

*Japan – Measures Affecting the Importation of Apples (WT/DS245)*

*Recourse by the United States to Article 21.5 of the DSU*

**Second Written Submission of the United States of America**

September 27, 2004

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## I. INTRODUCTION

1. Japan's first written submission narrows the focus of this dispute. In its attempt to justify its revised measures on U.S. apple fruit in that submission, Japan relies entirely on new "evidence" relating to apple fruit and fire blight. Japan's failure to draw support for its measures from the substantial record of scientific evidence in the original proceeding and the original panel findings on that evidence reinforces the argument set out by the United States at the outset of this proceeding - Japan's measures are not based on the scientific evidence relating to apple fruit and fire blight.<sup>1</sup>

2. Japan's failure to find support for its measures in the scientific evidence and the original panel's findings is not surprising given the nature of those findings, in particular that the scientific evidence does not establish that mature, and therefore symptomless, apple fruit will be infected with or harbor epiphytic populations of *E. amylovora*; that mature, and therefore symptomless, apple fruit will harbor epiphytic populations of *E. amylovora* capable of transmitting fire blight; or that apple fruit would serve as the pathway for introduction of fire blight into Japan.

3. In its attempt to construct a justification for its revised measures, Japan again posits a theory that there exists such a thing as a "mature, symptomless yet latently infected apple fruit."<sup>2</sup>

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<sup>1</sup> See, e.g., First Written Submission of Japan, para. 72 (making clear its view that the new evidence alone demonstrates a "risk": "[a]lthough surface contamination was found relatively insignificant, potential/actual infection of apple fruit was found to pose a risk of introduction of the disease. The *new evidence* appeared to show that the risk of latent infection of mature, symptomless apple fruit from a '(severely) blighted orchard' would be higher than previously believed"); para. 32 ("In any event the results of the [new] Study clearly show at the minimum that the completion of the pathway in Japan is more likely than thought *at the time of the original Panel.*") (Emphasis added).

<sup>2</sup> See First Written Submission of Japan, para. 74 ("the new pieces of evidence showed that even apparently healthy apple fruit could be latently infected by the bacteria").

Yet the original panel considered this argument, and rejected it.<sup>3</sup> Japan also has failed to identify any new scientific evidence that alters the scientific record on fire blight and apple fruit or that undermines the clear findings by the original panel on that scientific evidence. Japan has similarly failed to cast any doubt on the fact that there is no scientific evidence that, despite the billions of apple fruit shipped world-wide (the vast number of which were shipped without SPS measures for fire blight) apple fruit have ever introduced fire blight into a fire blight-free area.

4. Instead, Japan has submitted four new studies and a September 2004 Pest Risk Analysis (“2004 PRA”) revised on the basis of those studies in its attempt to demonstrate that the science relating to apple fruit and fire blight has changed. However, the studies contain no new scientific evidence – at most repeating 50-year old results achieved under artificial conditions – and are no more supportive of Japan’s revised measure than the already extensive scientific record examined by the original panel. A casual examination of the studies themselves demonstrates that they do not support the conclusions reached, nor do they meet the requirements of Article 2.2 of the *Agreement on the Application of Sanitary and Phytosanitary Measures* (“SPS Agreement”). Likewise, the recent 2004 PRA based on those studies fails to meet the requirements of Article 5.1.

5. With respect to the U.S. claim with regard to Article 5.6, Japan mischaracterizes the U.S.-proposed alternative measure in an effort to address its own argument, rather than the actual U.S. argument. Japan fails to rebut the U.S. demonstration that an alternative measure exists that fulfills the requirements of Article 5.6; therefore Japan is in breach of that provision.

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<sup>3</sup> See Panel Report, paras. 8.28, 8.73, 8.171.

6. Finally, Japan’s only rebuttal to the U.S. claims with respect to Article XI of the *General Agreement on Tariffs and Trade 1994* (“GATT 1994”) and Article 4.2 of the *Agreement on Agriculture* is that Japan’s revised measures are consistent with the SPS Agreement. Because they are not, and for the reasons set forth in the U.S. first written submission, Japan’s revised measures are inconsistent with GATT 1994 Article XI and Article 4.2 of the *Agreement on Agriculture*.

7. In sum, despite Japan’s attempts to prove otherwise, the scientific evidence relating to apple fruit and fire blight does, in fact, remain unchanged. Japan’s revised measures therefore continue to be unsupported by that scientific evidence, and thus fail to comply with the recommendations and rulings of the Dispute Settlement Body (“DSB”) and with Japan’s obligations under the SPS Agreement.

## **II. JAPAN’S REVISED MEASURES**

8. For the reasons set forth in the U.S. preliminary ruling request of September 27, 2004, the Operational Criteria<sup>4</sup> which Japan submitted for the first time with its first written submission are not a measure within the terms of reference of this dispute, and should be disregarded. However, even were the Panel to consider the Operational Criteria, it would not change the analysis of Japan’s measures. Notwithstanding Japan’s argument that the Operational Criteria are designed to prevent exportation from a “severely-blighted orchard,” they in fact enforce “fire blight-freedom,” the requirement set forth in the June 30, 2004 “Detailed Rules for Plant Quarantine Enforcement Regulation Concerning Fresh Fruit of Apple Produced in the United States of

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<sup>4</sup> “Operational Criteria for the Exportation of U.S. Apples to Japan” (Exhibit JPN-2).

America” (“Detailed Rules”). The Operational Criteria equate severely or “heavily blighted” with a scenario where “readily observable symptoms are found on the tree exterior, as seen from the official in the inspection automobile.”<sup>5</sup> However, under this standard, a single, “readily observable” fire blight strike on a single tree would disqualify an entire export orchard, as is the case with a “fire blight-free” measure. Rather than representing a relaxation of the inspection standard, Japan’s proposal would continue to disqualify orchards with any degree of infection.<sup>6</sup> In short, what Japan asserts is a “severely blighted” requirement is just the “fire blight-free requirement” by another name.

9. Further, the United States notes that Japan has presented its revised measures as consisting of only six elements: “(i) designation of an export orchard (1(1)A), (ii) a 10-meter border zone surrounding the orchard (1(1)B), (iii) one annual inspection of the orchard and the border zone, (iv) surface sterilization (5(1)C), (v) sterilization of packing facilities (3(2)) and (vi) sampling and export/import inspection (4(1), 5(2)B, 5(3), 8(1)).”<sup>7</sup> Japan’s assessment of the number of elements of the measure at issue in this proceeding is inconsistent with the actual amendments it has made to its import regime for U.S. apple fruit, and noticeably fails to include the requirement that apple fruit destined for Japan be segregated from other fruit post-harvest.

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<sup>5</sup> First Written Submission of Japan, paras. 10(v), 57.

<sup>6</sup> Japan refers to the 75-strike per tree criteria described by Dr. Hale, but then equates it to its “readily observable” standard. As explained in the text, the two are not the same, and “readily observable” is in fact equivalent to “fire blight-free.” Moreover, the United States notes that Dr. Hale never spoke of inspections for severe blight on an *individual tree*, rather he spoke of inspections for 75-100 strikes *per tree* in “severely blighted orchards.” See Panel Report, Annex 3, para. 294 (“In the work we have done we have talked about a heavily infected orchard in which we have said there are 75 to 100 strikes per tree. So this is a heavily infected orchard. If we find only the odd strike in the orchard, that is a lightly infected orchard.”); First Written Submission of Japan, para. 57.

<sup>7</sup> First Written Submission of Japan, para. 9.

The only element that has been entirely eliminated from Japan's original import regime is the requirement that packing materials be sterilized, thereby leaving nine of the ten elements of the original measure in place.<sup>8</sup> And, by failing to address post-harvest separation of apple fruit in its submission, Japan has failed to rebut the *prima facie* case raised by the United States that the post-harvest separation requirement is maintained without sufficient scientific evidence for purposes of Article 2.2 of the SPS Agreement.

### III. LEGAL ARGUMENTS

#### A. Japan's Revised Measures Are Maintained Without Sufficient Scientific Evidence in Breach of Article 2.2 of the SPS Agreement

10. As noted by the United States in its first written submission, Japan's revised measures are maintained without sufficient scientific evidence in breach of Article 2.2 of the SPS Agreement. Each of the restrictions comprising Japan's import regime for U.S. apples is maintained without sufficient scientific evidence because there is no rational or objective relationship between each restriction and the scientific evidence. As before, the scientific evidence does not establish that mature, symptomless apple fruit (the type of apple fruit exported from the United States) will either be infected with or harbor endophytic populations of *E. amylovora*, nor does it establish that mature, symptomless apple fruit will be epiphytically-infested with populations of *E. amylovora* bacteria that could serve as inoculum for new fire blight disease outbreaks.<sup>9</sup> Further, the scientific evidence does not establish that apple fruit would serve as a pathway for

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<sup>8</sup> See Panel Report, para. 8.25; First Written Submission of the United States, para. 12, fn. 22.

<sup>9</sup> Panel Report, paras. 8.128, 8.136, 8.171.



introduction of fire blight into a fire blight free area such as Japan.<sup>10</sup> The original panel reached these clear findings based on its exhaustive examination of the scientific evidence and after consultation with experts.<sup>11</sup> When analyzed in light of the scientific evidence, it is clear that Japan’s revised measures are maintained without sufficient scientific evidence within the meaning of Article 2.2 of the SPS Agreement.<sup>12</sup>

**1. Japan’s New Studies Do Not Change the Scientific Evidence Relating to Fire Blight and Mature, Symptomless Apple Fruit**

11. Japan’s first written submission is useful in confirming that its original and revised measures were not and are not supported by the scientific evidence as evaluated by the original panel; Japan does not attempt to justify its measures based on the panel findings and the scientific evidence in the original panel proceeding. Rather, Japan relies on “new evidence” in the form of new studies in an attempt to show that its import regime for U.S. apple fruit is rationally or objectively related to the scientific evidence.

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<sup>10</sup> Panel Report, paras. 8.168, 8.171, 8.176. As before, despite billions of apple fruit shipped world-wide without any phytosanitary measures for fire blight, there is no scientific evidence of apple fruit having introduced fire blight into a fire blight-free area. *See, e.g.*, Panel Report, para. 8.149.

<sup>11</sup> *See* First Written Submission of the United States, at para. 22 (highlighting statements from the experts on the science relating to apple fruit and fire blight).

<sup>12</sup> Japan alleges that the United States “mischaracterizes the issue” in its argument that Japan’s measures are maintained without sufficient scientific evidence. To the contrary, in its first written submission, the United States simply sets out the original panel’s findings on the scientific evidence and statements of experts relating to mature, symptomless apple fruit and apple fruit generally, and demonstrates that Japan’s measures do not bear a rational or objective relationship to those findings, statements and the scientific evidence. *See* U.S. First Written Submission, Section IV.A. As noted in Section II above, analysis of whether or not Japan’s revised measure is or is not maintained without sufficient science within the meaning of Article 2.2 must be restricted to the measures (Plant Protection Law No. 151; Plant Protection Law Enforcement Regulations; Ministry of Agriculture, Forestry and Fisheries (“MAFF”) Notification No. 354; and the Detailed Rules), as amended by the June 30, 2004 revision to the Detailed Rules.

12. Japan attempts to contradict the clear findings of the original panel and the long history of scientific study of fire blight and apple fruit by arguing that certain new “evidence” supplementing, and purportedly changing, the scientific evidence originally examined by the panel “has a rational relationship with the new *measure*.”<sup>13</sup> As discussed in detail below, Japan’s argument is unsupported by scientific evidence, in no way changes the scientific evidence, and fails to demonstrate a rational or objective relationship between Japan’s revised measures and the scientific evidence. Japan’s revised measures, as was the case with its very similar original measure on imported U.S. apple fruit, are maintained without sufficient scientific evidence in breach of Article 2.2 of the SPS Agreement.

13. In conducting new studies on the scientific issues in this dispute, Japan appears to have directed its efforts at supporting a conclusion, rather than drawing a conclusion from its research.<sup>14</sup> The conclusion Japan seeks to support, as noted above, is that apple fruit should not be exported from severely blighted orchards. Japan refers to statements by some of the experts<sup>15</sup>

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<sup>13</sup> First Written Submission of Japan, para. 36. (Emphasis in original).

<sup>14</sup> See, e.g., First Written Submission of Japan, para. 74 (“the new pieces of evidence showed that even apparently healthy apple fruit could be latently infected by the bacteria, and these results are consistent with the findings of the Panel regarding the exports from a ‘(severely) blighted’ orchard.”)

<sup>15</sup> Contrary to Japan’s suggestion that this was a “unanimous” view of the experts (First Written Submission of Japan, para. 46), Dr. Hayward (an expert who should not be included among those Japan asserts “unanimous[ly]” suggested an orchard inspection) stated:

I wish we could play back the answer Dr. Smith gave just a minute or two ago. On the basis of what you said and the experience of European trade in apples it might be unreasonable to expect any special treatment. Am I putting words in your mouth? Didn’t you just say that in spite of massive unregulated, uninspected, untreated trade in apples there has been no introduction of fire blight?

as “advising” this result,<sup>16</sup> ignoring the very same views of those experts on the scientific evidence,<sup>17</sup> and the ultimate panel findings on that evidence.<sup>18</sup>

14. In considering it necessary to create new scientific evidence to support a restriction against “severely blighted orchards,” Japan correctly appreciates that no such evidence previously existed. Japan does not apparently cite the statements of some of the experts regarding severely blighted orchards as themselves constituting scientific evidence,<sup>19</sup> for indeed

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<sup>16</sup> *E.g.*, First Written Submission of Japan, paras. 11, 46.

<sup>17</sup> A restriction on fruit from severely blighted orchards cannot be reconciled with the experts’ statements on the actual scientific evidence, namely that: there is no scientific evidence that mature apple fruit harbor endophytic populations of fire blight bacteria or that *E. amylovora* occurs as an endophyte in healthy-looking fruit; the scientific evidence does not establish that a mature apple fruit could be infected with fire blight; the scientific evidence demonstrates that even apple fruit that were harvested very close to sources of inoculum were not infested with significant populations of epiphytic bacteria; there is no scientific evidence that, in the rare event that a mature fruit is infested with bacteria in the calyx that the inside of the apple fruit will subsequently become infected; there is no scientific evidence that calyx-infested apple fruit will transmit fire blight; there is no scientific evidence that mature apple fruit has ever been the means of introduction of fire blight into an area free of the disease; and the scientific evidence does not establish that any pathway for introduction of fire blight via apple fruit, whether mature or immature, will be completed. Panel Report, para. 8.125; Panel Report, Annex 3, paras. 28, 29 (Dr. Hale), 54 (Dr. Smith), 57 (Dr. Geider), 59 (Dr. Hale), 63 (Dr. Geider), 75, 76 (Dr. Hayward), 80 (Dr. Geider), 82 (Dr. Hale), 360-363 (Drs. Geider, Hale, Hayward, Smith); Panel Report, para. 8.126; Panel Report, Annex 3, paras. 59 (Dr. Hale), 76 (Dr. Hayward), 82 (Dr. Hale); Panel Report, Annex 3, paras. 223-236 (Drs. Hale, Geider, Smith, Hayward); Panel Report, para. 8.117; Panel Report, Annex 3, paras. 364-367 (Drs. Geider, Hale, Hayward); Panel Report, Annex 3, paras. 382-385 (Drs. Geider, Hale, Hayward), 332 (Dr. Hayward); Panel Report, paras. 6.20-6.23, 6.31, 6.37-6.40. The panel noted that the experts “categorically stated that there was no evidence to suggest that mature apples had ever been the means of introduction (entry, establishment and spread) of fire blight into an area free of the disease.” Panel Report, para. 8.149. Further, the original panel points out, as noted by Dr. Smith, that “not only was there no evidence that fruits had ever introduced fire blight into an area, but there was no necessity to invoke such an improbable pathway since there were much more probable alternatives.” Panel Report, para. 8.149, *citing* para. 6.31.

<sup>18</sup> The original panel concluded that the scientific evidence, as analyzed and commented on by the experts, does not demonstrate that mature, symptomless apple fruit would be infected by or harbor endophytic populations of *E. amylovora*, infested with epiphytic populations of *E. amylovora* capable of transmitting fire blight, or that the pathway for introduction of fire blight via apple fruit will be completed. Panel Report, paras. 8.128, 8.136, 8.168, 8.171, 8.176.

<sup>19</sup> The original panel defined “scientific evidence” as “evidence gathered through scientific methods, excluding by the same token information not acquired through a scientific method”, and further excluding “not only insufficiently substantiated information, but also such things as non-demonstrated hypothesis.” Panel Report, paras. 8.92, 8.93, 8.101-8.103.

they are not – nor did the experts claim they were. In fact, one of those experts stated, “I am not sure this is something that has to be argued in scientific terms. It is a matter of public policy.”<sup>20</sup>

15. In the absence of any existing scientific evidence supporting its “severely blighted orchard” rationale, Japan submits four new studies on apple fruit and fire blight in its first written submission.<sup>21</sup> Based on these studies, Japan has revised its 1999 Pest Risk Analysis (“1999 PRA”) as recently as September 2004.<sup>22</sup> The linchpins to the new, intertwined studies are the following concepts: (1) mature, symptomless apple fruit can be latently infected with *Erwinia amylovora*, and (2) a potential pathway exists for introduction of fire blight into Japan from this

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<sup>20</sup> Panel Report, Annex 3, para. 423. Likewise, other statements of the experts indicate that their views on severely blighted orchards were not based on scientific evidence relating to apple fruit and fire blight, but on policy concerns or interpretations of the SPS Agreement (a task reserved for the panel). See, e.g., statement of Dr. Geider, who queried, if fire blight were introduced to Japan through a means other than apple fruit at the same time fruit were being imported, “[w]ould you blame us that we were not strict enough to seize that situation and that this is the situation which cannot be foreseen?” Panel Report, Annex 3, para. 398. Likewise, Dr. Geider responded to a Japanese question on whether all measures relating to apple fruit should be abolished, “I think it is probably you feel that sort of compromise. We are saying even with uninspected orchards the chance to transmit fire blight to Japan is very low. On the other hand, we do not feel that we could squeeze Japan into that situation and saying we are now helpless to all apple imports from other countries.” Panel Report, Annex 3, para. 409. Further, Dr. Hayward upon hearing a fellow expert suggest that an inspection for fire blight-freedom might be appropriate despite having just made the scientific observation that, despite completely unrestricted trade in apple fruit in Europe “nobody can cite an instance when fruits have transmitted fire blight”, stated “I wish we could play back the answer Dr. Smith gave just a minute or two ago. On the basis of what you said and the experience of European trade in apples it might be unreasonable to expect any special treatment. Am I putting words in your mouth? Didn’t you just say that in spite of massive unregulated, uninspected, untreated trade in apples there has been no introduction of fire blight.” Panel Report, Annex 3, para. 415. Dr. Smith offered his (legal) interpretation that the concept of “appropriate level of protection” permits countries to take more stringent measures even though, “from a scientific point of view it might appear to us as [scientific] experts that there was an inconsistency in the approaches” of these countries. Likewise, in explaining his view that it would be acceptable for Japan to remove its requirements in more than one step, Dr. Smith explained, “It is difficult for experts to make judgements on what should be the phytosanitary policies of countries. . . . I think it is not for us as scientific experts to try to make judgements on what governments should or should not do in those cases.” Panel Report, Annex 3, paras. 416, 419.

<sup>21</sup> None of these studies was shared with the United States prior to the filing of Japan’s first written submission. At least three of the studies relied on by Japan are as of yet unpublished. All of the studies are pre-dated 2005 (not “2004” or earlier)..

<sup>22</sup> See First Written Submission of Japan, para. 67. Again, this 2004 PRA was not shared with the United States prior to the filing of Japan’s first written submission.

latently-infected apple fruit.<sup>23</sup>

16. However, the new studies fail to contradict or amend the reams of peer-reviewed and time-tested science on apple fruit and fire blight. As a result, they also fail to establish that there is such a thing as a mature, symptomless yet latently infected apple fruit or that a pathway for the introduction of fire blight via apple fruit exists; fail to demonstrate that Japan’s revised measures are not maintained without sufficient scientific evidence; and fail to alter in any way the scientific evidence and previous findings on that evidence in this proceeding.

A. The Process of Fruit Infection Japan Describes Does Not and Would Not Occur In Nature, and Japan’s Studies Do Not Demonstrate Otherwise

i. Azegami et al., “Invasion and colonization of mature apple fruit by *Erwinia amylovora* tagged with bioluminescence genes”<sup>24</sup>

17. The Azegami *et al.* study accomplishes nothing more than to repeat a stab-inoculation study conducted over fifty years ago, in which *E. amylovora* bacteria were artificially introduced

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<sup>23</sup> K. Azegami *et al.*, “Invasion and colonization of mature apple fruit by *Erwinia amylovora* tagged with bioluminescence genes” (2005) (Exhibit JPN-6). Each of Japan’s other studies examining apple fruit infection relies on the Azegami study’s contention that such a commodity as a mature, symptomless yet latently infected apple fruit exists. As described in detail by the United States, *infra*, the Azegami study does not demonstrate that the scientific evidence regarding mature, symptomless apple fruit has changed since the original panel and experts originally examined the evidence, or that there is a commodity such as a “mature, symptomless yet latently infected apple fruit.” As further elaborated in Section IV.A, *infra*, the United States notes that, although it is not necessary to consult scientific experts in this proceeding, were the Panel to conclude otherwise, Japan’s heavy reliance on the Azegami study and the other three derivative studies it submitted with its first submission means that any consultation with experts would be limited to an analysis of these studies.

<sup>24</sup> Azegami *et al.* (2005), “Invasion and colonization of mature apple fruit by *Erwinia amylovora* tagged with bioluminescence genes”, *J. Gen. Plant Pathol.* (“Azegami *et al.*”, the “Azegami paper” or the “Azegami study”) (Exhibit JPN-6).

into wounded fruit.<sup>25</sup> Yet Japan relies on the Azegami *et al.* paper to support the hypothesis that a previously undiscovered commodity – mature, symptomless, yet latently infected fruit – exists. However, Japan itself is careful not to claim that such a commodity has ever been observed in nature; it states, “the risk of latent infection of ‘mature, symptomless’ apple fruit through pedicels is not theoretical but real, *at least under the experimental conditions.*”<sup>26</sup> In fact, the Azegami study appears to confirm that it is *only* under the experimental conditions of the study that *E. amylovora* bacteria can be isolated inside apple fruit, and that the original panel was correct in finding that this will not occur in mature, symptomless apples grown, harvested and packed under real-world conditions. Moreover, as noted above, even the conclusion that the bacteria can exist within fruit under certain artificial conditions is not new, but does no more than reproduce 50-year old science.

18. Central to the Azegami study, and its shortcomings, is its treatment of the apple pedicel (stem) and the pedicel’s abscission layer, which is located at the tip of the stem where it is attached to the fruiting spur (a short branch of the tree that flowers and produces fruit) and which acts as a natural barrier to desiccation (drying up) and invasion of apple fruit by microorganisms.<sup>27</sup> The fundamental flaw of the Azegami paper is its assertion that the results of

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<sup>25</sup> Azegami *et al.* appears to mirror the 1952 study by H.W. Anderson, who documented that, by stab-inoculating pear fruit with *E. amylovora* and then refrigerating the fruit over winter, viable populations of the bacterium could be recovered over time. See Anderson, H.W., “Maintaining Virulent Cultures of Erwinia Amylovora and Suggestion of Overwinter Survival in Mummied Fruit”, Plant Disease Reporter, Vol. 36, No. 7 (July 15, 1952) (Exhibit USA-18) (demonstrating that under artificial experimental conditions (*i.e.*, stab-inoculating pears with high concentrations of *E. amylovora*) it is possible to infect pear fruit).

<sup>26</sup> First Written Submission of Japan, para. 28 (emphasis added).

<sup>27</sup> See, e.g. Gonzalez-Carranza *et al.*, “Recent developments in abscission: shedding light on the shedding process”, Trends in Plant Science, Vol. 3, No. 1, January 1998, pp. 10-14 (noting that “[a]ssociated with cell

the experiment demonstrate that *E. amylovora* would invade and colonize mature apple fruit.

Yet, according to its own data, the Azegami study instead demonstrates that inoculation of (a) fruit pedicels that were cut (wounded) more than four days after harvest, or (b) fruit-bearing twigs with mature fruit still attached, and therefore having uninjured fruit pedicels,<sup>28</sup> *did not result in the movement of E. amylovora* into the stems or fruit cortex of mature apples. *Only by removing the abscission layer* from the distal end (situated at the furthest point of the pedicel from the apple fruit) of fruit pedicels and *then placing high levels of inoculum on the cut end* of the pedicel were the researchers able to demonstrate bioluminescence, and therefore the presence of the marked strain of *E. amylovora*, within the stem and fruit.

19. As noted, the abscission layer acts as a natural barrier to desiccation and invasion of the fruit by microorganisms.<sup>29</sup> The effectiveness of the abscission layer as a barrier is demonstrated in the “Results and Discussion” sections of the Azegami paper, where it is reported that, for the 60 fruit still attached to the (wound inoculated) fruiting spurs, “a luminous area was observed *on the abscission layer* of one fruit eight days after inoculation (Fig. 1F) but *not on any fruit*” and

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separation is an increase in the expression of a spectrum of gene products, including hydrolytic enzymes and peptides *that protect the exposed fracture surface from pathogenic attack.*”) (Emphasis added) (Exhibit USA-19).

<sup>28</sup> Azegami *et al.*, pp. 8-9.

<sup>29</sup> K. Esau, *Anatomy of Plants*, 2<sup>nd</sup> ed., (1977), p. 451. Esau describes the development of the abscission layer as follows: “In the separation layer [of the abscission zone] of mature apples, cells in several tiers increase in size, secondary walls in sclerenchyma lose their anisotropic qualities, and the middle lamella, primary walls, and much of the secondary wall thickening dissolve. Vessels [the vascular elements] and fibers collapse.” (Parentheticals inserted) (Exhibit USA-20).

that “pathogen progress *stopped at this layer* in the experiment.”<sup>30</sup> One can only conclude from these results that, because the apple fruit were mature with intact abscission layers, the abscission zone acted as a physical barrier to the movement of *E. amylovora* into the apple fruit.<sup>31</sup>

Inexplicably, however, the paper concludes that “the possibility that the pathogen may pass through the layer cannot be excluded,” a conclusion contradicted by the study’s own data.<sup>32</sup>

20. Further, the Azegami paper purports to demonstrate (as a consequence of artificial wounding of apple fruit and application of high levels of inoculum to those wounds) the

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<sup>30</sup> Azegami *et al.*, pp. 9-11 (emphasis added). The paper’s explanation for this halt in pathogen progress (at the abscission layer) is that “apples with twigs were harvested on 21 October, one day before inoculation *when all fruit were mature* . . . [s]o water flow across the layer is considered to be very limited.” Azegami *et al.*, pp. 11-12 (emphasis added). (Exhibit JPN-6).

<sup>31</sup> In addition, the Azegami paper references the 1990 van der Zwet paper in what appears to be an attempt to reintroduce the notion that *mature apple fruit can become infected under natural conditions*. In fact, in noting that the possibility of “latent” infection of mature apple fruit “will depend on the physiological conditions and activities of the bacteria from August to the end of the maturing process,” Japan intimates that those conditions may be proper for infection of mature fruit by citing the discovery of an epiphytically contaminated immature fruit by van der Zwet *et al.* First Written Submission of Japan, para. 39. Further, Japan’s reliance on the van der Zwet (1990) study ignores the letter from Professor Thomson clarifying the results of the van der Zwet study, and specifically indicating that the fruit discussed by the Azegami paper was immature when harvested, the Azegami paper presents the van der Zwet fruit as mature. See Azegami *et al.*, p. 3. This is not the only place in Japan’s Submission where the findings of the van der Zwet study appear to be distorted. For example, Japan cites the discovery of epiphytic *E. amylovora* on a Utah apple fruit during the month September (September 29<sup>th</sup>) as support for its contention that bacteria persist late into the growing season. See First Written Submission of Japan, para. 27 (In fact, Japan casts the discovery of the apple as “explaining recovery of *Erwinia amylovora* from *inside* Utah apple fruit.”) (Emphasis added). The United States fails to see how the discovery of this fruit in any way affects the science related to the commodity at issue in this dispute - mature, symptomless U.S. apple fruit. In his letter clarifying the results of the study, Dr. Thomson states that the fruit was “nearly mature” and that he discovered only “a *small number* (1-50 colonies) of *epiphytic E. amylovora in the calyx*” (not, as Japan contends, “inside” the fruit, thereby implying an endophytic population) of the single fruit, *i.e.*, the September 29<sup>th</sup> fruit was an epiphytically-infested (with a small number of bacteria), nearly mature fruit. See Exhibit JPN-13, Letter From Professor Sherman Thomson, dated August 23, 2002. (Emphasis added). The United States has never contested the scientific evidence that, on rare occasions, mature, symptomless apple fruit can harbor epiphytic populations of *E. amylovora* in populations incapable of transmitting fire blight. The United States does contest, however, Japan’s use of the discovery of this *epiphytically-infested fruit* as in any way supporting its contention that mature, symptomless apple fruit can become *latently infected* with fire blight bacteria or as support for the contention that bacteria can be found *inside* (thereby implying endophytic presence of bacteria) apple fruit late in the growing season.

<sup>32</sup> Azegami *et al.*, p. 12. (Exhibit JPN-6).



“invasion” of fire blight bacteria into the fruit. The paper overstates this fundamental conclusion because, in fact, rather than the apple fruit having been actively *invaded* by bacteria through the cut pedicels, it is just as likely that the bacterial inoculum deposited on the cut pedicel was *drawn into the vascular elements of the stem* and then distributed within the fruit *by transpiration*.<sup>33</sup> To illustrate this point, U.S. researchers deposited dye on a cut-pedicel (as inoculum was similarly placed on a cut-pedicel in Azegami *et al.*). The dye, which contains no active bacteria capable of “invading” fruit, spread into apple fruit in an identical fashion to the bioluminescence in Azegami, thereby demonstrating that spread of either bioluminescence or dye into apple fruit is as likely a consequence of the cut-pedicel method and transpiration as a result of active colonization and invasion by bacteria.<sup>34</sup> Further, the Azegami paper, while postulating in several places that *E. amylovora* colonized the apple fruit and increased its populations, makes no quantitative measurements of population size (measuring only the original inoculum level). Consequently, the study fails to demonstrate that spread of bioluminescence in the apple fruit was the result of invasion or colonization by *Erwinia amylovora*.

21. For the foregoing reasons, the Azegami study fails in any way to affect the scientific evidence relating to apple fruit and fire blight and the original panel’s findings on that evidence.

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<sup>33</sup> See Exhibit USA-21, Response to Exhibit JPN-6

<sup>34</sup> Plant *transpiration* is the evaporation of water from leaf and plant surfaces, and is the last step in the continuous water pathway from soil, into plant roots, through plant stems and leaves, and finally out into the atmosphere. Water conditions “drive” the system by pulling the water “uphill” through the entire pathway. Since water in this pathway also carries nutrients, transpiration is an essential process in plant life. Both evaporation and transpiration are driven by a tremendous drying force which the atmosphere exerts on soil and plant surfaces.

*Colonization* and *invasion* are terms used to describe a process by which microorganisms actively move into a previously uninhabited substrate by linear growth, as with the mycelium of fungal pathogens, or by flagellar movement (swimming) as with many bacterial plant pathogens.

As said before, there is no such thing as a mature, symptomless yet latently infected apple fruit.

- ii. Tsukamoto *et al.*, “Infection frequency of mature apple fruit with *Erwinia amylovora* deposited on pedicel and its survival in the fruit at low temperature”<sup>35</sup>

22. The Tsukamoto (I) study is a derivative of Azegami *et al.*, in that it employs the cut-pedicel method to inoculate apple fruit. Although it cites Azegami *et al.* in support of its findings and conclusions, Tsukamoto (I) makes repeated reference to the inoculum being deposited on the fruit pedicel in the Azegami study *without referencing the fact that the abscission layer of the pedicel had been artificially removed*. Accordingly, Tsukamoto (I)’s conclusion that “[t]his investigation showed that *E. amylovora* can infect mature apple fruit from *pedicels* and can survive more than six months at 5C” is a misstatement, as is evident from a review of the Azegami study, which only succeeded in “demonstrating” bioluminescence inside apple fruit by removing the abscission layer from the distal end of the pedicel and subsequently inoculating the fruit with a high level of bacteria.<sup>36</sup>

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<sup>35</sup> Tsukamoto *et al.*, “Infection frequency of mature apple fruit with *Erwinia amylovora* deposited on pedicel and its survival in the fruit stored at low temperature” (unpublished) (“Tsukamoto (I)”) (Exhibit JPN-8).

<sup>36</sup> As noted in Section III.A above, the presence of bioluminescence (or dye) in an apple fruit does not mean that the fruit has been “invaded” by bacteria.

B. The New Studies Attempt to Demonstrate a Process For the Spread of Fire Blight That Does Not and Would Not Occur In Nature

i. Tsukamoto, et al., “Transmission of *Erwinia amylovora* from blighted mature apple fruit to host plants via flies”<sup>37</sup>

23. The Tsukamoto (II) paper entitled “Transmission of *Erwinia amylovora* from blighted mature apple fruit to host plants via flies” does not succeed in demonstrating the very phenomenon advertised in its title because it fails to employ an experimental protocol that evaluates if flies will sequentially visit apple fruit infected with fire blight, acquire the bacteria and transmit the bacteria to a host, and whether fire blight infection will result. Instead, the authors succeed in demonstrating that: (1) they can contaminate flies by: (a) sedating them with CO<sub>2</sub> and then soaking them in a very heavy suspension of *E. amylovora*; or (b) putting the flies in a beaker (the volume of which is not recorded) for six hours with an apple fruit infected with fire blight; and (2) that flies contaminated by method (1)(a) (but not (1)(b)) transferred the bacterium to host tissues, resulting in fire blight disease when both (a) the host tissues were mechanically wounded with needles or the fruit had been peeled *and* (b) the flies and the host tissues were forced to cohabit a small plastic enclosure.<sup>38</sup>

24. Tsukamoto (II) fails to demonstrate that: (1) greenbottle flies acquired cells of *E. amylovora* from infected fruit of their own volition, *i.e.*, that they acquire bacteria when not artificially forced to associate with infected apple fruit; (2) the flies directly or indirectly vectored

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<sup>37</sup> Tsukamoto *et al.*, “Transmission of *Erwinia amylovora* from blighted mature apple fruit to host plants via flies”, Res. Bull. Plant Protection Service Japan 41 (unpublished) (“Tsukamoto (II)”) (Exhibit JPN-9).

<sup>38</sup> Tsukamoto (II), pp. 3, 4, 6.

*E. amylovora* from the *infected fruit* to the susceptible host material; and (3) infection and disease development was a result of a natural interaction between the flies and the host material (*i.e.*, feeding injury), and was not dependent on artificial mechanical injury.<sup>39</sup> In short, as noted above, there is a stark disparity between what the authors purport to accomplish in the title and introduction of the study, and what was actually accomplished in the study. The methods employed in the study are so far removed from what might actually take place under production orchard conditions that the resulting data is not useful in assessing the risk of transmission of fire blight or determining a probabilistic estimate of a real world event.

25. Therefore, the conclusions set out in Tsukamoto (II) in no way affect, add to, or alter the scientific evidence relating to fire blight and apple fruit and the original panel’s findings on that evidence.

- ii. Kimura *et al.*, “The probability of long-distance dissemination of bacterial diseases via fruit”<sup>40</sup>

26. The Kimura study on long-distance dissemination of disease purports to refute the scientific evidence and findings of the original panel as they relate to the long-distance spread of

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<sup>39</sup> Further, it is notable that Tsukamoto (II) did not employ unwounded host materials as controls in the enclosures, nor did it include fruit blossoms despite the fact that greenbottle flies are purportedly blossom visitors. In addition, the study fails to reference the most recent studies specific to the issue of short-distance dissemination of fire blight, Taylor, R.K. *et al.* (2003), “Survival of the fire blight pathogen, *Erwinia amylovora*, in calyxes of apple fruit discarded in an orchard” (Crop Protection 22: 603-608) and Taylor, R.K. *et al.* (2002), “The viability and persistence of *Erwinia amylovora* in apples discarded in an orchard environment” (Acta Horticulturae, 2002, No. 590, pp. 153-155 (the methodology and conclusions of which highlight the artificial and unrealistic methods employed in the Tsukamoto study).

<sup>40</sup> Kimura *et al.*, “The probability of long-distance dissemination of bacterial diseases via fruit”, J. Gen. Plant Pathol. (unpublished) (“Kimura *et al.*”, the “Kimura study”, or the “Kimura paper”) (Exhibit JPN-10).

fire blight. However, the Kimura paper is only able to reach a conclusion that apple fruit pose a risk of introducing fire blight into Japan by mischaracterizing previous studies and relying on the Azegami and Tsukamoto studies discussed above. In particular, the Kimura study characterizes Azegami's work as demonstrating that mature fruit are easily infected through a "small bruise" or "minute scars" on the fruit as well as "the possibility of infection of fruit from pedicels through fruit bearing branches."<sup>41</sup> In fact, Azegami's method was to either cut off the abscission layer of the apple fruit pedicel or to make multiple wounds (10 and 2) on the shoulder or calyx in the presence of high inoculum doses. Further, the Kimura paper concludes that "even at a stage where apple fruit get ripe, it is likely enough that *E. amylovora* in fruit bearing branches will infect the inside of apples."<sup>42</sup> This conclusion clearly assumes that infection is occurring through the tissues of the pedicel. As noted above, the Azegami paper did not demonstrate that such infection (through the pedicel/abscission layer of a mature apple fruit) is possible. In fact, the Azegami study appears to demonstrate just the opposite by noting that bioluminescence did not penetrate the pedicels of mature apple fruit.

27. Further, Kimura *et al.* cites Tsukamoto (II) for the proposition that *E. amylovora* was recovered from the "flesh" of apple fruit and not from the core, alleging that previous studies (*e.g.*, Roberts *et al.* (1989)) only sampled core tissues and therefore failed to identify *E. amylovora* in the apple fruit.<sup>43</sup> However, it is an anatomical fact that the vascular bundles in

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<sup>41</sup> Kimura *et al.*, p. 13.

<sup>42</sup> Kimura *et al.*, p. 12.

<sup>43</sup> Azegami *et al.* states that when fluorescence was detected in apple fruit "flesh" it was always centered in a vascular bundle. See Azegami *et al.*, pp. 2, 10.

which *E. amylovora* was detected in the Tsukamoto (II) study are contiguous with the vascular tissues of the apple fruit core. Furthermore, Kimura *et al.* mischaracterizes the results of previous studies, as Roberts *et al.* (1989) in fact reported that “[c]ore and cortex [*i.e.*, flesh] tissues, including the stem, if present, and the entire calyx were removed by passing an ethanol-flamed cork borer through the vertical axis of each fruit.”<sup>44</sup> Therefore, the studies described in Roberts *et al.* (1989) examined a portion of the apple fruit that includes the “flesh” discussed in Azegami, Tsukamoto, and Kimura.<sup>45</sup> The reason that *E. amylovora* was not detected in the Roberts study is that it was not present in the apple fruit. As noted above, the results presented in Roberts *et al.* (1989), *i.e.*, that *E. amylovora* was not present in mature apple fruit even when harvested from branches or fruiting spurs with fire blight disease, is unequivocally supported by the results in Azegami *et al.*, which demonstrated that *E. amylovora* did not move into mature apple fruit if the abscission layer of the pedicel was left intact (not cut off).

28. Interestingly, by arguing that previous studies have failed to identify *E. amylovora* in apple fruit because it was, according to Japan, in fact located in vascular bundles, or “flesh” rather than apple cores,<sup>46</sup> the Kimura study contradicts its own findings. In fact, the Kimura

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<sup>44</sup> Roberts *et al.*, “Evaluation of mature apple fruit from Washington state for the presence of *Erwinia amylovora*”, *Plant Disease* 73: 917-921, at 918 (1989). (Parenthetical inserted) (Exhibit USA-22).

<sup>45</sup> As noted above, the Roberts *et al.* (1989) studies examined core samples that included vascular bundles that were contiguous with those in the stem. Therefore the explanations in Kimura *et al.* and Tsukamoto (I) as to why the Roberts (1989) study did not detect *E. amylovora* are incorrect – Roberts *et al.* did, in fact, sample the very tissues most likely to contain *E. amylovora* if it were present inside an apple fruit. (Exhibit USA-22).

<sup>46</sup> See Tsukamoto (I), p. 13 (“Furthermore it was shown [by the Tsukamoto study] that *E. amylovora* existed densely almost always in the flesh *not* in the core of the fruit. Heretofore the core sections were mainly used to detect the internal *E. amylovora* (Roberts *et al.* 1989; Roberts 2002; van der Zwet *et al.* 1990).” (Emphasis added)).

study argues that the pathway for introduction of fire blight will consist of either discarded apple cores or apple peels because Japanese consumers consume the flesh (cortex) of the apple fruit.<sup>47</sup> However, Japan acknowledges that *E. amylovora* will not be isolated in the cores of mature, symptomless apple fruit.<sup>48</sup> Moreover, the scientific evidence does not demonstrate that epiphytic bacteria would be present in populations capable of transmitting fire blight or that there would be bacteria on an apple fruit peel. Nor has Japan attempted to refute existing scientific evidence relating to epiphytically-infested apple fruit and the original panel’s findings based on that evidence.<sup>49</sup> As a result, the conclusions of a study premised on a discarded commodity (apple core or apple skin of a mature apple fruit) that even Japan acknowledges will not harbor *E. amylovora* does not alter scientific evidence as it relates to apple fruit and fire blight.

29. Further, Kimura *et al.* mischaracterizes the results of Tsukamoto (II) by stating that greenbottle flies “gathered” to blighted fruit.<sup>50</sup> Rather, according to the methodology described in Tsukamoto (II), flies were imprisoned with blighted fruit inside a small enclosure, and were not allowed to forage freely. Kimura *et al.* further mischaracterizes the Tsukamoto (II) study by noting that the greenbottle flies “feasted” on infected apple fruit and then flew to pear fruitlets.

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<sup>47</sup> See Kimura *et al.*, p. 18 (noting that “[i]n general Japanese people pare apples, remove cores, and consume remaining flesh”, and that the vector, insects “gather to apple skins and cores that were discarded and allow *E. amylovora* to adhere to their mouthparts and legs.”)

<sup>48</sup> See Tsukamoto (I), p. 13; 2004 PRA, p. 17 (“Tsukamoto *et al.* (2005b) reported that *E. Amylovora* existed densely almost always in flesh not in core of fruit.”)

<sup>49</sup> *I.e.*, that the scientific evidence does not establish that mature symptomless apple fruit will be epiphytically infested with populations of *E. amylovora* capable of transmitting fire blight. Panel Report, paras. 8.136, 8.171.

<sup>50</sup> Kimura *et al.*, p. 19.

Instead, greenbottle flies were sedated and immersed in a suspension of inoculum before being exposed to wounded pear fruitlets.<sup>51</sup> Moreover, the flies that were trapped in an enclosed space with infected fruit did not transfer bacteria to host tissue.

30. In addition, Kimura’s high probability estimate of introduction of fire blight by apple fruit (once every 565 years) reflects the unrealistic and unsupported assumptions on which his analysis is based, such as the assumed infection rate of imported apple fruit (100%), to the number of apple cores discarded out of doors by Japanese families (according to the study, 10% of the total household garbage in Japan that is thrown out of doors consists of apple cores – this seems to be a very high estimate for a commodity that is not a staple of the Japanese diet, but is instead considered a specialty item).<sup>52</sup>

31. The results of the Kimura analysis also appear to suggest that apple fruit now pose a much greater risk of introducing fire blight than nursery stock (historically recognized as a potential pathway for the disease).<sup>53</sup> Kimura *et al.* estimates the risk of nursery/root stock introducing fire blight into Japan at once every 1,898 years, once every 1,781 years in scions or buds, and “once every 565 years or so in fruit.”<sup>54</sup> Not only does this probability estimate attempt to demonstrate that apple fruit presents approximately four times the risk of introducing fire

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<sup>51</sup> See Section III.A.1.b above.

<sup>52</sup> Kimura *et al.*, p. 14.

<sup>53</sup> “The most probable route identified by the experts was the entry of infected planting materials.” Panel Report, fn. 310.

<sup>54</sup> Kimura *et al.*, p. 23 (emphasis added).



blight as nursery stock, it contradicts the study’s own conclusion that “[a]ccording to our estimation of probabilities of establishment of fire blight, the *descending order of magnitude* is as follows. Nursery stock and/or rootstocks > Scions and/or buds > Fruit.”<sup>55</sup>

32. As with the Azegami and Tsukamoto studies, the Kimura study does not support its own conclusions. In fact, the study’s very data contradicts the study’s conclusions. That data does not, however, contradict the original panel’s findings or the scientific evidence on which those findings were based, since the new data were obtained, in Japan’s words, “under experimental conditions” – conditions in no way approximating those of the real world.

## **2. Japan’s Revised Measures Impose Restrictions Unsupported By Scientific Evidence**

33. Because, as discussed above, the scientific evidence does not establish that mature, symptomless apple fruit, the commodity exported by the United States, would be infected by or harbor endophytic populations of fire blight bacteria, infested with epiphytic populations of fire blight capable of transmitting the disease, or that apple fruit would serve as the pathway for introduction of fire blight into a fire blight-free area, Japan’s revised measures are maintained without sufficient scientific evidence in breach of Article 2.2 of the SPS Agreement.<sup>56</sup>

34. Nevertheless, Japan provides several explanations for its measures in an attempt to refute the arguments set out in the first written submission of the United States. As demonstrated

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<sup>55</sup> Kimura *et al.*, p. 23 (emphasis added).

<sup>56</sup> See Panel Report, paras. 8.136, 8.168, 8.171, 8.176.

below, none of Japan’s explanations or arguments finds support in the scientific evidence at issue in this dispute or the original panel’s findings on that evidence. Therefore, Japan has not successfully rebutted the U.S. arguments regarding Japan’s revised measures.

A. Prohibition of Fruit From Orchards in Which Fire Blight is Detected

35. As noted in Section II above, Japan has attempted to include in its revised measures certain Operational Criteria which ostensibly amend Japan’s “fire blight-free orchard” requirement to one of disqualification of an export orchard if a severely blighted tree is identified in a visual inspection. As noted by the United States, the Operational Criteria are not a part of the measure properly before the Panel in this proceeding. However, even were the Panel to consider the Operational Criteria, it would not change the analysis of Japan’s measure because the inspection requirement set out by the Criteria effects nothing less than a requirement of a fire blight-free orchard.<sup>57</sup>

36. In its first written submission, the United States demonstrated that, because the scientific evidence relating to fire blight and apple fruit does not establish that mature, symptomless fruit will be infected with, harbor endophytically, or be epiphytically-infested with populations of *E. amylovora* capable of transmitting fire blight and because that same evidence does not establish

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<sup>57</sup> As noted in Section II, the Operational Criteria call for orchard disqualification upon observance of a “(severely) infected tree”, a situation Japan describes as “when readily observable symptoms are found on the tree exterior.” First Written Submission of Japan, para. 57. However, a single blight strike could be as readily observable as two, three, seventy-five or a hundred blights in such an inspection. Thus, the Operational Criteria would disqualify an export orchard based on discovery of a single blighted tree. Moreover, whereas Dr. Hale spoke about severely blighted *orchards*, Japan attempts to use his statement in support of disqualification of an orchard containing a single blighted (whether severely or not) *tree*.

that apple fruit will act as a pathway for introduction of fire blight, the requirement of a fire blight-free orchard is maintained without sufficient scientific evidence within the meaning of Article 2.2 of the SPS Agreement. As illustrated in Section III.A above, Japan has not raised any new scientific evidence on apple fruit and fire blight that in any way alters this conclusion.

37. Further, the same scientific evidence that does not support a requirement of fire blight-freedom in orchards does not support a measure restricting fruit from severely blighted orchards. For example, even if, on a rare occasion, an apple fruit harvested from a severely blighted orchard possesses epiphytic bacteria in its calyx, the scientific evidence does not establish that those bacteria will be present in populations capable of transmitting fire blight.<sup>58</sup> Similarly, because the apple fruit harvested from the orchard will be mature, symptomless fruit, the scientific evidence does not establish that they will be infected with or harbor endophytic populations of *E. amylovora*.<sup>59</sup> Japan has attempted, through its new studies, to demonstrate that the supposed phenomenon of “mature, symptomless yet latently infected” fruit somehow turns this scientific evidence on its head. As demonstrated in Section III.A above, however, Japan’s studies do not affect the scientific evidence on mature apple fruit and fire blight and the original panel’s findings based on that evidence.

38. In addition, Japan’s arguments regarding apple fruit infection contradict the proposed “early fruitlet” timing of the orchard and buffer zone inspections. In support of its contention

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<sup>58</sup> Panel Report, para. 8.136, 8.171.

<sup>59</sup> Panel Report, para. 8.128, 8.171.

that mature apple fruit may become latently infected with fire blight, Japan notes that “the probability of latent infection of mature apple fruit will depend on the *physiological conditions and activities of the bacteria* from August to the end of the maturing process.”<sup>60</sup> If Japan is asserting that the proposed “risk” of apple fruit infection depends on the activity of bacteria until the end of the growing season when apple fruit are completely mature, there can be no rational relationship between that evidence and an “early fruitlet” inspection, which would occur months before harvest. Such an inspection would provide no assurances regarding the “physiological conditions and activities of the bacteria” at the “end of the maturing process.” Even were Japan’s reasoning valid, this would only support a harvest-time inspection. But again, not even a harvest-time inspection would rationally or objectively relate to the scientific evidence.

B. Prohibition of Fruit From Orchards in Which Fire Blight is Detected in a 10-Meter Buffer Zone Surrounding the Orchard

39. As noted in the first written submission of the United States, a measure requiring a fire blight-free buffer/border zone (or any border zone at all for that matter) bears no rational or objective relationship to the scientific evidence relating to apple fruit and fire blight.<sup>61</sup>

Nevertheless, Japan’s revised measures include a requirement that every export orchard be surrounded by a ten-meter wide, fire blight-free, buffer zone.<sup>62</sup> The requirement of a fire blight-

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<sup>60</sup> First Written Submission of Japan, para. 39.

<sup>61</sup> See First Written Submission of the United States, paras. 28, 29 ; Panel Report, paras. 8.136, 8.168, 8.171, 8.176; Panel Report, Annex 3, para. 314 (Dr. Smith) (“I doubt whether a buffer zone is really necessary in the case of fire blight.”), para. 315 (Dr. Hayward) (“[W]e do have evidence that Roberts (2002) in press has obtained results that have indicated that a buffer zone of any size provides no phytosanitary security.”)

<sup>62</sup> See First Written Submission of Japan, para. 56.

free buffer zone appears to contradict Japan’s subsequent argument that export orchards be inspected for severe or heavy blight.<sup>63</sup> Japan appears to imply that an orchard may still be eligible for export if it is not heavily-blighted (though, as explained earlier, this requirement actually enforces the requirement of fire-blight freedom), yet apparently an orchard will be disqualified even when a single fire blight strike in the border zone is discovered.<sup>64</sup> While the United States does not intend to suggest that the scientific evidence justifies either requirement, it notes that it is impossible for the scientific evidence to support both propositions, by permitting a certain amount of fire blight in an export orchard, yet none in the zone surrounding the orchard.

40. Japan’s argument fails to rebut the *prima facie* case established by the United States that a fire blight-free buffer/border zone requirement is not rationally related to the scientific evidence, because it disregards the scientific evidence relating to fire blight and apple fruit, which does not establish that mature, symptomless fruit will be infected with, harbor endophytically, or be epiphytically-infested with populations of *E. amylovora* capable of transmitting fire blight and because that same evidence does not establish that apple fruit will act as a pathway for introduction of fire blight. Therefore, the requirement of a fire blight-free buffer zone is

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<sup>63</sup> Japan’s revised measures require that buffer zones be fire blight-free (a requirement unchanged even in its *post hoc* Operational Criteria). Therefore, a single fire blight strike in the 10-meter buffer zone would disqualify an entire export orchard. Japan proposes, based on its new studies and the alleged discovery of the potential for a mature, symptomless yet latently infected apple fruit, that the inspection of orchards and buffer zones be conducted at the early fruitlet stage. However, the proposed timing of the inspection bears no rational relationship to Japan’s new “scientific evidence”, which purports to caution that fruit would become latently infected at harvest-time (*i.e.*, when it is mature). As noted by the United States, the newly proposed “severe blight” criteria set out by Japan call for a search for a single tree with visible symptoms. These criteria are indistinguishable from the fire blight-freedom requirement set out in the June 30, 2004 Detailed Rules.

<sup>64</sup> Japan’s Detailed Rules require that export orchards be surrounded by a 10-meter wide buffer zone that possesses “[n]o tree with fire blight symptoms.” Detailed Rules, § 1(1)(B)(b).

maintained without sufficient scientific evidence within the meaning of Article 2.2 of the SPS Agreement.<sup>65</sup>

C. Requirement That Surface of Apple Fruit be Disinfested with Sodium Hypochlorite (Chlorine)

41. Japan argues that surface disinfestation of apple fruit is necessary to eliminate the incidence of epiphytic bacteria on apple fruit, and deactivate the bacteria in the washing process. As noted in the first written submission of the United States, the scientific evidence does not establish that mature, symptomless apple fruit will harbor epiphytic populations of fire blight-causing bacteria capable of transmitting the disease.<sup>66</sup> Further, Japan has failed to raise any arguments that contradict the scientific evidence relating to mature apple fruit and epiphytic populations of *E. amylovora*. Therefore, there is no need to disinfest the surface of apple fruit to mitigate the hypothetical risk of exported apple fruit harboring epiphytic populations of fire blight-causing bacteria capable of disseminating the disease.

D. Prohibition of Imported Apple Fruit From U.S. States Other Than Washington and Oregon

42. As noted in the first written submission of the United States, Japan's measure restricting eligible apple fruit to fruit produced in orchards in Washington and Oregon States is maintained without sufficient scientific evidence within the meaning of Article 2.2 of the SPS Agreement.<sup>67</sup>

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<sup>65</sup> Panel Report, paras. 8.128, 8.136, 8.171, 8.176.

<sup>66</sup> See First Written Submission of the United States, para. 31; Panel Report, para. 8.171.

<sup>67</sup> First Written Submission of the United States, para. 32.

In its first written submission, Japan argues that its geographical restriction on U.S. apple exports is consistent with the SPS Agreement because it is “based on a procedural requirement” and that “[a]s long as the United States provides appropriate documentation of other quarantine pests and diseases” for other U.S. States, those States may begin exporting apple fruit to Japan.<sup>68</sup>

However, Japan’s rebuttal fails to address the U.S. argument regarding the restriction of eligible apple fruit to fruit from Oregon and Washington States premised on hypothetical fire blight concerns.

43. The United States does not contest that there may be paperwork and other procedural steps regarding other pests and diseases to be completed before U.S. States other than Washington and Oregon may ship apple fruit to Japan. However, the need for paperwork on other pests or diseases does not support or justify a fire blight-specific measure that restricts eligibility to apple growers from Washington and Oregon.<sup>69</sup>

44. There is simply no scientific evidence to support a measure restricting the eligibility of growers, vis-a-vis concerns regarding the hypothetical spread of fire blight, to growers in Washington and Oregon States. Japan can continue to demand and await paperwork on other plant diseases and quarantine pests. It cannot, however, enforce a measure addressing fire blight

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<sup>68</sup> First Written Submission of Japan, para. 64.

<sup>69</sup> MAFF Notification No. 354, which specifically sets out restrictions premised on hypothetical fire blight concerns, states that eligible growers are limited to the U.S. States of Washington and Oregon. See MAFF Notification No. 354, para. 1 (“[Imported fruit] must be Golden Delicious and Red Delicious varieties of fresh apple fruits, and *must be produced* in the areas designated by the U.S. plant protection authority as the areas . . . where the U.S. plant protection authority inspect for *fire blight* at proper times in the *States of Washington and Oregon, U.S.A.*”) (emphasis added). While Japan may theoretically be able to geographically restrict grower eligibility based on other phytosanitary concerns, it cannot, in light of the scientific evidence relating to fire blight and apple fruit, restrict eligibility in a fire blight-focused measure.

and apple fruit that specifically prohibits imports from other U.S. States based on hypothetical fire blight concerns. Instead, insofar as Japan’s measure purports to mitigate hypothetical fire blight concerns, it must, in light of the scientific evidence, permit apple growers from every apple-producing State to export mature, symptomless apple fruit to Japan. By failing to demonstrate that the scientific evidence on apple fruit and fire blight rationally or objectively relates to a measure geographically-restricting eligible growers to Washington and Oregon States, Japan has failed to rebut the United States’ *prima facie* case that such a restriction is maintained in breach of Article 2.2 of the SPS Agreement.

E. Prohibition of Imported Apples Unless Other Production, Harvesting, and Importation Requirements Are Met

45. Japan argues that various post-harvest measures, namely sterilization of packing facilities handling apples for export to Japan, and export and import inspection<sup>70</sup> are consistent with Article 2.2 of the SPS Agreement based on the fact that the original panel did not reach an analysis of these measures due to its exercise of judicial economy.<sup>71</sup> The absence of a finding by the panel on Japan’s post-harvest measures does not, *ipso facto*, mean that the measures are maintained with sufficient scientific evidence within the meaning of Article 2.2 of the SPS

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<sup>70</sup> As noted in Section II above, Japan does not assert that post-harvest separation of apples for export to Japan is part of its revised measure, nor does it attempt to rebut the U.S. argument that such a requirement is maintained without sufficient scientific evidence for purposes of Article 2.2 of the SPS Agreement. *See* First Written Submission of the United States, para. 33; *see* First Written Submission of Japan, para. 9.

<sup>71</sup> *See* First Written Submission of Japan, para. 63 (arguing that export and import inspections were scientifically justified because “[i]n any event, these inspections were found unlawful neither by the original Panel nor by its experts.”)



Agreement, and only highlight the need – recognized by Japan<sup>72</sup> – for findings on each of the specific elements of Japan’s import regime for U.S. apple fruit at issue in this proceeding.

46. In addition, Japan attempts to rebut U.S. arguments that certain of the post-harvest measures are maintained without sufficient scientific evidence by noting that one measure, sterilization of packing facilities, is a “normal requirement in any process” that “can be easily met,” and that another measure, export and import inspection, is “procedural in nature.”<sup>73</sup> Regardless of whether facility sterilization is or is not a “normal requirement”, at issue in this proceeding is whether or not facility sterilization premised on fire blight concerns is a requirement that bears a rational or objective relationship to the scientific evidence regarding fire blight and apple fruit. As noted in detail in the first submission of the United States, it does not.<sup>74</sup> Similarly, a measure requiring import and export inspections must bear a rational relationship to the same scientific evidence, and may not be premised on an assertion that it is merely “procedural in nature.”<sup>75</sup>

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<sup>72</sup> First Written Submission of Japan, para. 66.

<sup>73</sup> First Written Submission of Japan, paras. 62, 63.

<sup>74</sup> First Written Submission of the United States, para. 33.

<sup>75</sup> Interestingly, Japan notes in an earlier section of its submission that, in light of its new theory that there is such a commodity as a mature, symptomless, yet latently infected apple fruit, “*E. amylovora* can not be detected by visual export/import inspection alone, whether at the points of exportation or importation.” First Written Submission of Japan, para. 51. It is unclear how import/export inspections would serve any purpose whatsoever in mitigating this hypothetical, undetectable “risk” put forward by Japan.

**B. Japan’s Revised Measures Are Inconsistent With Article 5.6 of the SPS Agreement Because They Are More Trade-Restrictive Than Required to Achieve Japan’s Appropriate Level of Protection**

47. Japan argues that the United States has failed to establish a *prima facie* case of inconsistency of Japan’s revised measures with Article 5.6 of the SPS Agreement. However, Japan appears to address only one element of the U.S. claim – whether the U.S.-proposed alternative measure meets Japan’s appropriate level of protection<sup>76</sup> – and then does so only by mischaracterizing the U.S.-proposed alternative measure in an effort to address its own argument, rather than the actual U.S. argument. Japan’s arguments with regard to whether the U.S. proposed alternative measure meets Japan’s level of protection are unavailing.

48. Japan begins its cursory analysis by asserting that the U.S. does not clearly define what it proposes as the alternative measure.<sup>77</sup> It then ignores the U.S.-defined alternative measure – a Japanese “restriction of imports to mature apple fruit”<sup>78</sup> – and focuses instead on only one of several elements of the U.S. *argument* as to why the alternative measure meets the requirements of Article 5.6; namely, the fact that U.S. export standards require that fruit at least meet “US No. 1 Grade.” This is not the U.S. proposed alternative measure. The proposed alternative measure in an Article 5.6 argument is by necessity a measure to be implemented by the responding party due to the fact that the WTO-consistency of the responding party’s original measure is being challenged. As noted, the United States proposed the very measure – a Japanese measure

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<sup>76</sup> First Written Submission of Japan, para. 81.

<sup>77</sup> First Written Submission of Japan, para. 82.

<sup>78</sup> First Written Submission of the United States, para. 34.

requiring that imported apple fruit be mature, and therefore symptomless – that is supported by both the original panel’s findings and the voluminous scientific evidence on fire blight and apple fruit.

49. As set forth in great detail in the U.S. first written submission, the application of U.S. Federal Grade standards<sup>79</sup> is only one of the numerous layers of industry and regulatory practices and requirements which U.S. growers apply when growing, harvesting, packing and exporting apple fruit. These practices and requirements have assured that exported fruit is mature – and, contrary to Japan’s suggestion in paragraph 83 of its submission that there could be sorting errors – there is no evidence that U.S. growers have ever shipped anything other than mature, symptomless apple fruit.<sup>80</sup> Indeed, there is no evidence that the billions of apple fruit shipped internationally (a vast number of which were shipped without SPS measures for fire blight) have ever introduced fire blight into a fire blight-free area.<sup>81</sup>

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<sup>79</sup> The United States notes that, in Japan’s September 2004 PRA, Japan argues that the U.S. grade standards do not assure that exported fruit will be mature because, according to Japan, the standard allows a certain percentage of inspected fruit not to meet the standard. *See* 2004 PRA, p. 22 (“Washington States’ regulations on apples for export based on standards of the Department of Agriculture . . . tolerate that Defects . . . may be mixed in the consignment.”) The PRA’s reliance on the Washington regulations (based on USDA standards) is irrelevant because, as noted in the text above, the Grade standard is only one of numerous requirements and practices that assure that exported apple fruit are mature. Due to the several layers of quality controls already in effect, the United States has, in effect, a zero percent immature fruit tolerance – and would be willing to certify that no immature fruit was noted during the process of inspection.

<sup>80</sup> *See* First Written Submission of the United States, para. 45. Japan has presented no scientific evidence demonstrating that the United States has ever shipped anything other than mature, symptomless apple fruit. *See, e.g.*, Appellate Body Report on *Japan - Measures Affecting the Importation of Apples*, adopted on 10 December 2003 (WT/DS245/AB) (hereinafter, the “Appellate Body Report”), at fn. 289 (“In our view, there is no reason for the Panel to infer from [evidence submitted by Japan regarding the discovery of codling moth larvae in a U.S. apple shipment] that apples other than mature, symptomless ones have ever been exported from the United States to Japan.”)

<sup>81</sup> Panel Report, para. 8.149. The United States has shipped approximately 53.5 billion apples world-wide over the last 37 years (this statistic combines the last two years’ apple exports from the U.S. (572,258MT (2002), 528,309MT (2003)) with the 48.5 billion apple fruit figure presented by the United States in 2001). *See* First

50. Japan also suggests that the U.S. relies entirely on the original panel’s finding that the scientific evidence does not establish that the pathway will be completed in support of its Article 5.6 argument.<sup>82</sup> This is not correct. As already explained, there is no evidence that the United States has ever exported anything other than mature, symptomless apple fruit, and there are numerous requirements and practices in place which assure this. This is the reason to conclude that the alternative measure is technically feasible. To be clear, the U.S. statements referred to by Japan are only for the purpose of making the point that, even if immature fruit were somehow, hypothetically exported, the scientific evidence does not establish that the pathway would be completed. This only provides additional assurances against a hypothetical scenario. Again, there is no evidence this hypothetical scenario has ever occurred.

51. In sum, Japan fails to rebut the U.S. demonstration that an alternative measure fulfills the requirements of Article 5.6, and that Japan is therefore in breach of that provision.

**C. Japan’s Revised Measures Are Inconsistent With Article 5.1 of the SPS Agreement Because They Are Not Based on a Risk Assessment**

52. As noted in the first written submission of the United States, Japan’s revised measures on imported U.S. apple fruit are not based on a valid risk assessment, and are therefore maintained in breach of Article 5.1 of the SPS Agreement.<sup>83</sup> Japan has submitted a revised PRA, dated this month, September 2004, in support of its measures, implemented three months ago, and in an

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Written Submission of the United States, September 4, 2002, para. 27.

<sup>82</sup> First Written Submission of Japan, para. 83-84.

<sup>83</sup> See First Written Submission of the United States, Section IV.C.

attempt to rebut the Article 5.1 arguments set out by the United States in its first written submission one month ago.<sup>84</sup> Revisions of the PRA are ostensibly based on the four new studies put forward by Japan in its first written submission.<sup>85</sup> In fact, the first step in Japan’s revised pathway assumes the harvest of “[m]ature, apparently healthy apple fruit which have fire blight bacteria inside,” and that the “latently infected” fruit are then sold on the Japanese market.<sup>86</sup> As already demonstrated in detail by the United States, the four studies, and most notably the study purporting to identify the existence of mature, symptomless, yet latently infected fruit, do not alter in any way the original panel’s clear findings and the scientific evidence on apple fruit and fire blight. The studies do not establish that such a thing as a latently-infected mature fruit exists in nature or that a vector exists to complete the pathway. In short, the studies and, as a result the 2004 PRA, do not establish that a pathway for introduction of fire blight from mature apple fruit exists.

53. Accordingly, Japan’s revised measures cannot be “based on” its September 2004 PRA within the meaning of Article 5.1. Measures premised on the existence of “mature, symptomless

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<sup>84</sup> The United States analyzes Japan’s failure to base its measures on a risk assessment in detail in its first written submission. *See* First Written Submission of the United States, Section IV.C. The revised PRA was not shared with the United States until Japan’s recent submission. The United States notes that the final revision to Japan’s PRA, dated September 2004, must have occurred at some point after the United States filed its August 20, 2004 submission in this proceeding. The United States questions how Japan’s revised, June 30, 2004 measure (consisting of its original measure as amended by the June 30, 2004 Detailed Rules) could be based, *post facto*, on a PRA finalized in September 2004. *See* First Written Submission of Japan, para. 18. Further, the United States notes that its review of the Japan’s 2004 PRA is based on initial observations on the sufficiency of PRA given the short time schedule. In spite of this short review period, the United States demonstrates that the PRA fails to meet the requirements of Article 5.1. Nevertheless, the United States will continue to examine the revised PRA in greater detail.

<sup>85</sup> *See, e.g.*, First Written Submission of Japan, paras. 72, 73, 74, 75.

<sup>86</sup> *See* “An example of the pathways that Japan considers” (Exhibit JPN-12).

but latently infected apples” and a non-existent pathway for introduction, establishment and spread of fire blight do not rationally relate to a risk assessment that fails to identify any scientific evidence that such a commodity has ever been found in nature or could exist in nature, or that the pathway would be completed. In the absence of any scientific evidence of a fire blight-risk posed by mature, symptomless apple fruit, any risk analysis which concludes otherwise will not “take into account available scientific evidence,”<sup>87</sup> and will not meet the requirements for a risk assessment under Article 5.1. Therefore, despite Japan’s attempt to validate its revised measures through the production of this new PRA, it fails to do so, thus its revised measures are not based on a risk assessment and are maintained in breach of Article 5.1 of the SPS Agreement.<sup>88</sup>

54. In addition, Japan’s September 2004 PRA does not meet the requirements of Article 5.1 for many of the same reasons identified by the original panel. For example, the original panel found that Japan’s PRA failed to evaluate the likelihood of introduction of fire blight in Japan. It reached this conclusion in part because Japan’s 1999 PRA was “not sufficiently specific to the matter at issue” in failing to examine the risk from apple fruit.<sup>89</sup> Japan’s September 2004 PRA suffers from the same flaw by failing to address the commodity actually exported by the United States – mature, symptomless apple fruit – and instead relying on the existence of a commodity

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<sup>87</sup> SPS Agreement, Art. 5.2.

<sup>88</sup> Japan’s September 2004 PRA cannot be an appropriate basis for its revised measures, because as noted by the U.S. first written submission, in the absence of any scientific evidence of a fire blight risk posed by mature, symptomless apple fruit, it is not possible to produce a new, appropriate analysis of the risk of introduction of fire blight into Japan by mature, symptomless apple fruit. As noted by the United States in its first submission, because Japan’s revised measures are not legitimate SPS measures, they constitute non-tariff barriers in breach of Article XI of GATT 1994 and Article 4.2 of the *Agreement on Agriculture*.

<sup>89</sup> Panel Report, para. 8.271.

that does not exist in nature – mature, symptomless, yet latently infected apple fruit. In fact, if anything, the 2004 PRA recognizes that mature, symptomless fruit do not pose a risk of introducing fire blight:

[t]here appears to be *consensus* among foreign fire blight experts that mature symptomless apples are unlikely to be infected by the disease. Since *E. amylovora* have not been detected from apple fruit which were sampled from infected trees or orchard, Dueck 1974, Roberts *et al.* 1989 and Roberts (2002) concluded that the mature apple fruit is not infected with *E. amylovora*. This conclusion is *additionally supported* by the available literature that the pathogen will infect (immature) apples at an early stage of growth, and, by the time apples become mature, *only healthy apples will remain at harvest time.*<sup>90</sup>

However, because Japan appears to recognize that mature, symptomless apple fruit do not pose a risk of introducing fire blight, the revised 2004 PRA instead examines the risk from a non-existent commodity – mature, symptomless, but latently infected fruit – relying on the contention that “[o]n the other hand”, Azegami *et al.* (and a recurring reference to the late September van der Zwet *et al.* fruit which in fact, as discussed above, does little more than reiterate that nearly mature apple fruit can be epiphytically-infested with insignificant populations of *E. amylovora*) somehow refutes the scientific evidence on apple fruit and fire blight that has come before it. As noted above, the Azegami study does not succeed in doing so. As a result, the 2004 PRA fails to examine the actual risk – as established by the scientific evidence – from mature, symptomless apple fruit.

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<sup>90</sup> 2004 PRA, pp. 16-17.

55. Japan's 2004 PRA attempts to address the shortcomings of the original PRA, particularly those concerning the pathway for introduction of fire blight into Japan via apple fruit, by relying on the four flawed scientific studies discussed in detail above. As a result, the 2004 PRA fails to provide any (new) evidence that the hypothetical pathway will be completed. The missing elements of the pathway (*e.g.*, non-existence of infected mature apple fruit, failure to demonstrate that fire blight would be transmitted from infected fruit by some kind of vector) remain unaddressed in Japan's 2004 PRA insofar as Japan relies on the laboratory results generated in the Azegami, Tsukamoto (I), Tsukamoto (II) and Kimura studies to demonstrate its new pathway and presents these studies' results as being typical of events in U.S. apple production areas. Although Azegami *et al.* purports to demonstrate the existence of a mature, symptomless, yet latently infected fruit, it fails to establish that such a thing exists. Similarly, while Tsukamoto (II) concludes that flies are a vector of *E. amylovora*, it only achieves this result by failing to address real world, and real orchard, conditions; in fact, the flies inoculated with *E. amylovora* as a result of entrapment with blighted fruit *failed* to vector the inoculum to host plants. Further, although Kimura *et al.* purports to illustrate the probability of introduction of fire blight via apple fruit, it can only do so by relying on the Azegami and Tsukamoto studies, and even then its results contradict its conclusions. In short, Japan cannot prove that the hypothetical pathway will be completed by relying on its new studies which, as demonstrated by the United States in Section II.A.1, do not augment or change in any way the conclusions of existing scientific evidence on fire blight and apple fruit.<sup>91</sup>

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<sup>91</sup> In addition, Japan's revised PRA includes in its examination of measures which might be applied the option of maturity testing. Japan asserts this option "was proposed by the United States in the bilateral consultation." First Written Submission of Japan, para. 76. In support of this statement, Japan includes in its submission an e-mail



**D. Japan’s SPS Measures Are Non-Tariff Barriers Maintained in Breach of Article XI of GATT 1994 and Article 4.2 of the *Agreement on Agriculture***

56. Japan’s only rebuttal to the U.S. claims with respect to Article XI of the GATT 1994 and Article 4.2 of the *Agreement on Agriculture* is that Japan’s revised measures are consistent with the SPS Agreement.<sup>92</sup> Because they are not, and for the reasons set forth in the U.S. first written submission, Japan’s revised measures are inconsistent with GATT 1994 Article XI and *Agriculture Agreement Article 4.2*.

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from the United States government provided during those consultations.

The United States is surprised, concerned and deeply regrets that Japan has breached the confidentiality of the bilateral discussions which took place during the reasonable period of time, including the submission of a confidential communication between the parties. Throughout the consultations, Japan repeatedly emphasized the confidential nature of the talks, and repeatedly requested that the U.S. side refrain from publicly divulging the matters discussed. While the consultations were not formally conducted pursuant to DSU Article 4, the United States notes that Article 4.6 provides that, “[c]onsultations shall be confidential.” This requirement, enshrined in the DSU and insisted upon by Japan, is essential for a meaningful and frank exchange of views.

Further, Japan’s representation of the so-called U.S. “proposal” is misleading in the extreme. As is evident from the e-mail letter Japan submitted, the United States clearly indicated that it did not consider the maturity testing provided for therein to be in any way necessary to address any genuine risk from U.S. apple fruit. The United States made clear that it is under no obligation to address hypothetical uncertainties. Rather, the United States offered the steps outlined in its letter in order “to provide *additional* assurances that immature apples will not be exported.” See E-mail from Bruce R. Hirsh to Katsumi Omura, Attached Letter, p. 1 (Exhibit JPN-5). In further discussions between the parties, the United States made clear that it considered maturity testing to be a solution not to any genuine risk from apple fruit, but to the political difficulties Japan faces in removing its unsupported, unnecessary, WTO-inconsistent fire blight regime.

The United States further notes that the variation on maturity testing included in Japan’s PRA (5 apples per tree from a “statistically sufficient” number of trees) is not one presented during consultations by either party. See 2004 PRA, p. 52; see Exhibit JPN-5. Moreover, the United States withdrew its suggestion when it appeared that Japan intended to include maturity testing *in addition to* an orchard inspection and border zone. Japan’s revised version of maturity testing is, as Japan itself notes, highly burdensome. Again, no additional maturity testing is necessary to assure that exported U.S. apple fruit is in fact, mature.

<sup>92</sup> First Written Submission of Japan, paras. 87-88.

#### IV. SCIENTIFIC EXPERTS

##### A. Experts Need Not Be Consulted in This Proceeding Because the Science Relating to Fire Blight and Apple Fruit Remains Unchanged Since It Was First Evaluated by Experts and the Original Panel

57. As noted in detail above in the U.S. discussion of Japan’s four new studies relating to apple fruit and fire blight, the studies fail to introduce any new scientific evidence relating to either fire blight disease or the commodity at issue in this proceeding - mature, symptomless apple fruit exported from the United States. For example, one of Japan’s studies (mimicking a 50-year old study) establishes nothing more than that under extremely artificial conditions, apple fruit can be artificially wounded in several places and infected by placing high levels of inoculum on the fresh wound.

58. Further, in several cases, the results of the experiments appear to contradict the studies’ conclusions. For example, despite results evidencing that bioluminescence did not enter apple fruit through intact pedicels, the Azegami study concludes that “the possibility that the pathogen may pass through the layer cannot be excluded”; and despite a probability estimate of the risk of apple fruit introducing fire blight into Japan of “once every 565 years or so” (a risk found by the study’s data to be four-times that of fire blight being introduced by nursery stock), the study offers the contradictory conclusion that “[a]ccording to our estimation of probabilities of establishment of fire blight, the *descending order of magnitude* is as follows. Nursery stock and/or rootstocks > Scions and/or buds > Fruit.”<sup>93</sup>

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<sup>93</sup> Azegami *et al.*, p. 12; Kimura *et al.*, p. 23.

59. Japan's September 2004 PRA, the revisions of which are premised on the new studies, fails to propose a valid scientific analysis of any "risk" of fire blight from the commodity exported by the United States - mature, symptomless apple fruit. Instead, it relies on the proposition that mature, symptomless, yet latently infected fruit will somehow reach the Japanese market - a proposition unsupported by Japan's studies, as they do not demonstrate that such a commodity can exist in the real world.

60. Because even a cursory examination of Japan's studies indicates that they do not support the central assumptions on which Japan's revised PRA and measures are based, and do not amend, clarify or alter the scientific evidence at issue in this dispute, there is no need to re-consult experts. However, in the event that the Panel were to decide to consult experts in this proceeding, any such consultation should be limited to an evaluation of Japan's new studies rather than a reevaluation of science previously reviewed. As noted by the United States, Japan's argument hinges entirely on this new "science" rather than seeking support for its revised measures in the already extensive scientific record and the original panel's findings on that evidence.

## **V. CONCLUSION**

61. For the foregoing reasons, the United States respectfully requests that the Panel find that:

- (1) Japan has failed to ensure that its fire blight measures are not maintained without sufficient scientific evidence and these measures are therefore inconsistent with Article 2.2 of the SPS Agreement;

(2) Japan has failed to ensure that its fire blight measures are not more trade-restrictive than required to achieve its appropriate level of phytosanitary protection, taking into account technical and economic feasibility, and these measures are therefore inconsistent with Article 5.6 of the SPS Agreement;

(3) Japan has failed to ensure that its fire blight measures are based on an assessment of the risks to plant life or health, and therefore these measures are inconsistent with Article 5.1 of the SPS Agreement;

(4) Japan's fire blight measures are non-tariff barriers maintained in breach of Article XI of the GATT 1994 and Article 4.2 of the *Agreement on Agriculture*; and

(5) Japan has failed to comply with the recommendations and rulings of the DSB.