***Japan – Measures Affecting the Importation of Apples* (WT/DS245)**
***Recourse by the United States to Article 21.5 of the DSU***

**Opening Statement of the United States**
**at the Substantive Meeting of the Panel**

October 28, 2004

1. Mr. Chairman, members of the Panel, the scientific evidence relating to mature apple fruit and fire blight is clear. It was clear two years ago when the original panel first examined it and made its original findings, and it is equally clear today. Despite Japan's attempts to develop scientific studies during the course of this Article 21.5 proceeding, Japan has failed to present any new scientific evidence that affects or augments the discussion of and findings on the real world biology and epidemiology of fire blight and apple fruit set out by the original panel in its report. Put simply, as was the case two years ago, the scientific evidence does not establish that mature apple fruit will introduce fire blight into a fire blight-free area.

2. Japan's revised measures are premised solely on its new studies, and not on the decades-worth of studies originally examined by the panel. Those earlier studies fail to establish that mature, symptomless apple fruit will endophytically harbor let alone be infected with fire blight, or that the pathway for introduction of fire blight via apple fruit will be completed; rather, they strongly support the opposite conclusions. Japan does not contest the evidence in those studies, but is suggesting that its new studies somehow change the conclusion that its revised measures – which are little different from the original measures – are maintained without sufficient scientific evidence. Thus, the scientific focus of this dispute is narrow, and the question is simply whether Japan's new studies require that the DSB's ruling that Japan's measure does not rationally relate to the scientific evidence be revisited.

3. They do not. Japan's new studies propose two phenomena whose existence is unsupported by previous studies – the existence of a mature, symptomless yet latently infected apple fruit and the existence of a vector to transfer *Erwinia amylovora* from apple fruit to host material. However, as demonstrated by the United States in its second submission, the studies fail to demonstrate anything "new" regarding fire blight and apple fruit in two respects. The studies fail to present results that have any bearing on the real world study of the epidemiology and biology of fire blight and apple fruit. They also fail to demonstrate anything new in the laboratory. The infection study in particular merely demonstrates a proposition that scientists have been aware of since 1923 – that by artificially wounding or stab-inoculating apple fruit, you can infect the fruit with fire blight and later recover bacteria from the infected fruit. Further, in several instances that will be highlighted in this statement, Japan's studies simply do not contain the results necessary to support Japan's conclusions drawn from the studies.

4. Because Japan's new studies fail to present scientific evidence that in any way sheds light on the real world activity and interaction of fire blight and apple fruit, we are left where we were two years ago – with clear scientific evidence that fails to establish that mature apple fruit will endophytically harbor let alone be infected with fire blight, or that a vector exists to transmit *Erwinia amylovora* from a hypothetically infected fruit to host materials. Unfortunately, we find ourselves in the same position as two years ago in another regard: despite the clear evidence, the findings of the original panel on that evidence and the recommendations and rulings of the DSB, Japan has not eased its restrictions on mature U.S. apple fruit. Instead, Japan's revised measures retain the vast majority of the restrictive conditions first examined by the panel two years ago. As before, those measures are maintained without sufficient scientific evidence within the

meaning of Article 2.2 of the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement"); are not based on a proper risk assessment within the meaning of Article 5.1 and Annex A of the SPS Agreement; and are more trade restrictive than required in breach of Article 5.6 of the SPS Agreement. The United States will discuss these arguments in order.

*Article 2.2*

5. First, Japan's revised measures continue to be maintained without sufficient scientific evidence in breach of Article 2.2 of the SPS Agreement. Except for previously discredited arguments on the van der Zwet study, Japan does not seek support for its revised measures in the decades-worth of scientific literature and experiments reviewed by the original panel. Instead, Japan puts forward four "new" studies. Unfortunately, these studies do not accomplish anything "new" that in any way affects or augments previous findings on the real world epidemiology and biology of fire blight and apple fruit. As before, the scientific evidence fails to establish that mature apple fruit will endophytically harbor let alone be infected with fire blight, that such fruit will be infested with epiphytic bacteria in populations capable of initiating the disease, or that a vector exists to transmit bacteria from apple fruit to host materials.

6. Japan suggests that, "[c]learly, the new evidence casts fresh, different light on the issues."[1] Japan argues that its new studies point to a "real risk"[2] of introduction of fire blight into Japan, and that as a result its revised measures are no longer maintained without sufficient scientific evidence within the meaning of Article 2.2. In fact, Japan's studies fail to demonstrate

[1]Second Written Submission of Japan, para. 13.

[2]First Written Submission of Japan, paras. 28, 32, 40, 43, 51, 56, 85.

the central themes they set out to establish – that mature apple fruit will be infected with fire blight or that the pathway for introduction of fire blight into Japan from a hypothetically infected fruit will be completed. As we explained in our second submission, Japan's new studies demonstrate phenomena that have not been shown to occur in the real world, and that instead are limited to carefully contrived conditions existing only in the laboratory.

7. We do not discount the Japanese results because they are experimental, as Japan suggests;[3] rather, we discount the conclusions to be drawn from these very artificial experiments because one cannot extrapolate from them conclusions regarding the real world biology and epidemiology of fire blight. To put it another way, the studies' conclusions describing the activity and interaction of fire blight and mature apple fruit in the real world, or the orchard, lack relevant scientific support. Japan has again done no more than propose a hypothetical pathway for the introduction of fire blight via apple fruit.

8. Two studies in particular are critical to Japan's hypothetical pathway. Through them, Japan attempts to establish the existence of two missing elements from its proposed pathway – the existence of a mature, symptomless but latently infected apple fruit and the existence of a vector to transmit fire blight from apple fruit to host materials. However, neither study accomplishes its intended goal because neither study's results demonstrate that mature apple fruit will be infected by or endophytically harbor *Erwinia amylovora* under natural conditions or that hypothetically infected fruit will introduce the disease into Japan.

9. The first study is the Azegami study, through which Japan hopes to demonstrate that

[3]Second Written Submission of Japan, para. 33.

mature, symptomless apple fruit can be latently infected by the flow of bacterium through an apple fruit's pedicel or through wound-inoculating the fruit. Without this, the first step in Japan's proposed pathway – the presence of a mature, symptomless yet hypothetically infected apple fruit in Japan – fails. However, the Azegami study only succeeds in introducing bacteria into the fruit by *artificially cutting the pedicel off the fruit* and by *artificially wounding the fruit in several places* and then placing a suspension of *Erwinia amylovora* on the various wounds or cut pedicel.

10. In its discussion of the Azegami study in its second submission, the United States referred to a 1952 Anderson study in support of the notion that it is not a new concept or groundbreaking result for a scientist to artificially inoculate a piece of fruit with fire blight bacteria and then later recover bacteria from the fruit. Japan miscasts the U.S. reference to Anderson as an implicit recognition that the science relating to pear fruit and apple fruit are somehow interchangeable, later discussing pear fruit-related incidences in several places in its submission as germane to a discussion of fire blight and mature apple fruit.[4]

11. However, the United States did not raise the Anderson study because pear fruit and apple fruit science are interchangeable, but rather to highlight the fact that scientists, for generations, have been able to artificially inoculate fruit and cause fire blight. In fact, this concept was introduced vis-a-vis apple fruit in the 1920s by the Canadian scientist McLarty, who stab-inoculated mature apple fruit and later recovered bacteria from the fruit.[5] What can be artificially

[4]Second Written Submission of Japan, paras. 44, 64.

[5]McLarty, H.R., "Experiment to determine the possibility of fire blight bacteria living in apparently healthy fruit in badly blighted districts", Can. Dep. Agric. Bot. Rep. 1923: 31-32.

accomplished in the laboratory, however, does not demonstrate, in the case of fire blight and apple fruit, what occurs in the orchard or under real world conditions.

12. To emphasize this point, despite the more than eighty years that have passed between when McLarty first demonstrated that it was possible to artificially wound inoculate a fruit and when Azegami confirmed McLarty's findings in its own artificial wound inoculation study, not a single experiment has isolated fire blight bacteria from the internal tissues of mature, symptomless apple fruit in the orchard – even when those fruit are harvested from a severely blighted tree. In fact, Japan itself appears to acknowledge that latently-infected mature apple fruit are a product of the laboratory and not nature, stating that "a latently infected mature fruit is found only under experimental conditions."[6]

13. The Panel may recall a very similar study to that described in Azegami. Japan presented the results of just such a cut-pedicel study at the meeting with the experts in the original panel proceeding.[7] The experts unanimously dismissed the study because it was irrelevant to an analysis of fire blight and apple fruit. They concluded this because the pedicels had been artificially removed and a suspension of bacteria placed directly on the cut surface of the pedicel, whereas in nature the pedicels would be intact. In other words, the artificial construct of the experiment, like the other wound-inoculation studies which preceded it, did not assist in an analysis of how apple fruit and fire blight behave in nature. The study did not offer anything "new" to the experts' or panel's analysis of the science surrounding fire blight and apple fruit.

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[6]Second Written Submission of Japan, para. 68.

[7]*See* Panel Report on *Japan – Measures Affecting the Importation of Apples*, WT/DS245, adopted on 10 December 2003 (hereinafter "Panel Report"), Annex 3, paras. 129-143.

14. Dr. Hale commented that "[i]f you cut the surface and you put a pure suspension of *E. amylovora* on that cut surface then it is likely to be sucked into the vascular system . . . [b]ut I think it really is quite an artificial situation to cut the surface like that and then just let the bacteria get sucked in."[8]

15. Dr. Geider similarly observed the artificiality of the cut pedicel study, noting that "I think we all eat apples which are not harvested without pedicels so this could [be] some sort of attraction for fire blight which is in the stem," cautioning that "I think we should keep this an interesting experiment in the lab but a little bit cautious in interpretation if this clearly shows that apple can be infected just from fire blight coming through the stem section."[9]

16. Dr. Smith perhaps best summed up the experts' unanimous concerns regarding extrapolating real world conclusions from such an artificial study, stating "the first point in my mind, is what is supposed to happen in nature? Apples in fact are mainly attached to trees by their pedicels. They are not cut and so the question is, supposing that there were a canker on the branch, can the bacterium spread through the pedicel into the fruit under those conditions? And such an experiment would also have to be done to see whether the results obtained in the laboratory have any relation to a natural situation." Further, he noted that "all kinds of strange results can be obtained by artificially inoculating plants with high concentrations of pathogen. Such experiments can guide you as to what might happen, but they do not really provide conclusive evidence of what is happening on an apple tree."[10]

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[8]Panel Report, Annex 3, para. 140.

[9]Panel Report, Annex 3, paras. 138-139.

[10]Panel Report, Annex 3, para. 142.

17. Contrary to Japan's intent, the Azegami study's results bolster the United States' argument and previous scientific findings that mature, symptomless apple fruit will not endophytically harbor, let alone be internally infected with fire blight. As noted by Dr. Smith, results demonstrating infection caused by fire blight bacteria passing into an apple fruit through an intact pedicel attached to a branch or stem would come closer to approximating real orchard conditions. Yet the Azegami study's results clearly indicate that fire blight bacteria did not pass through the pedicels of mature fruit with intact pedicels (that is, pedicels still attached to the branch) – as apple fruit would be found in an actual orchard. Thus, Japan's conclusion that mature apple fruit "can be easily infected through pedicels"[11] is not even factually supported by the Azegami study's results.

18. Japan also appears to offer the undemonstrated supposition that bacterium could enter apple fruit prior to maturity and prior to the full development of the abscission layer in the pedicel, and that those bacteria would then remain in the apple fruit throughout the maturation process.[12] However, Japan's study does not demonstrate that this phenomenon could occur, and of greater significance is the fact that no study, other than artificial wound inoculation studies such as Azegami and its predecessor McLarty, has isolated *Erwinia amylovora* from the inside of mature, symptomless apple fruit, even those fruit harvested directly from heavily-blighted trees. If, as Japan contends, the pedicel is a conduit for entry of bacteria into maturing apple fruit,[13] the numerous earlier studies on mature, symptomless apple fruit harvested from severely blighted

[11]Second Written Submission of Japan, para. 22.

[12]*See* Second Written Submission of Japan, para. 35.

[13]Second Written Submission of Japan, para. 22.

trees would have isolated bacteria within the fruits' tissues.

19. Japan asserts that previous studies failed to isolate internal bacteria because they didn't examine the part of the fruit where the bacteria were hidden, the flesh.[14] As we discussed in our second submission, this is simply not the case. Earlier studies, including Roberts (1989), examined the "core and cortex [*i.e.*, flesh] tissues, including the stem, if present, and the entire calyx"[15] of apple fruit harvested from and near severely blighted trees, and failed to recover any *Erwinia amylovora.* Similarly, the 1974 Dueck study, which found that *Erwinia amylovora* is not internally-isolated in mature apple fruit, even when harvested from severely infected trees, sampled the internal and external parts of 60 mature apples from three severely blighted trees. This included three cylinders "from the cortex [*i.e.*, flesh] of each apple", the stem, the calyx and the core.[16]

20. In fact, Japan itself has failed to isolate bacteria from the inside of fruit from blighted orchards. In the course of the 2000 joint-study conducted by the United States and Japan, Japan's own Dr. Mizuno sampled cortex tissues from 100 fruit from heavily blighted Gala apple trees and discovered no internal populations of *Erwinia amylovora.* In sum, the Azegami study does not present evidence of the real world existence of a mature, symptomless fruit that is latently infected. Rather, it succeeds in presenting evidence that, if you artificially remove an apple's pedicel or artificially wound an apple fruit and then place a suspension of *Erwinia*

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[14]Second Written Submission of Japan, para. 36.

[15]Roberts *et al.*, "Evaluation of Mature Apple Fruit from Washington State for the Presence of *Erwinia amylovora*", Plant Disease 73: 917-921, p. 918. (Parenthetical inserted).

[16]Dueck, J., "Survival of *Erwinia Amylovora* in association with mature apple fruit", Can. J. Plant Sci. 54: 349-350 (1974). (Parenthetical inserted).

*amylovora* on the fresh wound, the bacteria will be drawn into the fruit. Again, as noted by the experts, this sort of artificial result is of no scientific value vis-a-vis assessing how fire blight bacteria and apple fruit interact in the orchard and has no weight in establishing a phytosanitary risk associated with such fruit.

21. As I mentioned earlier, Japan continues to cite the 1990 van der Zwet study as providing evidence of the discovery of *Erwinia amylovora* "inside" apple fruit "during the late maturing season," supposedly demonstrating a risk of mature apple fruit infection with, or contamination by, fire blight bacteria.[17] However, as discussed in great detail by the United States in its second submission, and as evidenced by the letters of Drs. van der Zwet and Thomson regarding the results of the study, the subject fruit were immature, and the one "nearly mature" fruit described in Japan's first submission was epiphytically infested with a small population of bacteria – a rare occurrence, but an occurrence consistent with the original panel findings on the scientific evidence. In short, the van der Zwet study simply does not stand for the premise that mature, symptomless apple fruit will endophytically harbor let alone be infected with fire blight, or that there is a risk of internal infection of mature apple fruit late in the growing season. At most, van der Zwet affirms the original panel's finding that mature apple fruit may rarely be infested by populations of *Erwinia amylovora* incapable of spreading fire blight.

22. Further, we note that Japan's Tsukamoto infection experiment, an off-shoot of the Azegami study, does nothing more than demonstrate that fire blight bacteria can be isolated from artificially, wound-inoculated fruit after a period of storage. Again, as scientists have been

[17] First Written Submission of Japan, para. 47.

artificially inoculating apple fruit for decades, so have they been recovering bacteria from the infected fruit, starting with McLarty in 1923, and continuing through Dueck in 1974. As discussed earlier, however, the experts unanimously dismissed this approach as being irrelevant to the issue at hand, and such experiments shed no light on the biology and epidemiology of fire blight and apple fruit in the real world. For these reasons, Japan fails to demonstrate that the first step of its proposed pathway exists – that is, that "Mature, apparently healthy apple fruit which have fire blight bacteria inside are harvested in the United States"[18] – making its proposed pathway nothing more than a hypothetical one.

23. The second study central to Japan's argument is the Tsukamoto greenbottle fly vector study, which purports to complete the sixth part of Japan's hypothetical pathway by demonstrating that a fly will transmit fire blight bacteria from an infected fruit to susceptible host material. Like Azegami, the Tsukamoto study fails to demonstrate that such an event could actually occur, demonstrating instead infection of host materials only under the most artificial of conditions. As with Azegami, Tsukamoto only bolsters the U.S. argument that Japan's measures are maintained without sufficient scientific evidence, and that Japan's proposed pathway is nothing more than hypothetical because the study fails to demonstrate that flies that obtain bacteria from infected fruit in fact transfer the bacteria to host materials. Japan itself recognizes this significant shortcoming, noting in its second submission that "the flies contaminated in a beaker (in other words, the flies exposed to infected fruit) did not directly become the source of infection of the pear fruit observed."[19]

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[18] *See* Exhibit JPN-12.

[19] Second Written Submission of Japan, para. 30. (Parenthetical inserted).

24. Despite this disconnect in the study, Japan draws the following conclusion from the study's results: "it is only logical to conclude" that the experiment's results demonstrate that there is a risk of completion of the pathway, and that the study demonstrates that "under plausible ecological conditions, the pathway of the disease will be completed."[20] It is unclear how enclosing artificially contaminated flies in a small plastic box with artificially wounded host materials in anyway approximates "plausible ecological conditions." It is also unclear how a study that only demonstrated infection of host materials when flies were soaked in a concentrated suspension of *Erwinia amylovora* and then forced to cohabit with host materials in a small enclosure demonstrates that, under real world conditions, flies will vector fire blight bacteria from hypothetically infected mature apple fruit and subsequently infect host material.

25. Nevertheless, Japan defends the artificial conditions and results of the vector study. In support of its methodology, Japan asserts that the United States failed to identify any other study whose methods better represent natural or real world conditions.[21] To the contrary, the United States referenced a recent study by Taylor *et al*. as an example of how an experiment can seek to realize real world conditions and, by contrast, how Japan's greenbottle fly vector study fails to do so.[22] A 1996 study by Hale *et al*. further highlights the artificial construct of Japan's vector study.[23] Both Hale and Taylor evaluated movement of the fire blight pathogen from contaminated apple fruits placed in orchards, and in some cases taped directly onto branches and

[20]Second Written Submission of Japan, paras. 31, 33.

[21]Second Written Submission of Japan, para. 32.

[22]First Written Submission of the United States, fn. 39.

[23]Hale *et al.*, "Ecology and Epidemiology of Fire Blight in New Zealand", Acta Horticulturae 411, 79-85 (1996).

adjacent to blossom clusters. Neither study reported a single instance of transmission of the fire blight pathogen from the contaminated fruit to either blossoms, leaves, fruit, or insects (including flies) under orchard conditions during three years of study, including during seasons with conditions conducive to fire blight development.

26. Regardless of the study's methodology, however, Tsukamoto's paper suffers from a more fundamental flaw. It fails to present any evidence that a vector exists that would transfer fire blight bacteria from apple fruit to host materials not only under real world or orchard conditions *but also* in the contrived, artificial setting of the laboratory. It fails to accomplish the very feat described in its title - "Transmission of *Erwinia amylovora* from blighted mature fruit to host plants via flies". Therefore, there is no scientific evidence that a critical element of the sixth step of Japan's hypothetical pathway will be completed, *i.e.*, that a vector exists to introduce fire blight from apple fruit to host materials.[24]

27. The discussion of hypothetical vectors for fire blight is not complete, however, without addressing two other vectors proposed by Japan in its Pest Risk Analysis – crows and "jungle crows." It is unclear from the PRA whether these crows are one and the same or two separate species. Together or apart, however, Japan neither produces nor cites any scientific evidence to support its conclusions that the crows will feed on and disperse infected apple fruit from garbage dumps or that "jungle crows" will peck through garbage bags to pull out infected fruit because they are attracted to the color red, the color of many (but not all) apple peels. Japan also fails to provide any evidence in support of its speculation that the jungle crows, having pecked apple

[24] *See* Exhibit JPN-12.

peels from garbage bags, will then carry the fruit near host materials, leaving the completion of the pathway to flies.[25] There is simply no scientific evidence to support this proposed link in the hypothetical vectoring "chain" for the introduction of fire blight in Japan.

28. In sum, Japan's new studies do not affect the analysis of how fire blight and apple fruit interact in a real world environment. As was the case when the original panel examined it, the scientific evidence fails to establish that mature apple fruit will endophytically harbor – let alone be infected with – fire blight, be infested with epiphytic bacteria in populations capable of initiating the disease, or that a vector exists to transmit bacteria from apple fruit to host materials. Japan's revised measures therefore continue to be maintained without sufficient science within the meaning of Article 2.2 of the SPS Agreement.

29. In examining Japan's revised measures, it is a task in itself to state with clarity what the measures, in fact, are. As we noted in our second submission, Japan has attempted to introduce, after the U.S. first submission was filed, a new set of "Operational Criteria" as part of Japan's revised measures. As we explained in detail in our preliminary ruling request and second submission, the Operational Criteria should not, for purposes of this Article 21.5 proceeding, be considered a measure taken to comply with the DSB's recommendations and rulings.

30. That being said, Japan suggests that the Operational Criteria change the standard for disqualifying an orchard from the "fire blight freedom" standard in the Detailed Rules to one of "heavy or severe blight." Japan points to the policy statements of the scientific experts as support for such an inspection for severe blight.[26] When discussing the actual scientific evidence

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[25]Pest Risk Analysis, September 2004, p. 25. (Exhibit JPN-3).

[26]First Written Submission of Japan, para. 11.

relating to fire blight and apple fruit the experts, to quote the original panel, "categorically stated that there was no evidence to suggest that mature apples had ever been the means of introduction of fire blight into an area free of the disease."[27] The experts further explained that even apple fruit harvested close to sources of inoculum were not infested with significant populations of *Erwinia amylovora*.[28] The experts' analysis of the scientific evidence accentuates the policy-driven nature of their comments regarding severely blighted orchards. Those statements simply are not supported by the scientific evidence that the experts themselves described and analyzed. That scientific evidence, which does not establish that mature apple fruit will endophytically harbor fire blight, let alone be infected with or transmit fire blight to a fire blight-free area, even when harvested from a severely blighted orchard, does not rationally or objectively relate to any orchard inspection whatsoever.

31. Regardless of this fact, on closer examination, the Operational Criteria propose nothing new at all vis-a-vis the level of fire blight that is necessary to disqualify an orchard, retaining in effect a fire-blight-free inspection requirement. This point can be illustrated by comparing Japan's description of the new "heavily blighted" requirement to the statements of the two MAFF officials who inspected orchards under a fire blight-free regime. The inspectors' descriptions of how an orchard is disqualified under a fire blight-free inspection is nearly identical to the description set out by Japan for its new "heavy blight" inspection in its revised PRA and Operational Criteria. Japan's PRA describes the Operational Criteria's new, severe blight inspection program as being "conducted from the officials in the inspecting car; *a* tree will

[27]Panel Report, para. 8.149.

[28]Panel Report, Annex 3, paras. 223-236.

be *presumed* to be '(severely) infected' when *readily observable symptoms* are found on the tree exterior, as seen from the officials in the inspecting car."[29]

32. Mr. Sotokawauchi, a MAFF inspector under the fire blight-free inspection regime, while inspecting an orchard in Brewster, Washington, disqualified the orchard as a result of a buggy car inspection when he "recognized *an* apple tree with *a* symptom of fire blight," thereby determining that "[o]n the basis of the epidemiology of fire blight, I have no doubt that an orchard which contains even one tree with such symptom will contain other blighted apple trees."[30] In short, Mr. Sotokawauchi disqualified an export orchard when he observed *a* fire blight symptom on *a* single tree while touring the orchard in a buggy car. He inferred, based on that discovery, and without further investigation of the orchard, that the orchard would contain other such trees. Mr. Sotokawauchi's narrative is telling because, even though it describes how he enforced the fire blight-freedom requirement, it mirrors what Japan's Operational Criteria describe as an inspection for "severely blighted" orchards – a buggy car inspection for readily observable symptoms on a single tree.

33. The second MAFF inspector similarly disqualified an orchard when, traveling in his buggy car, he observed "*an* apple tree" with "*a* typical fire blight symptom." The inspector said that discovery of this single blight strike on a single tree was clear evidence of pervasive blight in the orchard, stating, "I felt at the time that if I had walk through the orchard carefully and spent

[29]Pest Risk Analysis, September 2004, p. 48.

[30]Observation Regarding Fire Blight (Gebber Farms-Knapp), Kunita Sotokawauchi, October 12, 2004 (Exhibit JPN-15) (emphasis added).

more time for confirmation at the orchard, I would find numerous typical fire blight symptom."[31] Again, this highlights the fact that, while Japan has presented its Operational Criteria as a relaxation of the fire blight-freedom restriction, ostensibly through implementation of a severe blight criterion, the Criteria do not in fact represent a relaxation of the inspection requirement at all.

34. Further, even if they were construed to reflect a relaxation from a requirement of fire-blight freedom, the scientific evidence, as it did two years ago, simply does not establish that mature symptomless apple fruit will endophytically harbor or be infected with fire blight even when harvested from heavily blighted trees, or that epiphytically-infested apples harvested from heavily blighted trees will possess populations of *Erwinia amylovora* capable of transmitting fire blight. Disqualifying an orchard, or an export block, or any other subset of an orchard upon discovery of a single blighted tree, or several blighted trees for that matter, does not rationally or objectively relate to the scientific evidence regarding fire blight and apple fruit, as required by the SPS Agreement.

*Article 5.1*

35. Japan also purports to have fixed the flaws in its Pest Risk Analysis. Japan claims that the United States has failed to demonstrate shortcomings in the PRA's methodology, and as a result has failed to demonstrate that Japan's measures are not based on a proper risk assessment for purposes of Article 5.1 of the SPS Agreement.[32] However, constructing a framework of a risk

[31]Observation Concerning Fire Blight (Rodar IV), Shigeru Kimura, October 12, 2004 (Exhibit JPN-15) (emphasis added).

[32]Second Written Submission of Japan, para. 72.

analysis that touches on the benchmarks and deficiencies highlighted by the original panel and the experts, does not, in and of itself, mean that Japan has completed a risk analysis that evaluates the likelihood of entry, establishment, or spread of a pest or disease within Japan's territory within the meaning of Article 5.1 and Annex A of the SPS Agreement. As noted by the Appellate Body in *EC – Hormones*, for measures to be "based on" a risk assessment, the risk assessment "must sufficiently warrant – that is to say, reasonably support – the SPS measure."[33] Further, a risk assessment must evaluate the "likelihood" of introduction of fire blight via mature apple fruit, thereby requiring that there be a "probability" of entry, establishment or spread of the disease, not a mere "possibility."

36. However, in this instance, the probability of introduction of fire blight via imported mature U.S. apple fruit is essentially zero because the scientific evidence does not demonstrate that mature, symptomless apple fruit have ever introduced fire blight into a fire blight free area, despite, in many cases, unrestricted trade in apple fruit. Neither does the evidence establish that mature apple fruit will harbor endophytic populations of fire blight bacterium or be infected by fire blight, or that mature apple fruit will harbor epiphytic populations of bacteria capable of initiating the disease. As before, the evidence also does not establish that the pathway for introduction of fire blight via mature apple fruit will be completed. When, as is the case with mature apple fruit and fire blight, the scientific evidence confirms that imported U.S. apple fruit do not pose a risk to plant life or health in Japan, and when that scientific evidence fails to demonstrate a likelihood or probability of introduction of fire blight via mature apple fruit, the

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

result of the risk assessment cannot reasonably support, or sufficiently warrant, Japan's revised fire blight measures.

37. As discussed earlier, Japan's new studies fail to demonstrate that a likelihood of introduction of fire blight via mature apple fruit exists, and if anything, their results further solidify the earlier findings on the epidemiology of fire blight and the interaction between the pathogen and mature apple fruit. Thus, there continues to be no scientific evidence to establish a probability or likelihood of a risk to plant life or health due to imported U.S. apples, and Japan has failed to ensure that its fire blight measures are "based on" an assessment of the risks within the meaning of Article 5.1 and Annex A of the SPS Agreement.

38. In its second submission, Japan asserts that its PRA does not merely address the risk posed by latently infected mature fruit but that it also addresses the risk inherent in the hypothetical failure of U.S. quality controls, leading to "erroneous shipment[s] of infected apple fruit."[34] Japan then attempts to meet its burden of demonstrating that such an "erroneous" shipment may occur by claiming that the *United States* has failed to demonstrate how it could prevent such an occurrence. Not only is this an attempt to inappropriately reverse the burden of proof on this issue, it is factually simply not the case.

39. There is no evidence that the United States has ever exported anything other than mature, symptomless apple fruit. To the contrary, the United States has reviewed relevant databases and confirmed with relevant officials that no shipments of U.S. apple fruit have been rejected by foreign importers due to either immaturity or symptoms of fire blight. Specifically, we

[34]Second Written Submission of Japan, para. 68.

performed a search of the Foreign Notification of Non-compliance database, containing non-compliance statements collected by the United States Department of Agriculture from IPPC contact points, and checked with Federal, State and industry representatives responsible for overseeing apple export programs. Further, Japan has been unable to present any evidence of the failure of U.S. quality controls on apple fruit and fire blight, as even the Appellate Body noted.[35] Nevertheless, Japan now raises once again the anecdotal reference to infected *pear fruit* being shipped to Hawaii as evidence that U.S. controls on *apple fruit* may fail. As with Japan's irrelevant citation to codling moth in the earlier proceeding, there is no connection between this unsubstantiated, anecdotal reference to pear fruit and quality controls relating to U.S. apple fruit. Further, the United States goes into great detail in its first submission to describe the pre- and post-harvest controls, U.S. Federal and State regulations, and the various processes that have ensured that exported U.S. apple fruit is mature, symptomless apple fruit.

40. It is Japan that has failed to present any evidence that an "erroneous shipment" has or will occur. Japan apparently rests its argument on the Panel's statement that errors of handling or illegal actions are risks that "may be, *in principle*, legitimately considered by Japan,"[36] improperly inferring that this statement grants Japan a free pass to assume that U.S. quality controls would and will fail. In noting that it is a risk that may be considered, however, neither the original panel nor the Appellate Body absolved Japan from its obligation to present evidence that the risk of failure of U.S. apple fruit quality controls is more than just hypothetical. In fact,

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[35] *See* Appellate Body Report on Japan – Measures Affecting the Importation of Apples, AB-2003-4, adopted on 10 December 2003 (hereinafter "AB Report"), para. 141.

[36] Panel Report, para. 8.161.

the Appellate Body was careful to observe that the original panel's and experts' discussion of export controls was a discussion of those controls "in general,"[37] rather than an evaluation of the specific controls for apple fruit in place in the United States. There is no evidence that U.S. quality controls for maturity have ever failed, and Japan has not provided any evidence that they will. By failing to do so, Japan has done nothing more than to present yet another hypothetical pathway, unsupported by scientific evidence, for the introduction of fire blight via apple fruit.

41. Japan's Pest Risk Analysis gives, at best, short shrift to U.S. quality controls in its analysis, ignoring for the most part U.S. pre-harvest and post-harvest procedures. The PRA summarizes the controls as follows: "as apples are generally judged 'mature' or 'symptomless' by *visual sorting*, there is always a risk that something other than mature, symptomless apple fruit may be . . . present in the shipment."[38] Yet, as noted in the U.S. first submission, visual sorting is but one of the several steps undertaken in U.S. quality controls for apple fruit, including pre-harvest and post-harvest maturity testing, post-harvest mechanical screening, and highly accurate electronic scanning. By failing to address actual U.S. practices and to dispute the effectiveness of those practices, Japan has failed to take into account, pursuant to *International Standards for Phytosanitary Measures* ("ISPM") Number 11, the pest management, cultural and commercial procedures applied at the place of origin, thereby failing to properly evaluate the probability of the subject pest being associated with the pathway of origin for purposes of ISPM Number 11.[39]

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[37]AB Report, paras. 138, 141.

[38]Pest Risk Analysis, September 2004, p. 17. (Exhibit JPN-3).

[39]International Standards for Phytosanitary Measures ("ISPM") No. 11, "Pest Analysis for Quarantine Pests, Including Analysis of Environmental Risks and Living Modified Organisms", Section 2.2.1.2.

42. For these reasons, Japan's revised measures are not "based on" a proper assessment of the risks associated with fire blight and mature apple fruit, as required by Article 5.1 of the SPS Agreement.

*Article 5.6*

43. I would now like to address our Article 5.6 claim and Japan's arguments in response. Because the scientific evidence relating to fire blight and mature apple fruit remains unchanged since that evidence was originally examined by the panel two years ago, there is a measure that is not more trade restrictive than required in achieving Japan's appropriate level of protection – a Japanese measure restricting imported U.S. apple fruit to mature apple fruit.

44. Japan argues that the United States has failed to "define its alternative measure," and that it does not provide "the specifics of the 'mature, symptomless' specifications."[40] This ignores our explanation that the alternative measure is precisely what we stated, a requirement that apple fruit imported into Japan be mature and therefore symptomless. Further, while Japan pays lip service to the fact the original panel found, based in part on the OECD specifications and the clear views of the experts, that maturity is an objective concept, it ignores the fact that this <u>is</u> the specification for determining fruit maturity. The "required qualities/parameters" and "test methods" are those set forth in the OECD guidelines, which U.S. apple growers and packers apply, in particular the starch/iodine test, firmness measurements, and determination of soluble solids. Moreover, we pointed out the fact that there is no evidence that the United States has ever shipped anything but mature, symptomless apple fruit, and described in detail the processes that

[40]Second Written Submission of Japan, paras. 61-67.

are responsible for this result. This is anything but "an entirely open issue."[41]

45. The alternative of requiring that imported fruit be mature meets the requirement of Article 5.6, and Japan is therefore in breach of this provision.

*Conclusion*

46. In conclusion, Japan's defense of its new measures revolves around its new studies and the Pest Risk Analysis incorporating those new studies, as presented by Japan in its first submission. However, despite the United States' initial surprise at not hearing of these studies and PRA prior to their submission by Japan in this proceeding, it did not take long to realize that the studies and PRA do little, if anything, to support Japan's case. In fact, insofar as the results of the studies fail to develop the very evidence they set out to amass, they support the U.S. argument that the scientific evidence regarding apple fruit and fire blight remains unchanged, and that the scientific evidence fails to establish that mature apple fruit will endophytically harbor, let alone be infected with, fire blight, be infested with epiphytic bacteria in populations capable of initiating the disease, or that the pathway for introduction of fire blight via apple fruit will be completed.

47. Unfortunately, Japan has premised its revised measures on its new studies rather than crafting measures that would find support in the DSB recommendations and rulings and the vast number of studies reviewed and analyzed in this dispute. However, this is an Article 21.5 compliance proceeding. The findings of the DSB in the underlying dispute are taken as a given. The scientific evidence from the studies evaluated by the original panel remains the touchstone

[41] Second Written Submission of Japan, para. 61.

for evaluating Japan's new measures and Pest Risk Analysis. We therefore request that the Panel find that Japan's revised measures are inconsistent with its WTO obligations under the SPS Agreement, the Agreement on Agriculture and the GATT 1994. Further, we reiterate our request that, pursuant to our preliminary ruling request, the Panel find that Japan's Operational Criteria are not a measure subject to dispute settlement, and are not within the terms of reference of the Panel in this Article 21.5 proceeding.

48. Thank you for you attention. We look forward to your questions and to discussing these issues further.