Japan – Measures Affecting the Importation of Apples

(WT/DS245)

Answers of the United States of America

to Additional Questions from the Panel

at the Second Substantive Meeting

January 28, 2003

1. General

1. <u>To both parties</u>: Do you consider that there is one "measure at issue (Japan's systemic requirement as a whole), or that there are nine separate "measures"? If you consider that each of the nine requirements to be a separate measure, must there be sufficient scientific evidence to justify each of these requirements individually?

1. As stated in the U.S. request for the establishment of a panel,[1] Japan prohibits the importation of U.S. apples unless produced, harvested, and imported according to Japan's fire blight restrictions. These restrictions are currently maintained by means of Plant Protection Law No. 151 (May 4, 1950), Article 7; Plant Protection Law Enforcement Regulations (June 3, 1950), Article 9 & Annexed Table 2; Ministry of Agriculture, Forestry, and Fisheries (MAFF) Notification No. 354 (March 10, 1997); and the related MAFF Detailed Rules for U.S. Apples (April 1, 1997).[2] Through these means, Japan imposes nine restrictions or requirements (related to fire blight) that must be satisfied in order to import U.S. apples.[3]

2. Japan prohibits importation of U.S. apples unless *all nine* of these requirements are met. Thus, in the first instance, the Panel should find that by prohibiting importation of U.S. apples unless these requirements are met Japan has acted inconsistently with its WTO obligations, including the commitment under Article 2.2 not to maintain a phytosanitary measure without sufficient scientific evidence. Each of these nine requirements, moreover, may be considered a separate phytosanitary measure within the meaning of the SPS Agreement. As defined in Annex A (and as relevant to this dispute), an SPS measure is "[a]ny measure applied . . . to protect . . . plant life or health from risks arising from the entry, establishment or spread of pests, diseases, . . . or disease-causing organisms" and such "measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; [and] quarantine requirements."[4] Thus, each of the nine requirements and procedures necessary for importation of U.S. apples is a phytosanitary measure, and each requirement may be considered to be inconsistent with Japan's obligations under Article 2.2.

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[1]WT/DS245/2 (8 May 2002).

[2]*See* U.S. First Written Submission, paras. 16-19.

[3]These restrictions are: (1) production of apples within designated areas of the U.S. States of Washington or Oregon; (2) inspection of designated areas three times yearly for the presence of fire blight; (3) maintenance of fire blight-free export orchards (as well as freedom of fire blight hosts other than apple trees), (4) maintenance of a 500-meter fire blight-free buffer zone surrounding the export orchard, (5) post-harvest surface treatment with chlorine, (6) production requirements, such as chlorine treatment of containers for harvesting and of the interior of the packing facility; (7) post-harvest separation of fruit from fruit destined to other markets; (8) certification by U.S. plant protection officials that fruit are free of fire blight and have been treated post harvest with chlorine; and (9) confirmation by Japanese officials of the U.S. officials' certification and inspection by Japanese officials of disinfestation and packing facilities. *See id.*, para. 19.

[4]SPS Agreement, Annex A, para. 1.

3. Each of the Japanese fire blight restrictions (or requirements) may be considered to be maintained without sufficient scientific evidence because there is *no* scientific evidence that harvested, mature U.S. apples, the exported commodity, could serve as a pathway for introduction of fire blight to Japan. That is, where there is not scientific evidence that each and every step in any hypothetical pathway would be completed, there is no scientific evidence that the pathway would be completed and that exported apple fruit may serve to introduce the disease to Japan. Thus, imported U.S. apple fruit do not pose a phytosanitary risk to plant life or health within Japan. The imposition of *any* of the Japanese fire blight restrictions (or requirements) on such apple fruit is therefore inconsistent with Japan's obligations under Article 2.2 because there is not "sufficient scientific evidence" to support any measure other than restricting importation to the exported commodity.

4. We note that in the *Japan – Varietals* dispute, the Appellate Body endorsed the panel's reading of the phrase "sufficient scientific evidence" as requiring "a rational or objective relationship between the SPS measure and the scientific evidence."[5] As the preceding discussion makes clear, because a phytosanitary measure is applied "*to protect . . . plant life or health from risks* arising from the *entry, establishment or spread* of pests, diseases, . . . or disease-causing organisms,"[6] there must be a "rational or objective relationship" between the scientific evidence of a *risk to plant life or health within Japan* and the SPS measure. Article 5.1, which forms relevant context to Article 2.2,[7] also points to this relationship: Article 5.1 requires that any Japanese fire blight measure be "based on an assessment, as appropriate to the circumstances, of the risks to . . . plant life or health," and such an assessment of risks consists, in part, of an "evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of the importing Member."[8] Again, where there is no scientific evidence that the exported commodity poses a risk to plant life or health within Japan, there can be no rational or objective relationship between any of the nine fire blight restrictions (or requirements) imposed by Japan on that exported commodity and the scientific evidence.

3. <u>To the US</u>: Can the US confirm that the product it is seeking to export are "mature, symptomless" apple fruit (as opposed to "mature" apple fruit)?

5. The United States can confirm that the exported commodity consists of harvested, mature fruit, which of biological necessity will be symptomless.[9] As the experts have noted in their oral and written responses, exported apple fruit are harvested when horticulturally mature; such

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[5] *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R, para. 84 (footnote omitted) ("*Japan – Varietals*").

[6] SPS Agreement, Annex A, para. 1 (emphasis added).

[7] *Japan – Varietals*, WT/DS76/AB/R, paras. 74-78.

[8] SPS Agreement, Annex A, para. 4 (emphasis added).

[9] *See also* U.S. Reply to Question 2 from the Panel (Nov. 13, 2002); U.S. Reply to Question 16 from Japan.

mature fruit will not be infected[10] and, therefore, will not present symptoms of fire blight. Thus, the United States views the terms as consistent and necessary attributes of the exported commodity: a commercially harvested apple fruit will be "mature" and therefore also "symptomless."[11]

6. We note that Japan continues to insist that the terms "mature" and "symptomless" are subjective and not capable of precise definition, but Japan has not presented *any* scientific evidence to support its assertions. In fact, the scientific evidence wholly contradicts Japan's position. As the United States has argued and the experts have confirmed, harvested fruit for export will be "mature," both in physiological terms (that is, the fruit will continue to ripen even if detached from the tree) and in horticultural terms (that is, the fruit contain those characteristics of ripeness desired by consumers).[12] As horticultural maturity occurs at or after the time of physiological maturity, growers, distributors, and exporters utilize objective indices of horticultural maturity to determine the optimum time for harvest; these objective criteria include firmness, soluble solids (sugar content), and starch indices.[13] At the time of export, apple fruit are inspected by Federal-State inspectors for compliance with the applicable U.S. and state grade standards and the requirements of the U.S. Export Apple Act, which require that fruit be "mature."[14] The experts have also stated that a harvested, mature fruit will not be infected; by

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[10]*See, e.g.*, Response of Dr. Smith to Question 2 from the Panel ("A fruit naturally carrying bacteria can develop into a healthy-looking mature fruit *if these bacteria do not infect the fruit*; in fact, failing to infect, the bacteria would probably die long before the fruit matures.") (emphasis added).

[11]At the time of export, Federal-State inspectors will examine exported fruit for compliance with applicable grade standards, the U.S. Export Apple Act, and any phytosanitary requirements of the importing country. As the United States has previously noted, some importing countries require that a phytosanitary certificate accompany export shipments of apple fruit to certify that such shipments are free of fire blight. *See* U.S. First Written Submission, para. 106 & fn. 224. As Japan seeks to prevent introduction of fire blight, requiring a phytosanitary certificate of fire blight freedom for the exported commodity (mature apple fruit) would be a means for Japan to achieve its appropriate level of protection that is reasonably available and less trade restrictive than the current fire blight measures. Such a requirement would be fully consistent with the alternative measure proposed by the United States under its Article 5.6 claim. *See* U.S. Opening Statement at the Second Panel Meeting, paras. 8-9; U.S. First Written Submission, paras. 106-11.

[12]*See, e.g.*, Responses of Drs. Hale & Hayward to Question 1 from the Panel.

[13]*See* U.S. Reply to Questions 3 & 19 from the Panel (Nov. 13, 2002); U.S. Reply to Question 13 from Japan. The United States notes that as a general matter the U.S. apple industry utilizes objective maturity parameters consistent with those identified by New Zealand as "best practice guidelines" applied by New Zealand industry. *See* Answer of New Zealand to Question 5 from the Panel (Nov. 13, 2002). As the Washington State Apple Commission summarizes: "In mid-August, apple growers start testing the maturity of their apples to accurately predict when to harvest their crop to put in [controlled atmosphere] rooms so the apples are mature, but not too ripe. Firmness, skin color, seed color, sugar level and flesh chlorophyll are tested" (*see* http://www.bestapples.com/facts/controlled.html).

[14]*See* U.S. Reply to Question 21 from the Panel (Nov. 13, 2002). Again, the Washington State Apple Commission summarizes that "[r]andom samples of apples are tested for color, weight, pressure, sugar, grade and condition, . . . after harvest to enforce state and federal requirements" (*see* http://www.bestapples.com/facts/grades2.html). We also note that Washington State imposes minimum firmness

definition, then, it will be "symptomless." Japan has not presented *any* scientific evidence contradicting the evidence presented by the United States that infected fruit "fail to develop fully, turning brown to black, shriveling, and becoming mummified, frequently remaining attached to the limb."[15] Indeed, as Dr. Smith noted of Exhibit JPN-41 at the experts' session, the immature apple fruit in the photo showing bacterial ooze and premature red coloration are clearly not "symptomless." Thus, Japan has failed to present any scientific evidence to support its bald assertion that the terms "mature" and "symptomless" as applied to apple fruit are not objective concepts.

4. To what extent should scientific studies or evidence be taken into consideration by the Panel if they become available: (1) subsequent to the adoption of the measure(s) (2) subsequent to the formal request for consultations or (3) subsequent to the establishment of the Panel?

7. Japan's obligation to "ensure" that its measures satisfy its WTO commitments is ongoing. For example, under Article 2.2 of the SPS Agreement, Japan must ensure that its fire blight measures are not maintained without sufficient scientific evidence. Under Article 5.1 of the SPS Agreement, Japan must ensure that its fire blight measures are based on an assessment of the risks, as appropriate to the circumstances, to plant life or health within Japan. Thus, it would be inappropriate *not* to examine scientific studies or evidence that became available after adoption of the fire blight measures if such scientific evidence is relevant to the particular legal obligation at issue.

8. In general, the consistency of a measure with a Member's WTO obligations should be judged as of the time of establishment of the dispute settlement panel (assuming, for example, that the same measure was the subject of consultations). However, the timing of availability of any scientific evidence presented in this dispute does not alter the outcome of the Panel's analysis of any legal claim. As the experts have confirmed, there has never been any scientific evidence that mature apple fruit (the exported commodity) have ever transmitted fire blight or could serve as a pathway for introduction of fire blight to Japan. All of the most recent scientific evidence merely serves to confirm further this point.[16] As a result, there has *never* been

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requirements for Red Delicious, Delicious, Golden Delicious, Gala, and Jonagold varieties at the time of shipment. After physiological maturity and horticultural maturity have been reached, fruit will continue to ripen, resulting in decreasing firmness values. To ensure that Washington fruit are not *overripe* (and therefore not commercially desirable), the Washington law sets out minimum firmness requirements. *See* Washington Administrative Code § 16-403-142 (available at http://www.leg.wa.gov/wac/index.htm).

[15]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).

[16]For example, Roberts (2002), the joint Japanese-U.S. experiment conducted in 2000, merely confirms previous studies (Dueck (1974), Roberts *et al.* (1989), van der Zwet *et al.* (1990)) that endophytic bacteria will not be recovered from harvested mature fruit. *See* R.G. Roberts, *Evaluation of buffer zone size and inspection number*

"sufficient scientific evidence" that exported apple fruit pose a risk to plant life or health within Japan, and Japan has acted inconsistently with Article 2.2 since its WTO commitments came into effect in 1995.[17]

9. Finally, we would comment briefly on the written statements by Dr. van der Zwet and Professor Thomson clarifying important aspects of their 1990 paper that Japan has characterized as new evidence.[18] These written statements are not new scientific evidence or studies; rather, they merely confirm a proper reading of that 1990 paper.[19] Thus, these written statements merely confirm that there is no scientific evidence of endophytic (internal) bacteria in mature apple fruit,

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reduction on phytosanitary risk associated with fire blight and export of mature apple fruit, Acta Horticulturae 590: 47-53 (2002) (Exhibit USA-16). Taylor *et al.* (2002), which had previously been presented at the Ninth International Fire Blight Workshop in 2001, and Taylor *et al.* (2003), reporting data from an additional year (2001) of the same experiment, confirm previous work (Hale *et al.* (1996)) and the general understanding in the scientific literature that there is no vector to transfer any epiphytic bacteria from fruit calyxes to a susceptible host. R.K. Taylor *et al.*, *The viability and persistence of* Erwinia amylovora *in apples discarded in an orchard environment*, Acta Horticulturae 590: 153-55 (Exhibit USA-20); R.K. Taylor *et al.*, *Survival of the fire blight pathogen,* Erwinia amylovora*, in calyxes of apple fruit discarded in an orchard*, Crop Protection 21: (2003). Jock *et al.* (2002) similarly merely confirms the understanding in the literature that long-distance fire blight spread has occurred through shipments of latently infected host plants and not through trade in fruit. 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: 106-14 (2002) (Exhibit NZ-7).

[17]Similarly, because there has never been any scientific evidence that mature apple fruit have transmitted fire blight or could serve as a pathway to introduce fire blight, there has never been a probability or likelihood that the exported commodity will introduce fire blight to Japan. Because there is no scientific evidence to establish a probability or likelihood of a risk to plant life or health due to imported U.S. apples, Japan has not ensured that its fire blight measures are "based on" an assessment of risks within the meaning of Article 5.1 and Annex A of the SPS Agreement. Because there has never been any scientific evidence that mature apple fruit have transmitted fire blight or could serve as a pathway to introduce fire blight, there is an alternative measure that is less restrictive that Japan's current fire blight measures, is reasonably available, and achieves Japan's appropriate level of protection: restricting importation to mature apple fruit. Thus, since Japan's WTO obligations came into effect in 1995, Japan has acted inconsistently with its obligations under Article 5.6. In addition, because the scientific evidence has always indicated that apple fruit have not transmitted and do not serve as a pathway for introduction of fire blight, there has always been sufficient scientific evidence to make an objective assessment of risk; therefore, the qualified exemption under Article 5.7 for measures inconsistent with Article 2.2 has never been available to Japan.

[18]*See* Exhibits USA-19 (declaration of Dr. van der Zwet), USA-20 (letter from Professor Thomson).

[19]We note that in clarifying that no endophytic bacteria were recovered from any mature fruit in any of the experiments reported in the 1990 paper, the authors merely *confirmed* what a careful reading of the 1990 paper suggests. The *only* fruit expressly described in the paper as "mature" were those in the storage experiment reported in Table 2; as the scientific experts have noted, endophytic bacteria were not recovered from these "mature" fruit (the fruit were not even tested for internal bacteria) and thus the suspected symptoms were not confirmed as fire blight. *See, e.g.*, Response of Dr. Smith to Question 11 from the Panel. None of the fruit involved in the geographic experiment reported in Table 4 were described as "mature" in the 1990 paper, and the authors have confirmed that no endophytic bacteria were recovered from any mature or possibly mature fruit in that experiment. Thus, the 1990 paper itself did not claim that internal bacteria had been isolated from any "mature" fruit; the authors' recent statements merely confirm that fact.

a fact consistently demonstrated by the scientific literature.[20] We also note that the information provided in these written statements is no different than answers that the Panel could (and did) obtain from the scientific experts as to the proper reading and content of the scientific literature. Japan's argument that the statements should not be considered would be equally applicable to the statements of the experts or, for that matter, those of the parties, with respect to the scientific literature.

10. With respect to those exhibits that Japan presented to the scientific experts the day before and the day of the experts' session, we note that the issue of evidence generated after establishment of the Panel should not affect the Panel's legal determinations. Japan's presentation did not provide any scientific evidence of a risk to plant life or health within Japan posed by imported apple fruit.[21] As noted above, there has never been any scientific evidence that mature apple fruit have transmitted fire blight or could serve as a pathway to introduce fire blight; therefore, whether Japan presented evidence created after establishment of the Panel should not affect the Panel's legal analysis.

2. Article 2.2

6. <u>To the US</u>: could you please comment on the statement by Japan, in its second submission, that it "wishes to encourage the Panel to consider carefully, in line with the above interpretation, whether the 'mature, symptomless' criteria would objectively achieve Japan's level of protection. (...) If the Panel is not convinced by the assurance of the criteria, the case under Article 2.2 must be dismissed, because the burden of proof lies with the United States". More specifically, could you please clarify, in light of that statement,

(a) what should be, in your view, the relevance of "the 'mature symptomless' criteria in the Panel's assessment of the measures under Article 2.2?
(b) what is the relevance of Japan's appropriate level of protection to the Panel's assessment of whether the measures are maintained "without sufficient scientific evidence"?

11. Japan's statement appears to be directed to the U.S. claim under Article 5.6 rather than under Article 2.2. It would only be within the context of the U.S. claim under Article 5.6 that Japan's level of protection (to prevent introduction of fire blight) would be relevant. In its Article 5.6 claim, the United States has proposed as an alternative measure that Japan may utilize: restricting importation to mature, symptomless fruit. This alternative measure is reasonably available to Japan (the exported commodity consists of mature, symptomless fruit as

[20] *See* U.S. First Written Submission, para. 33.

[21] For further explanation of why the Japanese exhibits presented at the experts' session and the second panel meeting do not provide any evidence of a risk of introduction of fire blight to Japan, please see U.S. Answer to Additional Question 16 from the Panel (January 28, 2003).

required for commercial purposes and under U.S. law and grading standards), is less restrictive to trade than Japan's current fire blight measures (the exported commodity already consists of mature, symptomless fruit), and achieves Japan's appropriate level of protection (mature, symptomless fruit do not serve as a pathway for introduction of fire blight).[22]

12. (a) The mature, symptomless (or harvested, mature fruit) criteria that form the basis for the alterative measure proposed by the United States pursuant to its Article 5.6 claim are relevant to the Panel's assessment of Japan's fire blight measures under Article 2.2. Under Article 2.2, Japan must ensure that its fire blight measures are not maintained without sufficient scientific evidence, which requires that there be a rational or objective relationship between the scientific evidence and the measure.[23] As explained earlier,[24] Article 2.2. requires that there be a "rational or objective relationship" between the SPS measure imposed on an imported commodity and scientific evidence of a risk to plant life or health within Japan posed by such commodity. Because the exported commodity is mature (and therefore symptomless) apple fruit, to impose a phytosanitary measure on such fruit there must be scientific evidence that mature apple fruit pose a risk of introducing fire blight to Japan. As the scientific experts have confirmed, there is *no* scientific evidence that the exported commodity (mature apple fruit) poses a risk to plant life or health within Japan. Thus, there can be no rational or objective relationship between Japan's fire blight measures on U.S. apples and the scientific evidence, and there cannot be "sufficient scientific evidence" to maintain those measures.

13. (b) In this case, the United States does not believe that Japan's appropriate level of protection bears any relevance to an assessment under Article 2.2 of whether there is sufficient scientific evidence to maintain its measures. For the reasons previously discussed, where there is no scientific evidence that the exported commodity poses a risk to plant life or health within Japan, there cannot be sufficient scientific evidence to maintain Japan's fire blight measures. Put differently, where the exported commodity poses no risk to plant life or health within Japan, there can be no "rational or objective relationship" between the absence of scientific evidence of a risk to plant life or health within Japan posed by such commodity and an SPS measure imposed on that commodity. Japan's appropriate level of protection plays no part in that analysis.

14. The United States does not contest that fire blight is a serious plant disease and does not contest Japan's decision that it should apply measures to prevent introduction of fire blight. Neither would the United States contest the application of fire blight measures to imported goods for which there is scientific evidence of a risk to plant life or health within Japan – for example, fire blight host plants for planting, for which there exists substantial scientific evidence (according to the scientific experts) implicating trade in such hosts with long-distance fire blight

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[22]*See* U.S. Opening Statement at the Second Panel Meeting, paras. 8-9; U.S. First Written Submission, paras. 106-11.

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

[24]*See* U.S. Response to Additional Question 1 from the Panel (January 28, 2003).

spread. However, evidence of risks posed by such products is irrelevant to an evaluation of the risks posed by exported U.S. apples.[25] Japan's shifting arguments throughout the course of this dispute, at heart, share one similarity: evidence relating to risks posed by products *other than* the exported commodity are used in an attempt to suggest that mature apple fruit could serve to introduce fire blight to Japan. Such efforts are logically flawed and cannot justify maintenance of Japan's fire blight measures on exported U.S. apples.

7. <u>To the US</u>: you have indicated, in your response to a question by the Panel, that "the threshold of probability (likelihood) below which no measure could be justified is a question of the Member's appropriate level of protection (US answers to Questions by the Panel, para. 115). Could you please clarify, in light of that statement, what is, in your view, the role of the Member's appropriate level of protection:

(a) in an assessment of whether a measure is maintained "without sufficient scientific evidence" under Article 2.2 of the [SPS] Agreement?

(b) in an assessment of whether a measure is consistent with the terms of Article 5.7 of the SPS Agreement?

15. The United States appreciates the opportunity to clarify its statement. As indicated in paragraph 115 of the U.S. answers to the Panel's questions (Nov. 13, 2002), pursuant to Article 5.1 and Annex A of the SPS Agreement, if a risk assessment reveals that there is a likelihood of entry, establishment, or spread of a pest or disease within the territory of the importing Member, a Member may impose a phytosanitary measure if such a measure is "based on" the assessment of risks to plant life or health. However, an evaluation of "likelihood" requires a "probability" of entry, establishment, or spread,[26] not a mere "possibility" or theoretical uncertainty (since science can never provide absolute certainty).[27] In this case, there is no probability of introduction of fire blight through imported U.S. apples because there is no scientific evidence that mature apple fruit have ever transmitted or could serve as a pathway for fire blight. Thus, the Panel's analysis of whether Japan's fire blight measures are maintained without sufficient scientific evidence is

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[25]We recall that the International Plant Protection Convention's Standard for "Pest Risk Analysis for Quarantine Pests" states that "[a]ssessing the probability of introduction requires an analysis of *each of the pathways* with which a pest may be associated from its origin to its establishment in the [pest risk analysis] area," International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests, § 2.2, at 12 (2001) (emphasis added) (Exhibit USA-15), and, if the pest risk assessment concludes that measures are necessary to manage the risk of introduction of a quarantine pest, appropriate risk management measures must be selected and "*applied to pathways*, usually consignments of a host, from a specific origin," *id.* § 3.4, at 22 (emphasis added). Thus, any probability that a pest will be associated with another product (plants for planting, immature fruit) is not relevant to an assessment of the probability that the pest may be associated with the exported commodity (mature fruit) and therefore is not relevant to whether there is sufficient scientific evidence to maintain a phytosanitary measure on the exported commodity.

[26]*Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, para. 121.

[27]*European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, para. 186 ("*EC – Hormones*").

determined by the absence of any scientific evidence establishing a probability or likelihood of risk of fire blight introduction via imported apple fruit and does not require consideration of Japan's appropriate level of protection.

16. The United States' statement that "[t]he threshold of probability (likelihood) below which no measure could be justified is a question of the Member's appropriate level of protection" relates to those situations in which a probability or likelihood of entry, establishment, or spread has been found through a Member's objective assessment of risks. This situation does not exist in this dispute. Where an appropriate assessment of risks does find a probability or likelihood, a Member's selection of an SPS measure will be guided by its obligation under Article 5.6 to ensure that its measure is not more trade-restrictive than necessary to achieve its appropriate level of protection. The United States notes that as Article 5.1 should be read together with Article 2.2 as a specific application of the latter provision,[28] so too should Article 5.6 and Article 2.2 be read as providing context for each other. However, given that there is no scientific evidence of a risk to plant life or health within Japan through imported apple fruit, there is no need to consider Japan's appropriate level of protection to conclude that Japan's fire blight measures are maintained without sufficient scientific evidence.

17. Japan's appropriate level of protection would also not appear germane to the Panel's assessment of whether Japan's fire blight measures may benefit from the qualified exemption under Article 5.7. This provision operates as a limited exception to the obligation under Article 2.2 not to maintain a measure without sufficient scientific evidence. Article 5.7 allows a Member to adopt a provisional measure, *inter alia*, where "relevant scientific evidence is insufficient" to conduct an objective assessment of risk and only until that risk assessment is made.[29] Again, in this dispute the relevant scientific evidence is more than sufficient to conduct an objective assessment of risk; as the experts have demonstrated, there is no evidence that harvested, mature apple fruit pose a phytosanitary risk of introducing fire blight to Japan and a great deal of evidence to the contrary. Thus, the qualified exemption under Article 5.7 is not available to Japan, regardless of Japan's appropriate level of protection.

8. <u>To the US</u>: you have indicated that "the scientific evidence demonstrates that steps in the hypothetical pathway will either not *or are very unlikely* to be completed". Could you please clarify whether, in your view, the fact that a certain [event] is "very unlikely" implies that no phytosanitary measure can be applied in relation to it?

[28] *EC – Hormones*, WT/DS26/AB/R, paras. 180-81.

[29] *See* U.S. Answer to Question 40 from the Panel (Nov. 13, 2002).

18. In the quoted passage,[30] the United States is referring to whether there is scientific evidence that *each* step in any hypothetical pathway would be completed. Therefore, as the scientific experts confirmed for the Panel, the United States accurately explained that several steps are very unlikely to be completed in any hypothetical pathway identified by Japan (for example, epiphytic bacteria in the calyx of a mature, harvested fruit or bacterial survival of commercial handling, cold storage, and transport). However, as the experts have also confirmed, the United States accurately explained that several steps in any hypothetical pathway involving imported apple fruit will *not* be completed (for example, the very existence of a "mature, apparently healthy, but infected fruit," as asserted by Japan). Therefore, there is no scientific evidence that any hypothetical pathway will be completed, and there is no scientific evidence that imported apple fruit pose a risk of introduction of fire blight into Japan.[31] As a result, no measure may be imposed on imported apple fruit consistent with the SPS Agreement to protect against introduction of fire blight *except* restricting importation to the exported commodity: mature (and therefore symptomless) apple fruit.[32]

19. The "event" for which Japan must have scientific evidence establishing a *probability* (not a mere possibility) of occurrence is *introduction of fire blight via imported apple fruit.* A phytosanitary measure is any measure applied "to protect . . . plant life or health from risks arising from the entry, establishment or spread of pests, diseases, . . . or disease-causing organisms."[33] Under Article 5.1 Japan must ensure that any fire blight measure is "based on an assessment, as appropriate to the circumstances, of the risks to . . . plant life or health"; such an assessment of risks consists, in part, of an "evaluation of the *likelihood* of entry, establishment or spread of a pest or disease *within the territory of the importing Member*."[34] Thus, to be consistent with Article 5.1, a fire blight measure on an imported commodity must be based on a likelihood or probability of introduction of fire blight within Japan via the imported commodity. Likewise, under Article 2.2, for there to be "sufficient scientific evidence" to maintain a fire

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[30]The question does not indicate from which U.S. submission the quoted passage is drawn. The United States has several times noted that, for several steps in the hypothetical pathway identified by the United States, the scientific evidence is that each such step is very unlikely to be completed (for example, external or epiphytic bacterial contamination of harvested, mature fruit) and that, for the step of transfer (or vectoring) of any hypothetically surviving epiphytic bacteria to a susceptible host, *there is no scientific evidence that this step could be completed*. *See, e.g.*, U.S. Second Written Submission, paras. 12, 16; U.S. Answers to Questions from the Panel, paras. 9, 103 (Nov. 13, 2002). In addition, as indicated at the second substantive meeting and in the text above, Japan's hypothetical pathway includes a step ("mature, apparently healthy, but infected fruit") for which *there is no scientific evidence in support*. Thus, there is no scientific evidence that the hypothetical pathway identified either by the United States or Japan could be completed.

[31]*See* U.S. Closing Statement at the Second Substantive Meeting, para. 4; U.S. Opening Statement at the Second Substantive Meeting, para. 2.

[32]*See* U.S. Closing Statement at the Second Substantive Meeting, paras. 7-8, 11; U.S. Opening Statement at the Second Substantive Meeting, paras. 8-9.

[33]SPS Agreement, Annex A, para. 1.

[34]SPS Agreement, Annex A, para. 4 (emphasis added).

blight measure on imported apple fruit, there must be a "rational or objective relationship" between the scientific evidence of a risk to plant life or health within Japan posed by imported apple fruit and that fire blight measure. Again, where there is no scientific evidence that mature apple fruit have ever transmitted fire blight and where there is no scientific evidence that any hypothetical pathway involving mature apple fruit would be completed, the exported commodity poses no risk to plant life or health within Japan, and no fire blight measure may be maintained on that commodity.

20. The experts have confirmed that any hypothetical pathway would *not* be completed because for every such pathway there is *at least* one step for which there is no scientific evidence in support. For example, in the hypothetical pathway put forward by Japan as Exhibit JPN-34, the experts have confirmed that there is no scientific evidence that a harvested fruit with epiphytic bacteria in the calyx would become infected.[35] Thus, there is no scientific evidence to support the third step in Japan's hypothetical pathway, that imported apple fruit would result in the presence of a "mature, apparently healthy but infected fruit" within Japan.[36] Japan's hypothetical pathway is severed at this point, establishing that there is no scientific evidence that the pathway would be completed.[37] Thus, there is no probability or likelihood of introduction of fire blight to Japan via imported U.S. apples.

21. The Panel's analytical task is made slightly more complex by Japan's suggestion, in the course of this proceeding, of at least two other hypothetical pathways. However, the Panel's task is not made more *difficult* by Japan's shifting arguments as neither of these pathways is supported by scientific evidence that establishes that the exported commodity presents a probability or likelihood of introduction of fire blight to Japan.

22. As noted by the United States at the second substantive meeting, Japan presented a different hypothetical scenario to the experts at the experts' session than the pathway Japan identified for the Panel.[38] Japan asked the experts to *assume* that an infected fruit would be

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[35]The experts' answers to questions posed by the Panel and by the United States at the experts' session support the critique of Japan's hypothetical pathway presented to the Panel by the United States. *See* Exhibit USA-27 (U.S. comment on Exhibit JPN-14); U.S. Second Written Submission, paras. 9-15; U.S. answer to Question 5 from the Panel (Nov. 13, 2002).

[36]As the United States noted in its preliminary oral answer to this question, it follows that there is no scientific evidence supporting the succeeding steps in Japan's hypothetical pathway either – that is, "infected" fruit would not be placed in fields and there is no production or "dissemination of bacterial ooze."

[37]As noted at the second substantive meeting, Japan did not attempt to walk the experts through this hypothetical pathway step-by-step. The United States did walk the experts through this pathway, and their answers confirm that there is not scientific evidence that the pathway Japan presented to the Panel (in response to Question 5 from the Panel) would be completed. We believe the Panel may infer from Japan's failure to present this pathway to the experts that Japan is aware of the lack of scientific evidence supporting completion of the pathway. *See* U.S. Closing Statement at the Second Substantive Meeting, paras. 1-4.

[38]U.S. Closing Statement at the Second Substantive Meeting, paras. 2-7.

imported. The experts clarified that harvested and exported fruit are mature and therefore *not* infected; an infected fruit arriving in Japan would have to be *immature* and would therefore not pass through normal commercial processes of picking, sorting, storage, inspection, and export. Thus, Japan's discussion with the experts did not demonstrate any risk posed by the exported commodity (harvested mature apple fruit) but rather was based solely on the risk posed by something *other than* that commodity (*infected, immature* apple fruit). As noted earlier, to be consistent with the SPS Agreement, a phytosanitary measure imposed on an exported commodity must be based on a risk to plant life or health within Japan posed by that exported commodity.[39]

23. The scientific evidence establishes that a harvested fruit will be horticulturally mature, and the experts confirmed that mature apples are not infected. Horticultural maturity is measured according to objective criteria, and growers, distributors, and exporters apply such criteria to ensure product that is commercially saleable and of high quality. U.S. grading standards and law, enforced by Federal-State inspectors, require exported apples to be mature and symptomless. Indeed, Japan has conceded that exported U.S. apples are mature and apparently healthy.[40] Therefore, the scientific evidence indicates that exported U.S. apples are not infected and do not pose a risk of introducing fire blight to Japan, even according to this alternative hypothetical pathway Japan presented to the experts.

24. As noted in the U.S. second written submission, Japan may have presented yet another hypothetical pathway in its first written submission: in this additional two-step pathway, (1) mature apple fruit are either infected or endophytically contaminated[41] and (2) such fruit then somehow transmit *E. amylovora* and fire blight. We have previously demonstrated, and the experts have confirmed, that the first step in this pathway is not supported by any scientific evidence.[42] We have also demonstrated, at length, that none of the alleged four instances of trans-oceanic dissemination of fire blight cited by Japan as "indirect" evidence provide any *scientific* evidence to establish a probability or likelihood that imported mature apple fruit could introduce fire blight to Japan.[43] Japan also did not present this "evidence" to the experts for

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[39]In addition, we would note that this hypothetical pathway presented by Japan to the experts (an infected, immature fruit somehow being imported along with the exported commodity) is inconsistent with the hypothetical pathway Japan presented to the Panel, which does not suggest that an immature, infected fruit is harvested and passes through normal commercial handling, storage, grading, and export. *See* Exhibits JPN-14 & JPN-34. Again, the Panel may infer that Japan asked the experts to *assume* that an infected, and therefore immature, fruit arrives in Japan because it knows – as the experts explicitly stated – that there is no scientific evidence that a "mature, apparently healthy, but infected" fruit (step 3 in Japan's hypothetical pathway) exists and, therefore, that such a hypothetical pathway could be completed.

[40]*See* Japan's Answer to Question 2 from the Panel (Nov. 13, 2002).

[41]Contrast this first step with that in Exhibit JPN-34; the latter hypothetical pathway starts with "*E. amylovora* inside or in the calyx of mature, apparently healthy fruit."

[42]*See* U.S. Second Written Submission, paras. 16-17.

[43]*See id.*, paras. 18-22.

comment; nonetheless, the experts made clear that there *is* scientific evidence that trade in fire blight host plants poses a risk of introduction of fire blight (the most likely explanation for those instances of trans-oceanic fire blight dissemination that are confirmed) and that, despite decades of barely controlled or uncontrolled trade in apple fruit, there is *no scientific evidence* that apple fruit are implicated in the spread of fire blight. None.

12. To the US: Could you please comment on the following statement made by Japan in its second submission (at para. 52):

> **"the US and Japan may not have to be in disagreement on this magnitude [of the risk]. Both parties are looking at the same evidence. Japan submits that the substantial differences in opinion results in large part from different evaluations of the same risk".**

25. The United States agrees that we may not have to be in disagreement with Japan on the magnitude of the risk if Japan is conceding that there is no scientific evidence that imported U.S. apples pose a risk of introduction of fire blight into Japan. However, as Japan has not been willing to concede that there is no scientific evidence to support its position, we suspect that Japan's statement is intended for rhetorical rather than logical consumption.

26. The story of this dispute has been one of shifting arguments by Japan[44] to suggest that events could occur for which there is no scientific evidence in support, in an effort to establish the existence of *some* evidence that imported apple fruit could serve as a pathway for introduction of fire blight. As the United States (and the experts) have explained, these efforts fail: there is no scientific evidence that any hypothetical pathway for dissemination of fire blight via imported apple fruit would be completed. Therefore, Japan is left with nothing more than theoretical uncertainties (for example, *what if* an infected, immature fruit were *somehow* imported along with the exported commodity – even though the experts have stated such fruit would *not* be harvested because they are immature and have symptoms of fire blight), and such theoretical uncertainties are not the type of risk which a risk assessment, and therefore any Japanese fire blight measure, is to address.[45]

3. Article 5.7

14. To both parties: What are, in your view, the conditions for a measure to be considered to have been "provisionally adopt[ed] under Article 5.7? Does a provisional measure need to be so identified (eg, in its title, introductory or explanatory text) at the time it is adopted?

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[44] *See* U.S. Answer to Additional Question 8 from the Panel (January 28, 2003) (describing 3 hypothetical pathways identified by Japan at various points in the dispute).

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

27. The United States does not believe that a provisional measure need be so identified at the time it is adopted as Article 5.7 does not provide for such a requirement. However, Article 5.7 does impose requirements that Japan has failed to meet.

28. Article 5.7 allows a WTO Member to "provisionally adopt" a measure that would otherwise be inconsistent with 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." As the Appellate Body has stated, these 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."[46]

29. The conditions in the second sentence of Article 5.7 establish two criteria that would assist in determining whether a provisionally adopted measure that satisfies the requirements of the first sentence may continue to benefit from the qualified exemption under Article 5.7. That is, the first sentence of Article 5.7 establishes circumstances in which a Member is allowed to provisionally *adopt* a measure otherwise inconsistent with Article 2.2, and the second sentence indicates at what point a provisionally adopted measure may no longer be considered exempt from the requirement under Article 2.2 that a measure not be *maintained* without sufficient scientific evidence. Thus, while it is not, in the abstract, necessary for a provisionally adopted measure to be so identified at the time it is adopted, subsequent actions by the Member adopting the measure may demonstrate that a provisionally adopted measure that satisfies the requirements of the first sentence may *not* continue to benefit from the qualified exemption under Article 5.7.

15. <u>To both parties</u>: Article 5.7 of the SPS Agreement requires provisional measures to be adopted "on the basis of available pertinent information". Could you please clarify whether there is, in your view, a difference between the notion of "pertinent information" and the notion of "scientific evidence" as contained in Article 5.7 and other provisions of the SPS Agreement?

30. The phrases "available pertinent information" and "scientific evidence" are different and carry different meanings. The former phrase suggests a category of information that may not rise to the level of scientific evidence. However, in this dispute any differences in meaning between the two terms will not be relevant to the Panel's analysis 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.

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

31. The United States has explained in some detail why the qualified exemption under Article 5.7 is not available to Japan.[47] Crucially, Japan has not demonstrated that the first requirement under Article 5.7 – that the provisional measure be imposed only "[i]n cases where relevant scientific evidence is insufficient" – has been met. This phrase indicates that a provisional measure may be taken only where the scientific evidence to conduct an objective assessment of risk is insufficient. Japan has not demonstrated that the relevant scientific evidence is insufficient; in fact, 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.

32. The United States notes that only if the scientific evidence is insufficient to conduct an objective risk assessment (and assuming that the other requirements in Article 5.7 are met) may provisional measures then 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." Thus, the Panel need not in this dispute reach the issue of the precise scope of "pertinent information" required to adopt a provisional measure. However, the United States suggests that, if the Panel were to examine whether a provisional measure had been adopted "on the basis of available pertinent information," the Panel should conclude that Japan has not demonstrated that this element has been satisfied. Japan has cited no specific "available pertinent information" as the basis for its measure. Indeed, there is no such "pertinent information" upon which a measure can be based because none of the information presented by Japan suggests that mature apple fruit can serve as a pathway for fire blight. Japan's "available pertinent information," like its "scientific evidence," is thus either not "pertinent" to exported apple fruit, or, with respect to its suggested pathway, is little more than speculative.

4. Article 5.1

16. <u>To both parties</u>: Independently of your respective assessments of the likelihood of transmission of fire blight through apple fruit, could you please indicate in light of your respective pictorial exhibits of the pathway, whether you agree on the identification of the various steps that would need to be completed in order to establish the pathway?

33. The United States does not believe that the parties are in agreement on the identification of the various steps that would need to be completed in order to establish that imported apple

[47] *See* U.S. Answer to Question 40 from the Panel (paras. 98-109) (Nov. 13, 2002). With respect to the other two requirements necessary to claim the qualified exemption under Article 5.7 not discussed in the text above, the United States does not believe that Japan has satisfied these either. Japan has not sought to obtain additional information necessary for a more objective assessment of risk as no study in which Japan has participated since adoption of the fire blight measures provides additional information with respect to steps in the hypothetical pathway that the experts have concluded will not be completed. For the same reason, Japan cannot be deemed to have reviewed its measure within a reasonable time. Thus, Japan has not demonstrated that the qualified exemption under Article 5.7 from Japan's commitments under Article 2.2 is available to it.

fruit could serve as a pathway for fire blight. The steps in the hypothetical pathway presented by the United States (Exhibit USA-26) track the five steps identified by the International Plant Protection Convention's Guidelines for Pest Risk Analysis as comprising an analysis of the probability of entry.[48] As Exhibit USA-26 indicates, there is a "discontinuity" (in Dr. Hale's words) in the pathway because there is no evidence that any hypothetically surviving epiphytic bacteria in the calyx of an imported fruit could be transferred to a susceptible host. Thus, there is no scientific evidence that imported U.S. apple fruit could serve as a pathway for introduction of fire blight to Japan.

34. All of the various hypothetical pathways identified by Japan in the course of this dispute identify steps for which there is no scientific evidence.[49] Consider the pathway that Japan has presented to the Panel in its answer to Question 5 from the Panel following the first substantive meeting and in Exhibit JPN-34. This hypothetical pathway purports to present the probability of fire blight dissemination via "mature, apparently healthy fruits" but identifies a step ("mature, apparently healthy but infected apple fruits") for which there is no scientific evidence. That is, the scientific experts have confirmed that (1) there is no scientific evidence that epiphytic bacterial population in the calyx (step one of Japan's hypothetical pathway) can "infect" a harvested mature fruit and (2) there is no scientific evidence that an "infected" fruit can be "mature" and "apparently healthy." This is not an issue of disagreement over the likelihood of transmission of fire blight through apple fruit; this is an issue of Japan inventing a step in its hypothetical pathway for which there is no scientific evidence.

35. Consider also the pathway that Japan has presented to the experts during the experts' session: an infected, and therefore immature, fruit (which the experts stated would not reach maturity and would not pass through normal commercial processes of harvesting, sorting, storage, inspection, and export) is somehow imported into Japan. Thus, step one of this hypothetical pathway identifies immature, infected fruit as the pathway for introduction of fire

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[48] *See* U.S. Second Written Submission, paras. 9-10; U.S. Answer to Question 5 from the Panel (paras. 8-9) (Nov. 13, 2002). The five steps that comprise an evaluation of the probability of entry are: (1) identification of relevant pathways; (2) the probability of the pest being associated with the pathway at origin; (3) the probability of survival of the pest during transport or storage; (4) the probability of the pest surviving existing pest management procedures; and (5) the probability of transfer of the pest to a suitable host. *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) (Exhibit USA-15).

[49] We have noted earlier that in its first written submission Japan asserted a two-step pathway: infected or endophytically contaminated mature fruit (for which the experts confirm there is no scientific evidence) and transmission (somehow) of fire blight to Japan (for which Japan presented four alleged instances of trans-oceanic dissemination that do not provide any scientific evidence of a risk of introduction via imported apple fruit). As Japan did not raise these four alleged instances of trans-oceanic dissemination of fire blight with either the scientific experts or in the second substantive meeting, *see* Closing Statement of Japan at the Second Substantive Meeting, paras. 19-26, the Panel may infer that Japan is no longer suggesting that this two-step analysis adequately identifies necessary steps in a hypothetical pathway. Thus, in this answer, we focus on the other two hypothetical pathways Japan has continued to assert.

blight, counter to the hypothetical pathway Japan has identified for the Panel in Exhibit JPN–34. That is, in this scenario Japan has identified a pathway that is not even based on a risk posed by the exported commodity (harvested apple fruit, which are mature and symptomless). Thus, the United States does not find that the parties have agreed on the identification of the steps necessary for a pathway to be completed.

36. We also take this opportunity to address Japan's failed efforts at the second substantive meeting to present "scientific evidence" for which no evidence exists: specifically, the presence of endophytic bacteria within mature apple fruit and vectoring of any hypothetically surviving epiphytic bacteria from a discarded fruit to a susceptible host.

37. First, it is clear that the purpose of the two Japanese experiments conducted in December was to attempt to manufacture a means by which endophytic bacteria could be recovered inside of mature apple fruit.[50] Unfortunately for Japan, the experiment *failed to recover any endophytic bacteria from the inside (cortex) of the fruit*, and the paper admits this: "*The fruit infection via pedicel by E. amylovora was not able to be confirmed* in this experiment as follows. . . . . Detection of *E. amylovora* from these disks [gouged from the mesocarp of the fruit] was carried out as described above, and *no E. amylovora was detected in any disk*."[51] Thus, given that the experiment failed to recover any endophytic bacteria from inside the fruit, despite cutting the pedicel and applying high populations of bacteria to the cut surface, it is beyond a stretch for Japan to claim that "[a]ll experts acknowledged the preliminary results of the experiments on the possible introduction of the bacteria through the pedicel part and the residual population inside the part of the apple."[52] In fact, Japan's inaccurate presentation of the (lack of) experimental results is evidently not driven by science but by its desire to manufacture evidence of internal bacteria in mature fruit: "*We will* continue this study and *demonstrate* that pedicel infection by *E. amylovora* can cause latent infection (endophyte) inside apple fruit."[53] Japan's experiments do *not* provide any scientific evidence to contradict the experts' statement that harvested mature fruit are not infected with *E. amylovora* and do not contain endophytic bacteria.[54]

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[50]*See* Exhibit JPN-39, at 1 (Purposes: "This experiment was conducted to clarify the ability of *E. amylovora* to invade fruit pedicel, to multiply in this tissue, and *to move further to inside of apple fruit*.") (emphasis added).

[51]*See* Exhibit JPN-39, at 3 (Discussion, paras. 2 & 4) (emphasis added).

[52]Japanese Opening Statement at the Second Substantive Meeting, para. 18 (emphasis added). In fact, the experts did not appear to have examined Exhibits JPN-39 and JPN-42 closely, referring exclusively to the photographs (and expressing great skepticism of Japan's claim that the visible rotting could be fire blight) rather than the experimental results. When presented with those results by the United States, Dr. Hayward agreed that the Japanese paper reports that endophytic bacteria were not recovered from inside the apple fruit.

[53]*See* Exhibit JPN-39, at 3 (Discussion, para. 3) (emphasis added).

[54]Should the Panel wish to consider the lack of any new or relevant scientific evidence produced by these two experiments further, the United States attaches a brief report by Dr. Roberts highlighting some of the key findings and deficiencies in these papers. *See* Exhibit USA-48.

38. Second, Japan asserted in its preliminary oral response to this question from the Panel that its Exhibit JPN-40 (the bird exhibit) established the existence of a vector to transfer bacteria from a discarded fruit to a susceptible fire blight host. With due respect, as indicated at the panel meeting, this exhibit does not rise to the level of scientific evidence; one suspects that if Japan had confidence that it did, Japan would have presented the evidence to the scientific experts for them to evaluate and confirm the value of the information presented in the exhibit. The United States notes that the exhibit merely presents photographic evidence that certain birds in Japan may eat apple fruit and visit alternative fire blight hosts. Thus, this is not scientific evidence of any vectoring of fire blight bacteria from the calyx of a discarded fruit to a susceptible host.[55] In fact, the text of the exhibit states: "When *blighted fruit* are discarded as garbage, . . . those birds eat the blighted fruit and then visit host plants of fire blight . . . ." Thus, on its face, this exhibit does not purport to be new evidence of vectoring of *epiphytic* bacteria from discarded fruit; rather, it merely suggests that there exist bird vectors of *bacterial ooze* (produced by blighted fruit) within Japan. The United States has never suggested that there are not vectors of bacterial ooze within Japan, but we have demonstrated, and the scientific experts have confirmed, that *there is no scientific evidence that imported apple fruit will be blighted*. Thus, once again, Exhibit JPN-40 does not provide evidence that Japan's hypothetical pathway would be completed.[56]

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[55]This exhibit falls far short of providing scientific evidence of the existence of a vector to transfer epiphytic bacteria from the calyx region of a discarded fruit to a susceptible host. The exhibit does not provide any evidence that the identified birds would even come into contact with the calyx region of the fruit; the pictures merely show the birds feeding on the flesh of the fruit. The exhibit also does not report any attempt to recover bacteria from the identified birds that had been present on the fruit. Dr. Hale has described experiments his team conducted over three different years in which they were not able to detect any movement of epiphytic bacteria from the calyxes of discarded fruit, and the experts have confirmed that there is no evidence of any vectoring of fire blight bacteria from the calyx of a discarded fruit to a susceptible host. *See, e.g.*, Response of Dr. Hale to Question 16 from the Panel.

Dr. Geider commented that because it would be very difficult to conduct an experiment to see if epiphytic bacteria in the calyxes of discarded fruit would be vectored to susceptible hosts, a fire blight-free island nation would have to volunteer to be the site of the experiment. The United States suggests that Hawaii has served as just such a real-world experimental site. The Japanese white-eye is present in Hawaii (*see* http://www.honoluluzoo.org/japanese_white-eye.htm); apple fruit is discarded in Hawaii (in fact, because of the large number of Japanese citizens and U.S. citizens of Japanese descent living in Hawaii, one suspects the same cultural discard practices detailed in the exhibit would be found in Hawaii); fire blight host plants (such as pyracantha and loquat) are present in Hawaii; and there have been unrestricted shipments of apple fruit from the U.S. mainland for decades (20 million fruit annually in recent years, according to U.S. industry estimates). Nonetheless, there has been no introduction of fire blight to Hawaii. Thus, the real-world evidence supports the conclusion that there is no vectoring of epiphytic bacteria from the calyx region of a discarded fruit to a susceptible host, consistent with the scientific evidence in Dr. Hale's (published and peer-reviewed) studies.

We will not belabor the point, but similar criticism may be made of Japan's "evidence" with respect to the brown-eared bulbul as this bird exists in Taiwan (*see* http://www.geocities.com/RainForest/9003/lifelist.htm). Taiwan imports substantial quantities of apple fruit without measures similar to the Japanese fire blight restrictions, yet remains fire blight-free. *See* U.S. First Written Submission, para. 27.

[56]The United States also notes that Japan did not make any reference to Exhibit JPN-40 in its closing statement (that is, when it finally took the "opportunity to discuss the entire pathway with scientific evidence") even when discussing the scientific evidence relating to vectors of bacterial ooze. *See* Japanese Closing Statement at the

17. To both parties: Article 5.1 requires an assessment "as appropriate to the circumstances". Could you please comment on what are, in your view, the relevant circumstances to be taken into account in this instance under this provision?

39. The phrase "as appropriate to the circumstances" suggests that Members have some flexibility in conducting an assessment of risks that otherwise conforms to the requirements of Article 5.1 and Annex A of the SPS Agreement. In this dispute, the relevant circumstances are that Japan seeks to prevent introduction of fire blight, but there is no scientific evidence that harvested, mature apple fruit have ever transmitted fire blight or could serve as a pathway for introduction of the disease. An assessment of risks within the meaning of Article 5.1 and Annex A must evaluate the likelihood or probability of introduction of fire blight via imported apple fruit. Where there is no scientific evidence establishing a likelihood or probability of introduction, there is no risk to plant life or health within Japan through apple fruit imports. Thus, Japan has not based its fire blight measures on U.S. apples on an assessment of risks under Article 5.1.

40. As the United States has previously noted[57] and the experts have confirmed,[58] Japan's assessment of risks does not evaluate the likelihood – *i.e.*, the probability – of entry, establishment, or spread of fire blight through imports of apple fruit (because Japan has not identified necessary steps for apple fruit to serve as a pathway, identified and evaluated the scientific evidence (or lack thereof) related to each step, and therefore evaluated the resulting likelihood of the pathway being completed). Even Japan's efforts in the course of this dispute to illustrate a hypothetical pathway for introduction of fire blight via mature apple fruit fail to evaluate the likelihood (or probability) of each identified step (and therefore the pathway as a whole) being completed.[59] Most importantly, Japan's hypothetical pathway relies on events for which the scientific experts unanimously concur there is no scientific evidence – specifically, that a calyx-infested fruit that is harvested and exported will become infected and produce bacterial ooze. Again, where there is no scientific evidence that this step will be completed and therefore that the hypothetical pathway will be completed, there is no likelihood or probability that

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Second Substantive Meeting, para. 23.

[57]*See, e.g.*, U.S. First Written Submission, paras. 63-94.

[58]*See* Reply of Dr. Hale to Question 33 from the Panel (noting that Japan "has prejudged the outcome of its risk assessment" and "has not provided an evaluation of likelihood that the steps necessary for entry of fire blight bacteria would be completed"); Reply of Dr. Hayward to Question 33 from the Panel (noting that Japan has not assessed the probability of completion of each step in the hypothetical pathway); Reply of Dr. Smith to Question 33 from the Panel (in the Japanese PRA, "[c]omparisons are made with measures used in other parts of the world, but only to verify their effectiveness, not to establish their appropriateness for one particular pathway (imported fruits).").

[59]*See* Exhibit JPN-34; Japan's Answer to Question 5 from the Panel (Nov. 13, 2002); Japan's Closing Statement at the Second Substantive Meeting, paras. 19-26.

harvested mature apple fruit will introduce fire blight into Japan or pose a risk to plant life or health. Thus, Japan has failed to ensure that its fire blight measures are based on an assessment of the risks to Japanese plant life or health within the meaning of Article 5.1 and Annex A of the SPS Agreement; its assessment of risks can therefore not be deemed to be appropriate to the circumstances.[60]

18. To both parties: The Appellate Body has noted that an evaluation of whether a measure is "based on" a risk assessment within the meaning of Article 5.1 should be performed "on a case-by-case" basis, after account is taken of all considerations rationally bearing upon the issue of potential health effects" (AB Hormones, para. 194). Could you please indicate what are, in your view, the "considerations rationally bearing upon the issue of potential (plant)n [sic] health effects" that should be taken into account in this case?

41. The obligation under Article 5.1 that Japan's fire blight measures on imported U.S. apple fruit must be "based on" an assessment of the risks to plant life or health within Japan posed by those fruit requires that the result of the risk assessment "must sufficiently warrant – that is to say, reasonably support – the SPS measure."[61] In this dispute, there is no scientific evidence that mature apple fruit have ever transmitted or could serve as a pathway for introduction of fire blight. Therefore, there is no likelihood or probability of fire blight introduction via imported U.S. apple fruit, and there are no other "considerations rationally bearing upon the issue of potential health effects" that need be taken into account. Where imported U.S. apple fruit do not pose a risk to plant life or health within Japan, the result of the risk assessment does not reasonably support (or sufficiently warrant) Japan's fire blight measures. The only phytosanitary measure that is reasonably supported by the scientific evidence is restricting importation of U.S. apples to the exported commodity: mature (and therefore symptomless) apple fruit.

5. Article 7

19. To the US: Please clarify your claim regarding violation of Article 7 of the SPS Agreement in the light of Japan's notification of December 1996 of changes to its Enforcement Ordinance of the Plant Protection Law (G/SPS/N/JPN/19).

42. The Japanese notification of December 1996 provided notice that Japan's Plant Protection Law Enforcement Regulations would be amended to designate *Erwinia amylovora* as

[60]We also note that Japan's assessment of risks may not be appropriate to the circumstances in that Japan has failed to take into account certain information in its assessment of risks inconsistently with Article 5.2 of the SPS Agreement. For example, Japan has not taken into account the available scientific evidence that mature apple fruit have not been implicated in the spread of fire blight – despite decades of worldwide trade in apple fruit – and that necessary steps in its hypothetical pathway would not be completed, both points that were confirmed by the scientific experts.

[61]*EC – Hormones*, WT/DS26/AB/R, para. 193.

a pest subject to import prohibition. However, any changes to the listing of prohibited pests in Annexed Table 2 of the Plant Protection Law Enforcement Regulations would not require changes to Japan's measures establishing the specific fire blight restrictions and requirements imposed on U.S. apples; therefore, notification of changes to the Plant Protection Law Enforcement Regulations cannot be deemed to constitute notification of any changes to other fire blight measures.

43. Japan promulgated MAFF Notification No. 354 and its accompanying Detailed Rules for U.S. Apples in March and April 1997, respectively, replacing the 1994 MAFF Notification No. 1184 and related Detailed Rules. Japan has not denied that the current fire blight measures include those promulgated in 1997. 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 in 1997 with MAFF Notification No. 354 and the related Detailed Rules, these changes in Japan's fire blight measures were required to be notified. The December 1996 notification did not notify these 1997 measures.

6. Factual issues

21. To the US: Are apple orchards in Washington or Oregon ever inter-planted with pear? Is this practice found in States other than Washington or Oregon?

44. As Dr. Roberts stated at the second substantive meeting, the answer to both of these question is "No." As a practical matter, apples and pear orchards have very different management practices, such as spray schedules and spray materials, that preclude interplanting to two crops. Furthermore, national laws that apply to all U.S. States restrict the use of certain pesticides to those crops for which they are labeled – so an interplanted orchard would pose legal problems to growers as well as practical orchard management difficulties. These issues are effectively addressed by not interplanting pear and apple trees in commercial orchards.

22. To Japan: You had requested the US to make available information referred to by Dr. Geider in his answer to Question 12 of the Panel's written questions to the experts. This was with respect to information provided by the successor of Dr. van der Zwet on a fire blight outbreak. We understood Dr. Geider to have clarified, on Monday, that he received this information in an oral conversation. Does this satisfy Japan's request?

45. Per the Panel's request, the United States has inquired of Dr. Norelli, the researcher with whom Dr. Geider conversed, what were the circumstances of the fire blight outbreak to which Dr. Geider referred and which has elicited such interest from Japan. On January 27, 2003, Dr. Norelli stated in a telephone conversation with Dr. Roberts that a severe hailstorm occurred in the area (around Kearneysville, West Virginia) during the 2002 growing season and that widespread fire blight resulted. In cooperation with extension agents from Virginia and West

Virginia, Dr. Norelli obtained approximately 1,000 isolates of *E. amylovora* from blighted tissues, in some instances from infected, oozing fruitlets that were 1 inch or less in diameter. *No isolations were obtained from mature fruit.* The purpose of the study was to evaluate streptomycin resistance in their fruit growing area. As such, Dr. Norelli's oral comments to Dr. Roberts are entirely consistent with Dr. Geider's written comment about this incident and with the scientific evidence that immature fruit may become infected with fire blight but that harvested, mature fruit will not. We trust that the Panel will be satisfied that there is no basis for Japan's accusation that the United States is withholding evidence of mature fruit infection in West Virginia in 2002.

Additional Questions from the Panel through Its Fax of 20 January 2003

> **To both parties: Japan's description of its current requirements on the importation of mature apples from the United States contains 7 elements (paragraph 148, Japan's First Written Submission). In contrast, the United States' description of Japan's current requirements contains 9 elements (paragraph 19, US First Written Submission). . . . . Please explain the differences in these two descriptions, and indicate which most completely describes the current requirements, as now applied by Japan.**

46. The United States believes that its description of the Japanese fire blight restrictions and requirements imposed on imported U.S. apples accurately conveys all of the elements contained in the Japanese fire blight measures. With respect to the second Japanese fire blight requirement identified by the United States (inspections), we would note that the number of inspections required by Japan is *at least* three, given that the Detailed Rules require additional inspections in case of strong storms, such as hail storms.[62] We can also confirm that, in practice, the blossom and fruitlet inspections had been conducted by U.S. plant protection officials, and the harvest season inspection had been conducted jointly by Japanese and U.S. officials – when there was participation in the program. In addition, we can confirm that the required post-harvest chlorine treatment (the fifth Japanese fire blight requirement identified by the United States) is to soak the fruit in a sodium hypochlorite solution (minimum 100 parts per million chlorine) for one minute or more.[63]

> **To the United States: With reference to questions 21 and 22 by the Panel,**
> **(1) could you please clarify the following statement contained in paragraph 58 of your answer to question 22 "The United States is not arguing that compliance**

[62] *See* U.S. First Written Submission, para. 19 fn. 23; *see also* Exhibit JPN-23, para. 1(2) (Japanese provisional translation of 1997 Detailed Rules).

[63] *See* U.S. First Written Submission, para. 19 fn. 26; *see also* Exhibit JPN-23, para. 6(1)(c) (Japanese provisional translation of 1997 Detailed Rules).

with the U.S. Export Apple Act as such would constitute the alternative measure reasonably available...."

(2) could you please clarify whether compliance with the US Export Apple Act, or other relevant State regulations, involves orchard inspections by any federal, state or other authority (please provide extracts of any relevant text).

47. (1) The scientific evidence demonstrates that the exported commodity, mature, symptomless apple fruit, do not pose a risk to plant life or health within Japan. Therefore, the only measure that Japan may impose, consistent with the scientific evidence, on the exported commodity is to limit importation to that commodity: that is, require that imported fruit be mature and therefore symptomless. This alternative measure is reasonably available to Japan, is significantly less restrictive to trade than Japan's current fire blight measures, and achieves Japan's appropriate level of protection (to prevent introduction of fire blight). We note that a phytosanitary measure taken by Japan can be, *inter alia*, any law, regulation, or requirement applied to protect plant life or health within Japan from risks arising from the introduction of a pest or disease. Thus, the only fire blight measure that *Japan* may impose on imported U.S. apples consistent with its obligations under the SPS Agreement would be a requirement *by Japan* that imported fruit be restricted to harvested, mature fruit.

48. The United States has demonstrated (and the experts have confirmed) that the exported commodity is mature and symptomless because (1) harvested fruit are horticulturally mature, (2) mature fruit are not infected with fire blight (and therefore are symptomless), (3) any infected, immature fruit would not pass through normal harvesting, sorting, and storage procedures developed and applied by growers, distributors, and exporters, and (4) any infected, immature fruit would not pass through grading and inspection procedures by Federal-State inspectors, including application of the standards of the U.S. Apple Export Act. However, these are not measures that *Japan* would apply; rather, they are the means by which *the United States* produces an exported commodity that is mature and symptomless.

49. (2) Compliance with the U.S. Export Apple Act does not require inspection of apple orchards, and there is no state regulation or requirement that requires orchard inspections. The Export Apple Act states that exported apple fruit satisfy at least the requirements for "U.S. No. 1" grade, pursuant to which apple fruit must be "mature" and "free from damage caused by . . . disease."[64] There is no scientific evidence that orchard inspections would be necessary or even relevant to ensure that fruit are mature and thus symptomless. As the experts have confirmed, fruit are harvested at horticultural maturity, which is measured according to objective criteria such as sugar content, firmness, and starch pattern. The experts also confirmed that there is no scientific evidence that horticulturally mature fruit will be infected with fire blight (and therefore present fire blight symptoms). Because harvested fruit will be mature and symptomless, *regardless* of whether they are harvested from orchards with fire blight or without, orchard

[64] *See* U.S. First Written Submission, para. 23 & fn. 38.

inspections for fire blight are neither necessary nor relevant to ensure that exported apple fruit will be mature and symptomless. Thus, orchard inspections do not form part of the requirements of the U.S. Apple Export Act.