.58.

according to their argument, it must have been some time after 1994 that the alleged new information became available and Japan could not lawfully refuse the new proposals." Japan has used almost identical terms to describe the U.S. claim in paragraph 23 of its first written submission. As stated in the U.S. closing statement and in response to a question at the first meeting of the Panel with the parties, the United States is not claiming that the scientific evidence suddenly became insufficient to support Japan's fire blight measures at some point after 1994. In fact, the evidence has always been the same: there has never been any scientific evidence that mature apple fruit serve to introduce fire blight. The scientific evidence that mature apple fruit have never introduced fire blight and are not a pathway for the disease has been presented repeatedly by the United States – most recently in the U.S. answer to Question 40. This evidence predates the entry into force of the Japanese fire blight measures in 1994 and continues to this day. Thus, Japan has been acting inconsistently with its commitment under Article 2.2 not to maintain its fire blight measures without sufficient scientific evidence since the entry into force of the SPS Agreement in 1995, and Japan has not yet removed that inconsistency. (The United States notes, in its answer to Question 25, that it acquiesced to the Japanese fire blight measures without accepting their consistency with Japan's WTO obligations.)

42. In light of the US claims that the measures at issue are inconsistent with Articles 2.2 and 5.1 of the SPS Agreement, could you please comment on the following statement by the panel in Australia - Salmon that "in the event a sanitary measure is not based on a risk assessment as required in Articles 5.1 and 5.2, this measure can be presumed, more generally, not to be based on scientific principles or to be maintained without scientific evidence" (Australia - Measures Affecting the Importation of Salmon, Report of the Panel, WT/DS18/R, para. 8.52).

111. This statement by the *Australia – Salmon* panel, endorsed by the Appellate Body,[101] highlights the close relationship between Articles 2.2, 5.1, and 5.2. The latter two provisions set out the method by which risk is to be assessed[102] and the data to be taken into account in that evaluation (such as "available scientific evidence"); Article 5.1 then requires a Member to base its SPS measure on such an assessment of risks. For a measure to be "based on" the assessment of risks, the results of the assessment must "sufficiently warrant – that is to say, reasonably support – the SPS measure."[103] Thus, to the extent a measure is not reasonably supported by a proper assessment of risks, which will have taken into account "available scientific evidence," it follows that the measures will not have been maintained with "sufficient scientific evidence" – that is, there will not be a "rational or objective relationship between the SPS measure and the

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[101]*Australia – Salmon*, WT/DS18/AB/R, paras. 135-37.

[102]Pursuant to Annex A, paragraph 5, as read in WTO dispute settlement proceedings, a "risk assessment" is the evaluation of the likelihood – *i.e.*, the probability – of entry, establishment, or spread of a disease within the territory of the importing Member according to the SPS measures that might be applied.

[103]*EC–Hormones*, WT/DS26/AB/R, para. 193 ("[T]he results of the risk assessment must sufficiently warrant–that is to say, reasonably support–the SPS measure.").

scientific evidence."[104] As the United States has noted in its first written submission, because Japan has maintained the fire blight measures without basing them on a risk assessment under Article 5.1, Japan has also acted inconsistently with Article 2.2.[105]

112. Nevertheless, the United States has claimed, and requests that the Panel find, that Japan has breached Article 2.2 independently of its breach of Article 5.1. Japan's measure is maintained without *any* evidence with respect to critical elements of the pathway for the introduction of fire blight, with insufficient evidence with respect to others, and in the face of affirmative contrary evidence with respect to all. DSU Article 3.4 provides that "[r]ecommendations and rulings of the DSB shall be aimed at achieving a satisfactory settlement of the matter in accordance with the rights and obligations under this Understanding and under the covered agreements." An independent finding under Article 2.2 would assist the parties in achieving a satisfactory settlement, and avoid the potential for further litigation, by making clear that Japan's breach cannot be cured through mere redrafting of an analysis not based on scientific evidence.

43. What is the relevance of conditions for establishing disease-free conditions on the site of production (or for eradication programmes) for ensuring that fruit is disease free?

113. The use of pest-free places of production or pest-free production sites is one type of measure that may be considered to manage the risk that a pathway (such as a traded commodity) is deemed to pose as determined by a proper pest risk assessment.[106] Japan has asserted that imported apple fruit may serve as a pathway. However, Japan's pest risk assessment does not evaluate the likelihood (*i.e.*, the probability) of entry, establishment or spread of fire blight by imported apple fruit,[107] and the scientific evidence demonstrates that the traded commodity (mature apple fruit) does not serve as a pathway for the introduction of fire blight.[108] Thus, the conditions for establishing pest free places of production or production sites are not relevant to ensuring that imported fruit are disease-free and do not transmit fire blight. The United States also notes that under U.S. law and regulations, exported apple fruit must be disease-free

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[104]*Japan – Varietals*, WT/DS76/AB/R, para. 84.

[105]U.S. First Written Submission, para. 94.

[106]*See* International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests § 3.4, at 22-24 (2001) (International Standards for Phytosanitary Measures Publication No. 11) (Identification and selection of appropriate pest risk management options) (Exhibit USA-15); International Plant Protection Convention, Guidelines for Pest Risk Analysis § 3, at 17 (1996) (International Standards for Phytosanitary Measures Publication No. 2) (Stage 3: Pest Risk Management) (Exhibit JPN-30).

[107]*See* U.S. First Written Submission, paras. 63-95 (U.S. claim under Article 5.1 of the SPS Agreement).

[108]*See* U.S. First Written Submission, paras. 20-62 (U.S. claim under Article 2.2 of the SPS Agreement).

(symptomless).[109] Thus, even if fire blight disease is present in a production site or area, exported mature apple fruit do not facilitate the introduction of *Erwinia amylovora* to new areas.

44. Annex A, paragraph 4 of the SPS Agreement requires the evaluation of "the likelihood of entry, establishment or spread (...)". What is, in your view, the influence of a finding of "low" probability of entry, establishment or spread in the context of a risk assessment? Is there, in the US view, a threshold of probability/likelihood below which no measure can be justified?

114. In the context of a risk assessment the influence of a finding of “low” probability of entry, establishment or spread is seen on the SPS measures that may be required to achieve a Member’s appropriate level of protection. As the IPPC pest risk guidelines note: “The conclusions from pest risk assessment are used to decide whether risk management is required and the strength of the measures to be used.”[110] Furthermore, “Pest risk management . . . to protect the endangered areas should be proportional to the risk identified in the pest risk assessment.”[111] Thus, a low level of risk could affect the risk mitigation actions taken by the importing country.

115. The threshold of probability (likelihood) below which no measure is justified is a question of the Member’s appropriate level of protection. Furthermore, an SPS measure cannot be maintained without sufficient scientific evidence (Article 2.2). The SPS measure must also be based on an assessment of risk, which requires an evaluation of the likelihood of entry, establishment, or spread (Article 5.1 & Annex A); mere theoretical uncertainty is not the kind of risk which a risk assessment and, therefore, an SPS measure, is to address.[112] Thus, where there is no scientific evidence that mature apple fruit transmit fire blight, there is no probability or likelihood that mature apple fruit may transmit fire blight; where there is no real risk (as opposed to conjecture or theoretical uncertainty) for the measure to mitigate, no measure may be maintained.

45. Japan claims that its 1999 risk assessment is based on the 1996 IPPC guidelines. These guidelines were revised in 2001. In your view, can a risk assessment be assessed

[109] U.S. First Written Submission, fn. 38 (detailing requirements of U.S. Export Apple Act and United States Standards for Grades of Apples).

[110] International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests § 3, at 21 (2001) (International Standards for Phytosanitary Measures Publication No. 11) (Stage 3: Pest Risk Management) (Exhibit USA-15).

[111] International Plant Protection Convention, Guidelines for Pest Risk Analysis § 3, at 17 (1996) (International Standards for Phytosanitary Measures Publication No. 2) (Stage 3: Pest Risk Management) (Exhibit JPN-30).

[112] *See European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, para. 186; WT/DS26/R, paras. 8.152-8.153 (adopted February 13, 1998).

under Article 5.1 in the light of the "relevant risk assessment techniques" developed subsequently?

116. The obligation under Article 5.1 of the SPS Agreement is to ensure that a Member's SPS measure is "based on an assessment, as appropriate to the circumstances, of the risks to human, animal, or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations." Annex A further specifies that a "[r]isk assessment" is the "evaluation of the likelihood of entry, establishment, or spread of a pest or disease within the territory of the importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences." Thus, a Member's obligation is not to apply any particular set of risk assessment techniques but rather to assess risk by evaluating the likelihood of entry, establishment, or spread of a pest or disease. Japan's 1999 Pest Risk Analysis manifestly fails to evaluate the likelihood – *i.e.*, the probability – of entry, establishment, or spread by failing to identify the steps necessary for imported apple fruit to serve as a pathway and by failing to evaluate the likelihood of the pathway being completed.

117. The International Plant Protection Convention 2001 guidelines for pest risk analysis for quarantine pests provide expanded specifications, more details, and richer terminology but had no effect on the steps necessary for the imported commodity to serve as a pathway for introduction of fire blight to Japan (and could have had none unless the biology of *Erwinia amylovora* had radically changed between 1996 and 2001). It is not surprising, then, that the 1996 guidelines identify essentially the same steps necessary for introduction of a disease through an imported commodity as the 2001 guidelines – for example, the probability of introduction depends upon the identification of a "pathway[] from the exporting country to the destination," the "frequency and quantity of pests associated with" such a pathway, the "survival of the pest under the environmental conditions of transport," the "ease or difficulty of detecting the pest at entry inspection," and the "environmental conditions and availability of hosts at the destination and during transport in the PRA area."[113] Thus, the Panel's evaluation of whether Japan's assessment of risk satisfies the obligation under SPS Agreement Article 5.1 does not turn on the particular guidelines that were taken into account in making that assessment.

118. The United States notes that Japan has stated that "the 2001 Guidelines were developed from the PRA Guidelines of 1996, and both have substantially the same framework. For this

[113]International Plant Protection Convention, Guidelines for Pest Risk Analysis § 2.3, at 14 (1996) (International Standards for Phytosanitary Measures Publication No. 2) (Introduction Potential) (Exhibit JPN-30). Of the five steps that comprise an evaluation of the probability of entry set out in the 2001 guidelines, the only step arguably not explicitly mentioned in the 1996 guidelines is step 5, the probability of transfer of the pest to a suitable host (although implicit in the analysis of environmental conditions and availability of hosts). *See* International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests § 2.2.1.1-2.2.1.5, at 13-14 (2001) (International Standards for Phytosanitary Measures Publication No. 11) (Probability of entry of a pest) (Exhibit USA-15). We do not understand Japan to argue that it *failed* to evaluate the likelihood that fire blight bacteria would be transferred to host plants within Japan because the 1996 guidelines may have failed to instruct it explicitly to do so.

reason, Japan does not believe it is necessary to review the 1999 PRA even after the adoption of the 2001 Guidelines."[114] That is, Japan asserts that its 1999 assessment of risks, which took "into account risk assessment techniques developed by the" IPPC in 1996, also took into account the 2001 risk assessment techniques because the 2001 guidelines did not materially differ from the 1996 guidelines. Inasmuch as the 2001 guidelines elaborate the concepts of the 1996 document, with specific reference to quarantine pests, it may make more sense to use that document to guide the Panel's evaluation of Japan's assessment of risks. In this matter, however, any differences between the two documents are irrelevant to the determination that Japan has failed to evaluate the likelihood – *i.e.*, the probability – of entry, establishment, or spread of fire blight through imported apple fruit.

<u>TO JAPAN</u>

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56. In its first submission, at paragraph 94, Japan states that Roberts et al (1998) assigns too low values to three probabilities (P3 through P5). In the same paragraph, Japan notes that Yamamura et al uses "more statistically adequate methods for calculation of P1." Does Japan consider that the calculation of P1 in the Roberts et al (1998) study is also too low? Describe how the methods used by Yamamura are "more statistically adequate" than those used by Roberts.

119. As a preliminary matter, the United States notes that any evaluation of the rate of contamination of harvested mature apple fruit presented in Yamamura *et al*. (2001), Japan's Exhibit JPN-16, the "Verification" of Roberts *et al.* (1998), or in the original Roberts *et al.* (1998) hypothetical risk model will be vastly overstated because of errors in that data set. That is, the 1998 hypothetical risk paper incorrectly included certain results (primarily from van der Zwet *et al.* (1990)) as positive detections from mature fruit when those detections were, in fact, from immature fruit. Dr. Roberts has prepared a revised hypothetical risk model, incorporating necessary changes in the detections of epiphytic bacteria from mature fruit as well as incorporating additional relevant data published in the years since 1998. The revised model also estimates the hypothetical risk using several different levels of export. The revised model is presented in Exhibit USA-47 and estimates that, were Japan to accept mature fruit from any source without imposing any fire blight measures at all, the estimated years until outbreak would be 217,925 years (assuming 20 million fruit exported per year) as compared to an estimate of 11,364 years in the 1998 model.

120. The Panel asks how the methods used by Yamamura are "more statistically adequate" than those used by Roberts. The answer is that the methods used by Yamamura are not

[114] First Written Submission of Japan, para. 187.

statistically more adequate than those of Roberts.[115] There are two cases to consider: models treating P1 as constant, and the model of Yamamura treating P1 as a random variable.

121. In the first case (constant P1), Yamamura *et al*. (2001) estimated the mean value of P1 by utilizing all of the data in Roberts, Table 1. The number of infested fruit, from all studies, was divided by the total number of fruit assayed, yielding the estimate P1 = 109/4650 = 0.0234. While this is the correct method of obtaining a ratio estimate of the proportion infested among all studies reported in the table, *it is inappropriate for the purpose at hand*. This is because the data in Table 1 do not represent a random sample of fruit shipped from any production area. Rather, the data in Table 1 represent the results of several studies of the pathogen *E. amylovora* conducted under various circumstances for various reasons. In general, the studies included orchards where fire blight was known to be present. The mean infestation rate from Table 1 is a biased estimate of the rate for the production areas of concern in this trade issue. In particular, it is likely to be too high, *overestimating* the true rate of infestation. Therefore, it is inappropriate to apply such a biased estimate to the production area as a whole, and using it in the model violates the basic assumption that every consignment contains fruits that were drawn at random from the population of the production area (see U.S. answer to Question 13 from the Panel).

122. Roberts *et al*. (1998), on the other hand, examined the circumstances of each study cited in Table 1, and segregated the data into three classes representing orchards meeting different phytosanitary requirements. Then, applying professional knowledge of the frequency of orchards in the state of Washington falling into each of the three categories, they obtained appropriately weighted estimates of the infestation rates for scenarios S1, S2 and S3. This emulates a well-known technique in sampling theory called stratified sampling. Roberts correctly applied the theory to obtain a "stratified" estimate of the mean infestation rate for the population of apples exported from the state. The statistical method employed by Roberts is much to be preferred over that of Yamamura *et al*. (2001). In fact, it is difficult to imagine how Yamamura made such a mistake.

123. In the second case Yamamura *et al*. (2001) considered P1 to be a random variable and attempted to describe its variability with a probability distribution. While it is worth considering the role of variation in the parameter's value, it is not necessarily more valid statistically. Both the model of Roberts and the model of Yamamura are multiplicative (the estimated risk of invasion is the mathematical product of many factors, F1, P1, P2, etc.). For a multiplicative model, variation in one of the parameters does not affect the expected value of the outcome. Because Yamamura *et al*. (2001) were concerned only with the expected frequency of outbreaks of fire blight in the importing country, their model incorporating variability is no more valid, statistically, than that of Roberts.

[115] *See* Exhibit USA-40 (report by Dr. Alan Sawyer on Yamamura *et al.* (2001)).

124. Yamamura modeled variation in the rate of infestation with a beta distribution. This is often a reasonable model for variation in a proportion. Yamamura carried out the mechanics of maximum likelihood estimation correctly in attempting to estimate the parameters (a and b) of a beta distribution from the data of Roberts, Table 1. However, because these data were not a random sample and did not represent the entire area of production, it was *not appropriate* to use the data from Table 1 directly to fit the beta distribution. The resulting estimate of the mean infestation rate, E[P1] = a/(a+b) = 0.1200, is meaningless. It applies not to the population of *all* apples exported to Japan, but only to the data from Table 1, treated as a biased sample. Yamamura *et al*. (2001) could have properly weighted the data from Table 1 as Roberts did, prior to fitting a statistical model, but did not do so.

125. Because Yamamura's two models (one treating P1 as a constant, the other treating it as a random variable) employed very different estimates of the mean infestation rate (0.0234 and 0.1200, respectively), the resulting predicted frequency of outbreaks and time between infestations cannot be compared. The differences found by Yamamura in the predictions of these two models were due entirely to the different mean values of P1, *not to variation* in the parameter P1 *per se*, as they concluded. This, too, was a major mistake. Thus, the primary point of Yamamura *et al*. (2001) and the paper's key conclusion relating to the role of variation in the rate of infection are both negated.

126. Our review of these two cases (*i.e.*, treating P1 as a constant and treating P1 as a random variable) demonstrate that the methods of Yamamura are not "more adequate statistically" than those used by Roberts. In fact, given the treatment of the essential data set (Roberts, Table 1) by both parties, the methods used by Roberts *et al*. (1998) are by far superior.

127. Finally, we note that Japan has pointedly *not* asserted that the calculation of P1 in Exhibit JPN-16, the "Verification" of Roberts *et al.* (1998) is "more statistically adequate" than that in the 1998 hypothetical risk model – even though Japan has cited to the estimated number of years until introduction of fire blight presented by that "Verification." The United States suspects that Japan has not drawn attention to the calculation of P1 because it is so statistically inadequate. In the "Verification," only the U.S. data from Table 1 were used, but an incorrect method of obtaining an average rate was employed. The estimated infestation rate for each of 10 U.S. studies was calculated without regard for the number of fruit represented in each study. The resulting 10 infestation rates were simply summed and divided by 10, producing an unweighted average, P1 = 0.0425, that did not account for the unequal sizes of the constituent samples. This is *not* an appropriate method for obtaining an overall proportion from pooled data. Individual estimates from small samples (*e.g.*, 20 fruit) are less reliable than estimates from large samples (*e.g.*, 1,455 fruit) but were given equal weight in Japan's "Verification." Thus, the "Verification" produces a gross overestimation of the infestation rate (P1); by way of comparison, the correct value for P1 using only U.S. data from Table 1 of Roberts *et al.* (1998) is 0.0157, nearly three times *lower* than the estimate of the Verification, and the corrected value for

P1 using only U.S. data from Table 1 of the revised Roberts model[116] is 0.002, which is more than 20 times lower than the value calculated in Japan's "Verification."

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[116] *See* Exhibit USA-47 (R. Roberts, Update to the 1998 Pest Risk Assessment for U.S. Apples to Japan, Revised Table 1 (2002)).