

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

Recourse by the United States to Article 21.5 of the DSU

**Executive Summary
of the Written Submissions and Oral Statements
of the United States of America
to Date**

November 15, 2004

FIRST WRITTEN SUBMISSION

INTRODUCTION

1. On December 10, 2003, the Dispute Settlement Body (“DSB”) adopted its recommendations and rulings in *Japan - Measures Affecting the Importation of Apples*. The DSB found that Japan’s phytosanitary measure on imported U.S. apples was inconsistent with Articles 2.2 and 5.1 of the *Agreement on the Application of Sanitary and Phytosanitary Measures* (“SPS Agreement”). Central to these findings were two sets of conclusions about the scientific evidence. The first set of conclusions is that the scientific evidence does not establish that *mature, symptomless* apple fruit:

- a) will be infected by fire blight;
- b) harbor endophytic populations of the fire blight-causing bacteria, *Erwinia amylovora*; or
- c) harbor epiphytic populations of bacteria capable of transmitting fire blight.

2. The second set of conclusions is that the scientific evidence does not establish that apple fruit – *whether mature or immature* – would serve as a means or pathway of introduction of fire blight to a fire blight-free area.

3. Although the reasonable period of time for Japan to comply with its obligations expired on June 30, 2004, Japan has not brought its phytosanitary measure into conformity with the DSB’s recommendations and rulings. To the contrary, Japan issued a set of phytosanitary measures remarkably similar to the elements of its previous WTO-inconsistent apple import regime. To address Japan’s continuing breach of its SPS Agreement obligations, the United States requested that this Panel be convened pursuant to Article 21.5 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (“DSU”).

JAPAN’S REVISED MEASURES

4. On June 30, 2004, the date the reasonable period of time expired in this matter, Japan amended one of the measures establishing its import regime for U.S. apple fruit, entitled “The Detailed Rules for Plant Quarantine Enforcement Regulation Concerning Fresh Fruit of Apple Produced in the United States of America” (“Detailed Rules”). The Detailed Rules are one of four measures comprising Japan’s import regime for U.S. apple fruit. The remaining three measures are unchanged.

A. Elements of Japan’s Revised Measures

5. Japan’s revised measures impose several restrictions on imported U.S. apple fruit in connection with fire blight or the disease-causing bacteria, *E. amylovora*. First, fruit must be produced in fire blight-free orchards designated by the United States Department of Agriculture (“USDA”). Designation may only be made for orchards in the U.S. States of Washington and Oregon; Second, each export orchard must be free of trees infected with fire blight; Third, the fire blight-free orchard must be surrounded by a 10-meter buffer zone that is also free of fire

blight; Fourth, export orchards and buffer zones must be inspected at least once a year, at the early fruitlet stage, for the presence of fire blight; Any detection of fire blight in an export orchard or buffer zone will disqualify the orchard from exporting its apple fruit to Japan; Fifth, harvested apple fruit must be treated with a surface disinfectant; Sixth, the interior of the packing facility must be disinfected with a chlorine treatment; Seventh, fruit intended for export to Japan must be kept separated post-harvest from other fruit; Eighth, U.S. plant protection officials must certify or declare that apple fruit is free of quarantine pests, not infected or infested with fire blight, and has been treated with chlorine; Ninth, Japanese officials must confirm that U.S. officials have made the necessary certifications and that chlorine treatments and orchard designations were made properly. Japanese officials also inspect the disinfestation and packing facilities as well as each shipment of apple fruit on entry into Japan.

B. Comparison Between Japan’s Original Measure and Its Revised Measures

6. Japan’s original, WTO-inconsistent measure consisted of 10 elements. Instead of opting to bring its measure into conformity with the DSB’s recommendations and rulings, Japan merely chose to alter certain restrictions and eliminate only one of the measure’s several elements.

LEGAL ARGUMENTS

7. The fact that this Panel has been established under Article 21.5 of the DSU carries with it certain consequences. Of most immediate relevance to the legal arguments of the parties is the consequence that, as the Appellate Body has made clear, an Article 21.5 panel “conduct[s] its work against the background of the original proceedings, and with full cognizance of the reasons provided by the original panel. The original determination and original panel proceedings, as well as the redetermination and the panel proceedings under Article 21.5, form part of a continuum of events.” It is well established that adopted panel and Appellate Body reports “are treated as a final resolution to a dispute between the parties to that dispute.”

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

8. The United States is unaware of any scientific evidence regarding apple fruit and fire blight that contradicts, draws into question or in any way alters the evidence examined by the panel two years ago, or the conclusions drawn from that evidence. That evidence and those conclusions remain equally valid in this proceeding. As before, the scientific evidence does not establish that mature, symptomless apple fruit 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 capable of transmitting fire blight. Further, the scientific evidence does not establish that apple fruit would serve as a pathway for introduction of fire blight into Japan. To the contrary, despite the billions of apple fruit shipped internationally (the vast majority of which were shipped without SPS measures for fire blight) there is no evidence of apple fruit having introduced fire blight into a fire blight-free

area. Accordingly, the panel's findings are as sound today as they were almost two years ago.

9. In making its findings, the panel analyzed the scientific evidence relating to apple fruit and fire blight. Its analysis was based in part on the written and oral statements of a panel of scientific experts on the scientific evidence on fire blight and apple fruit. The scientific experts concluded 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; scientific evidence does not establish that a mature apple fruit could be infected with fire blight; 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 be 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.

10. Japan's new measures subject imported U.S. apple fruit to numerous restrictive conditions in order to be eligible for import into Japan. Each of these restrictions is maintained without sufficient scientific evidence because there is no rational relationship between each restriction and the scientific evidence, *i.e.*, that mature, symptomless apple fruit will not harbor populations of *E. amylovora* bacteria capable of transmitting fire blight or serve as a pathway for introduction of fire blight. Therefore, each of these measures is maintained in violation of Article 2.2.

11. There is no new scientific evidence that would in any way affect the panel's findings since it and the experts examined the relevant scientific data and studies. Examined in light of those findings, Japan's revised measures, as described in paragraph 5 above, fail to implement the DSB's recommendations and rulings and remain inconsistent with Japan's SPS Agreement obligations.

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

12. Japan's fire blight measures are more trade-restrictive than required to achieve its appropriate level of protection. An alternative measure exists that is significantly less trade-restrictive than the nine measures currently applied by Japan on imported U.S. apple fruit, is reasonably available taking into account technical and economic feasibility, and achieves Japan's appropriate level of protection: the restriction of imports to mature apple fruit. In light of the existence of this less trade-restrictive alternative, Japan maintains its current import regime in breach of Article 5.6 of the SPS Agreement.

13. First, a measure restricting imports to Japan to mature U.S. apple fruit is reasonably available taking into account technical and economic feasibility. The U.S. apple industry already employs a series of quality controls on apple fruit that ensure their maturity in order to meet the requirements of U.S. laws and regulations, as well as to meet the demanding standards of export markets. Because these measures are already in effect and regularly applied to U.S. apple fruit exports, a measure restricting exports to mature fruit is reasonably available and technically and economically feasible.

14. Second, a measure restricting apple fruit imports to mature U.S. apple fruit more than achieves Japan's appropriate level of protection because, as the panel has found, scientific evidence does not establish that mature, symptomless apple fruit would be infected with or harbor endophytic populations of *E. amylovora*; that mature, symptomless apple fruit would be infested with epiphytic populations of *E. amylovora* capable of transmitting fire blight; or that apple fruit, regardless of its maturity, would serve as a pathway for the introduction of fire blight into Japan.¹ Therefore, a measure requiring shipments be mature U.S. apple fruit would meet Japan's appropriate level of protection.

15. Third, a restriction of imports to mature U.S. apple fruit would be significantly less trade-restrictive than the nine-measure import regime currently maintained by Japan. Under the proposed alternative of restricting trade to mature U.S. apple fruit, entire orchards will no longer be disqualified for discovery of a single fire blight strike on a tree or in a buffer zone, and all mature apple fruit would be eligible for export to Japan. If imports were restricted to mature apple fruit, American apple growers would financially be able to compete to fill orders for export to Japan. The fact that Japan's fire blight measures are more trade-restrictive than required is further evidenced by the range of alternative measures that are both less trade-restrictive and would more than achieve Japan's appropriate level of protection. For example, Japan might require the import of mature apple fruit coupled with a phytosanitary certificate or mature fruit coupled with a chlorine dip.

C. Japan's Revised Measures on Imported U.S. Apple Fruit Are Inconsistent With Article 5.1 of the SPS Agreement Because They Are Not Based on a Risk Assessment

16. In addition to breaching Articles 2.2 and 5.6 of the SPS Agreement, Japan's measures on imported U.S. apple fruit are not based on a risk assessment, and are therefore maintained in violation of Article 5.1 of the SPS Agreement. The panel found, and the Appellate Body upheld the panel's findings, that Japan's 1999 Pest Risk Analysis ("PRA") was not a risk assessment within the meaning of Article 5.1 of the SPS Agreement, and that Japan's measures were therefore not based on a risk assessment. Japan has not conducted any new risk assessments relating to fire blight and apple fruit that the United States is aware of, and continues to base its

¹ Japan's appropriate level of protection is the level of protection that would allow Japan to prevent the introduction of fire blight and maintain its fire blight-free status.

measures on the 1999 PRA, which does not satisfy the definition of a risk assessment for purposes of the SPS Agreement. Accordingly, Japan’s revised measures violate Article 5.1 because they are not based on a risk assessment.

17. The panel found, and Appellate Body confirmed, that Japan’s 1999 PRA is not a risk assessment for purposes of Article 5.1 and paragraph 4 of Annex A because, *inter alia*, it fails to evaluate the likelihood of introduction of fire blight in Japan and it fails to evaluate the likelihood of introduction of fire blight in Japan according to measures that might be applied. Because Japan has not produced – nor, in light of the absence of scientific evidence of any risk from mature fruit, could Japan produce – any new, appropriate analysis of the risk of introduction of fire blight into Japan via apple fruit, Japan’s revised measures are not based on a risk assessment as required by Article 5.1 of the SPS Agreement.

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*

18. Finally, Japan’s measures are not legitimate SPS measures. Instead, they are non-tariff trade barriers in breach of Article XI of the *General Agreement on Tariffs and Trade 1994* (“GATT 1994”) and Article 4.2 of the *Agreement on Agriculture*.

CONCLUSION

19. The United States respectfully requests that the Panel find that Japan has acted inconsistently with its obligations under Articles 2.2, 5.1, and 5.6 of the SPS Agreement, Article XI of GATT 1994 and Article 4.2 of the *Agreement on Agriculture*. The United States further requests that the Panel recommend that Japan bring its measures into conformity with its obligations under the SPS Agreement and the recommendations and rulings of the DSB.

PRELIMINARY RULING REQUEST

I. Introduction

1. Japan’s Operational Criteria are not within the Panel’s terms of reference for several reasons. First, they are not a measure – they are at most a proposed measure not yet in effect; “Japan intends to adopt” them. Moreover, since the Criteria are not currently in effect, they were not “taken” by the time of the establishment of the Panel and so could not be within the Panel’s terms of reference.

II. The Operational Criteria Are Not a Measure Taken to Comply and Are Therefore Not Within the Terms of Reference of the Panel in This DSU Article 21.5 Proceeding

2. The DSU provides a means to resolve disputes arising from “*measures taken* by another Member.” More particularly, Article 21.5 proceedings are to address “disagreement[s] as to the existence or consistency of *measures taken* to comply with the recommendations and rulings [of the DSB].” No GATT or WTO panel, or the Appellate Body, has ever issued findings on a proposed measure, nor, under the DSU, is there any authority for a panel to make such “advisory rulings”. As the panel in *United States - Lumber Preliminary Determinations* stated with respect to a request to make findings on an event which had yet to occur, “The WTO dispute settlement system allows a Member to challenge a law as such or its actual application in a particular case, but not its possible future application.”

3. The Criteria were not among the “measures taken to comply with the recommendations and rulings” which Japan notified to the WTO, nor did Japan refer to them in its July 29 request for arbitration under Article 22.6 of the DSU nor in its July 30 DSB statement. Notwithstanding that Japan apparently intended to discuss and agree to the Criteria with the United States, it did not do so, and the United States first learned of the Criteria when it received Japan’s first submission. Further, Japan presently only “intends to adopt” the Operational Criteria.

III. Conclusion

4. The purpose of this proceeding is not to consider whether potential future measures might comply with Japan’s WTO obligations; it is to determine whether the measures Japan has already taken to comply - as set forth in the U.S. panel request, are consistent with the provisions of the WTO Agreement cited in that request. Therefore, the United States requests that the Panel find that the Operational Criteria are not a measure subject to dispute settlement, and are not within the terms of reference of the Panel in this Article 21.5 proceeding.

SECOND WRITTEN SUBMISSION

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.

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 endophytic 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.” Yet the original panel considered this argument, and rejected it. 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.

5. 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

6. For the reasons set forth in the U.S. preliminary ruling request of September 27, 2004, the Operational Criteria 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.

7. 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)).” 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. 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. 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

8. 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.

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

9. 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.

10. 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*."

11. 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. 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 as "advising" this result, ignoring the very same views of those experts on the scientific evidence, and the ultimate panel findings on that evidence.

12. 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. Based on these studies, Japan has revised its 1999 Pest Risk Analysis (“1999 PRA”) as recently as September 2004. 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 latently-infected apple fruit.

13. 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

14. 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 into wounded fruit.² 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.*” 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.

15. 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. The fundamental flaw of the Azegami paper is its assertion that the results of 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, *did not result in the movement of E. amylovora* into the stems or fruit cortex of mature apples. *Only by removing the abscission*

² 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).

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.

16. The abscission layer acts as a natural barrier to desiccation and invasion of the fruit by microorganisms. 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 that “pathogen progress *stopped at this layer* in the experiment.” 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. 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.

17. 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 “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*. 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.

18. 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.

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

19. 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 CO₂ 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.

20. 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 *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. 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.

21. 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 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.” 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.” 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.

22. 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. However, it is an anatomical fact that the vascular bundles in 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.” 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. 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).

23. 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, the Kimura study contradicts its own findings. In fact, the Kimura 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. However, Japan acknowledges that *E. amylovora* will not be isolated in the cores of mature, symptomless apple fruit.

24. Further, Kimura *et al.* mischaracterizes the results of Tsukamoto (II) by stating that greenbottle flies “gathered” to blighted fruit. 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. Instead, greenbottle flies were sedated and immersed in a suspension of inoculum before being exposed to wounded pear fruitlets. Moreover, the flies that were trapped in an enclosed space with infected fruit did not transfer bacteria to host tissue.

25. 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).

26. 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). 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.” Not only does this probability estimate attempt to demonstrate that apple fruit presents approximately four times the risk of introducing fire 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.”

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

27. 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 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

28. 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.

29. 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 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. Japan has not raised any new scientific evidence on apple fruit and fire blight that in any way alters this conclusion.

30. 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. 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*.

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

31. 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. Nevertheless, Japan's revised measures include a requirement that every export orchard be surrounded by a ten-meter wide, fire blight-free, buffer zone. The requirement of a fire blight-free buffer zone appears to contradict Japan's subsequent argument that export orchards be inspected for severe or heavy blight. 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.

32. 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.

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

33. 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. 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

34. 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. 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. 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. 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.

35. 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

36. Japan argues that various post-harvest measures, namely sterilization of packing facilities handling apples for export to Japan, and export and import inspection 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. 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 Agreement, and only highlight the need – recognized by Japan – for findings on each of the specific elements of Japan’s import regime for U.S. apple fruit at issue in this proceeding.

37. 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.” 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. 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.”

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

38. 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 – 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.

39. Japan begins its cursory analysis by asserting that the U.S. does not clearly define what it proposes as the alternative measure. It then ignores the U.S.-defined alternative measure – a Japanese “restriction of imports to mature apple fruit” – 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 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.

40. The application of U.S. Federal Grade standards 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. 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.

41. 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. 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.

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

42. 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. Japan has submitted a revised PRA, dated this month, September 2004, in support of its measures, implemented three months ago, and in an attempt to rebut the Article 5.1 arguments set out by the United States in its first written submission one month ago. Revisions of the PRA are ostensibly based on the four new studies put forward by Japan in its first written submission. 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. As already demonstrated in detail by the United States, the four studies 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.

43. 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 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,” 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.

44. 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. 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 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. 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 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. 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.

45. 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 do not augment or change in any way the conclusions of existing scientific evidence on fire blight and apple fruit.

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*

46. 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. 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.

IV. SCIENTIFIC EXPERTS

47. As noted in detail 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. Because Japan’s studies 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

48. The United States respectfully requests that the Panel find that Japan has acted inconsistently with its obligations under Articles 2.2, 5.1, and 5.6 of the SPS Agreement, Article XI of GATT 1994 and Article 4.2 of the Agreement on Agriculture. The United States further requests that the Panel recommend that Japan bring its measures into conformity with its obligations under the SPS Agreement and the recommendations and rulings of the DSB.

ORAL STATEMENTS

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

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

51. As demonstrated by the United States in its second submission, Japan's studies fail to demonstrate anything "new" regarding fire blight and apple fruit in two respects. They fail to present results that have any bearing on the real world study of the epidemiology and biology of fire blight and apple fruit. They also fail to demonstrate anything new in the laboratory. The infection study in particular merely demonstrates a proposition that scientists have been aware of since 1923 – that by artificially wounding or stab-inoculating apple fruit, you can infect the fruit

with fire blight and later recover bacteria from the infected fruit. Further, in several instances that will be highlighted in this statement, Japan’s studies simply do not contain the results necessary to support Japan’s conclusions drawn from the studies.

Article 2.2

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

53. Japan suggests that, “[c]learly, the new evidence casts fresh, different light on the issues.” Japan argues that its new studies point to a “real risk” of introduction of fire blight into Japan, and that as a result its revised measures are no longer maintained without sufficient scientific evidence within the meaning of Article 2.2. In fact, Japan’s studies fail to demonstrate the central themes they set out to establish – that mature apple fruit will be infected with fire blight or that the pathway for introduction of fire blight into Japan from a hypothetically infected fruit will be completed.

54. We do not discount the Japanese results because they are experimental, as Japan suggests; rather, we discount the conclusions to be drawn from these very artificial experiments because one cannot extrapolate from them conclusions regarding the real world biology and epidemiology of fire blight.

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

56. In fact, this concept was introduced vis-a-vis apple fruit in the 1920s by the Canadian scientist McLarty, who stab-inoculated mature apple fruit and later recovered bacteria from the fruit. What can be artificially accomplished in the laboratory, however, does not demonstrate, in the case of fire blight and apple fruit, what occurs in the orchard or under real world conditions.

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

58. Japan presented the results of just such a cut-pedicel study at the meeting with the experts in the original panel proceeding. The experts unanimously dismissed the study because it was irrelevant to an analysis of fire blight and apple fruit. They concluded this because the pedicels had been artificially removed and a suspension of bacteria placed directly on the cut surface of the pedicel, whereas in nature the pedicels would be intact.

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

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

61. Japan asserts that previous studies failed to isolate internal bacteria because they didn't examine the part of the fruit where the bacteria were hidden, the flesh. However, earlier studies, including Roberts (1989), examined the “core and cortex [*i.e.*, flesh] tissues, including the stem, if present, and the entire calyx” of apple fruit harvested from and near severely blighted trees, and failed to recover any *Erwinia amylovora*. Similarly, the 1974 Dueck study, which found that *Erwinia amylovora* is not internally-isolated in mature apple fruit, even when harvested from severely infected trees, sampled the internal and external parts of 60 mature apples from three

severely blighted trees. This included three cylinders “from the cortex [*i.e.*, flesh] of each apple”, the stem, the calyx and the core.

62. Further, we note that Japan’s Tsukamoto infection experiment, an off-shoot of the Azegami study, does nothing more than demonstrate that fire blight bacteria can be isolated from artificially, wound-inoculated fruit after a period of storage. For these reasons, Japan fails to demonstrate that the first step of its proposed pathway exists – that is, that “Mature, apparently healthy apple fruit which have fire blight bacteria inside are harvested in the United States” – making its proposed pathway nothing more than a hypothetical one.

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

64. Despite this disconnect in the study, Japan draws the following conclusion from the study’s results: “it is only logical to conclude” that the experiment’s results demonstrate that there is a risk of completion of the pathway, and that the study demonstrates that “under plausible ecological conditions, the pathway of the disease will be completed.”

65. Japan defends the artificial conditions and results of the vector study. In support of its methodology, Japan asserts that the United States failed to identify any other study whose methods better represent natural or real world conditions. To the contrary, the United States referenced a recent study by Taylor *et al.* as an example of how an experiment can seek to realize real world conditions and, by contrast, how Japan’s greenbottle fly vector study fails to do so. A 1996 study by Hale *et al.* further highlights the artificial construct of Japan’s vector study.

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

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

68. In sum, Japan’s new studies do not affect the analysis of how fire blight and apple fruit interact in a real world environment. Japan’s revised measures therefore continue to be maintained without sufficient science within the meaning of Article 2.2 of the SPS Agreement.

69. Japan’s Operational Criteria propose nothing new at all vis-a-vis the level of fire blight that is necessary to disqualify an orchard, retaining in effect a fire-blight-free inspection requirement. This point can be illustrated by comparing Japan’s description of the new “heavily blighted” requirement to the statements of the two MAFF officials who inspected orchards under a fire blight-free regime. Japan’s PRA describes the Operational Criteria’s new, severe blight inspection program as being “conducted from the officials in the inspecting car; a tree will be *presumed* to be ‘(severely) infected’ when *readily observable symptoms* are found on the tree exterior, as seen from the officials in the inspecting car.”

Article 5.1

70. Japan also purports to have fixed the flaws in its Pest Risk Analysis. Japan claims that the United States has failed to demonstrate shortcomings in the PRA’s methodology, and as a result has failed to demonstrate that Japan’s measures are not based on a proper risk assessment for purposes of Article 5.1 of the SPS Agreement. However, constructing a framework of a risk analysis that touches on the benchmarks and deficiencies highlighted by the original panel and the experts, does not, in and of itself, mean that Japan has completed a risk analysis that evaluates the likelihood of entry, establishment, or spread of a pest or disease within Japan’s territory within the meaning of Article 5.1 and Annex A of the SPS Agreement. As noted by the Appellate Body in *EC – Hormones*, for measures to be “based on” a risk assessment, the risk assessment “must sufficiently warrant – that is to say, reasonably support – the SPS measure.” Further, a risk assessment must evaluate the “likelihood” of introduction of fire blight via mature apple fruit, thereby requiring that there be a “probability” of entry, establishment or spread of the disease, not a mere “possibility.”

71. However, in this instance, the probability of introduction of fire blight via imported mature U.S. apple fruit is essentially zero because the scientific evidence does not demonstrate that mature, symptomless apple fruit have ever introduced fire blight into a fire blight free area, despite, in many cases, unrestricted trade in apple fruit. Neither does the evidence establish that mature apple fruit will harbor endophytic populations of fire blight bacterium or be infected by fire blight, or that mature apple fruit will harbor epiphytic populations of bacteria capable of

initiating the disease. When, as is the case with mature apple fruit and fire blight, the scientific evidence confirms that imported U.S. apple fruit do not pose a risk to plant life or health in Japan, and when that scientific evidence fails to demonstrate a likelihood or probability of introduction of fire blight via mature apple fruit, the result of the risk assessment cannot reasonably support, or sufficiently warrant, Japan’s revised fire blight measures.

72. In its second submission, Japan asserts that its PRA does not merely address the risk posed by latently infected mature fruit but that it also addresses the risk inherent in the hypothetical failure of U.S. quality controls, leading to “erroneous shipment[s] of infected apple fruit.” Japan then attempts to meet its burden of demonstrating that such an “erroneous” shipment may occur by claiming that the *United States* has failed to demonstrate how it could prevent such an occurrence.

73. There is no evidence that the United States has ever exported anything other than mature, symptomless apple fruit. To the contrary, the United States has reviewed relevant databases and confirmed with relevant officials that no shipments of U.S. apple fruit have been rejected by foreign importers due to either immaturity or symptoms of fire blight. Specifically, we performed a search of the Foreign Notification of Non-compliance database, containing non-compliance statements collected by the United States Department of Agriculture from IPPC contact points, and checked with Federal, State and industry representatives responsible for overseeing apple export programs. Further, Japan has been unable to present any evidence of the failure of U.S. quality controls on apple fruit and fire blight, as even the Appellate Body noted.

74. It is Japan that has failed to present any evidence that an “erroneous shipment” has or will occur. Japan apparently rests its argument on the Panel’s statement that errors of handling or illegal actions are risks that “may be, *in principle*, legitimately considered by Japan,” improperly inferring that this statement grants Japan a free pass to assume that U.S. quality controls would and will fail. In noting that it is a risk that may be considered, however, neither the original panel nor the Appellate Body absolved Japan from its obligation to present evidence that the risk of failure of U.S. apple fruit quality controls is more than just hypothetical. In fact, the Appellate Body was careful to observe that the original panel’s and experts’ discussion of export controls was a discussion of those controls “in general,” rather than an evaluation of the specific controls for apple fruit in place in the United States.

75. Japan’s Pest Risk Analysis gives, at best, short shrift to U.S. quality controls in its analysis, ignoring for the most part U.S. pre-harvest and post-harvest procedures. The PRA summarizes the controls as follows: “as apples are generally judged ‘mature’ or ‘symptomless’ by *visual sorting*, there is always a risk that something other than mature, symptomless apple fruit may be . . . present in the shipment.” By failing to address actual U.S. practices and to dispute the effectiveness of those practices, Japan has failed to take into account, pursuant to *International Standards for Phytosanitary Measures* (“ISPM”) Number 11.

76. Because the scientific evidence relating to fire blight and mature apple fruit remains unchanged since that evidence was originally examined by the panel two years ago, there is a measure that is not more trade restrictive than required in achieving Japan’s appropriate level of protection – a Japanese measure restricting imported U.S. apple fruit to mature apple fruit.

77. Japan argues that the United States has failed to “define its alternative measure,” and that it does not provide “the specifics of the ‘mature, symptomless’ specifications.” This ignores our explanation that the alternative measure is precisely what we stated, a requirement that apple fruit imported into Japan be mature and therefore symptomless. Further, while Japan pays lip service to the fact the original panel found, based in part on the OECD specifications and the clear views of the experts, that maturity is an objective concept, it ignores the fact that this is the specification for determining fruit maturity.

Conclusion

78. The United States requests that the Panel find that Japan’s revised measures are inconsistent with its WTO obligations under the SPS Agreement, the Agreement on Agriculture and the GATT 1994. Further, we reiterate our request that, pursuant to our preliminary ruling request, the Panel find that Japan’s Operational Criteria are not a measure subject to dispute settlement, and are not within the terms of reference of the Panel in this Article 21.5 proceeding.

79. On a procedural note, Japan has indicated that it intends to submit new evidence in its answers to Panel questions. The United States is surprised that Japan intends to provide evidence at this late date. The Working Procedures are clear that evidence should be provided no later than during the substantive meeting. We are also surprised that Japan would submit its new scientific evidence in response to questions that do not yet exist. Responses to questions do not grant Japan *carte blanche* to provide new evidence. Japan should appreciate the Working Procedures in this context.