

**BEFORE THE
WORLD TRADE ORGANIZATION
APPELLATE BODY**

Japan – Measures Affecting the Importation of Apples

(AB-2003-4)

APPELLEE'S SUBMISSION OF THE UNITED STATES

September 22, 2003

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SERVICE LIST

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I. INTRODUCTION

1. Over three years have passed since the Dispute Settlement Body (“DSB”) adopted recommendations and rulings in the *Japan Varietals* dispute, which also involved Japan’s unsupported phytosanitary restrictions on U.S. apples.^{1/} This dispute involves yet another set of phytosanitary requirements designed to protect Japan’s apple growers by restricting apple imports – Japan’s requirements ostensibly relate to the plant disease fire blight, which is caused by the bacterium *Erwinia amylovora*. As with its earlier varietal testing restrictions, Japan’s fire blight measure is maintained without sufficient scientific evidence and is not based on a risk assessment within the meaning of Article 5.1 of the *Agreement on the Application of Sanitary and Phytosanitary Measures* (“SPS Agreement”), as the Panel correctly found in its report on *Japan – Measures Affecting the Importation of Apples*^{2/} (hereinafter “Panel Report”).

2. In particular, the United States argued, the experts confirmed, and the Panel concluded that there is not sufficient scientific evidence to conclude, with respect to exported apples – that is, apples which are mature and therefore symptomless – (1) that such apples would harbor endophytic populations of bacteria; (2) that such apples would harbor epiphytic populations of bacteria capable of transmitting *E. amylovora*; (3) that such apples would be infected by fire blight; and (4) that the last stage of the pathway (transmission of fire blight to a host plant) would likely be completed. Accordingly, after also concluding that the wealth of information available on fire blight means that Article 5.7 is not available as justifying Japan’s measures under it, the Panel concluded that Japan has breached its obligation under Article 2.2 not to maintain its measure without sufficient scientific evidence. Further, the Panel examined Japan’s asserted risk assessment, and found that it failed to meet Article 5.1 requirements on a number of counts.

^{1/} Panel and Appellate Body Reports, *Japan – Measures Affecting Agricultural Products*, adopted 19 March 1999, WT/DS76/R (“*Japan Varietals*”).

^{2/} Panel Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/R, 15 July 2003 (“Panel Report”).

3. The United States in its Other Appellant's Submission discussed why the Panel erred in extending its analysis to immature fruit, an issue which overlaps with Japan's appeal. With the exception of that issue, however, Japan in its Appellant's Submission fails to identify any legal error justifying reversal of the Panel's findings. Rather, Japan reintroduces discredited evidence and takes issue with how the Panel weighs the evidence, and argues for legal standards rejected in previous SPS disputes that would eviscerate the disciplines of the SPS Agreement. It also misrepresents both the Panel's findings and conclusions, and the arguments of the United States. The Appellate Body should reject Japan's efforts and uphold all Panel findings relating to mature fruit, while reversing Panel conclusions relating to immature fruit, as set forth in the U.S. Other Appellant's Submission. To the extent the Appellate Body considers that the Panel was correct to examine immature fruit, however, all findings relating to that product should stand.

4. Japan fundamentally misunderstands the scientific method and scientific evidence. A consistent theme runs through Japan's Appellant's Submission, *i.e.*, for Japan, a Member may stop or restrict imports unless there is total scientific certainty about every conceivable aspect of a product. In other words, under the SPS Agreement, mere speculation and conjecture are sufficient foundation for a measure. Japan's approach would stand the SPS Agreement on its head. Rather than requiring that a Member not maintain a measure without sufficient scientific evidence, a Member could maintain a measure unless there is absolute scientific certainty. Of course, this also requires standing the scientific method on its head. Science is not about certainty, and cannot provide certainty, as the experts confirmed during the Panel hearings.^{3/} Science is about testing hypotheses using real data and evidence. Japan's approach is fundamentally flawed and should be rejected.

^{3/} See *e.g.*, Panel Report, Annex 3, paras. 372, 376, and 381.

II. ARGUMENTS REGARDING SPECIFIC ISSUES UNDER APPEAL

A. The Panel Erred in Offering Conclusions and Findings with Respect to Immature and Infected Apples.

5. In its Appellant's Submission, Japan argues that the Panel erred in offering findings on infected apples, with respect to which the United States presented no claims. While this argument distorts the U.S. argument – the United States presented no claims with respect to immature apples, the only apples which might be infected – the United States agrees that the Panel should not have issued conclusions and findings with respect to immature, potentially infected, apples. However, as explained in the U.S. Other Appellant's Submission, the United States considers that the Panel error identified by Japan requires that *all* Panel conclusions with respect to immature and/or infected apples be reversed or considered without effect, including its discussion of whether infected apples themselves are capable of harboring populations of bacteria which could survive commercial handling, storage and transportation,^{4/} and that errors of handling or illegal actions are risks that may, "in principle," legitimately be considered by Japan.^{5/} In this regard, it is important to bear in mind that while the United States put forward no claims with respect to these topics, *Japan* also put forward no scientific evidence on these topics. As discussed further below, however, the United States notes that reversal of Panel findings with respect to immature and infected apples should not affect the Panel's conclusion in paragraph 8.166 on completion of the pathway as it relates to mature fruit, with respect to which the United States fully met its burden. Further, to the extent that the Appellate Body concludes that the Panel did not err in examining immature fruit, all of its findings with respect to that fruit should stand.

1. As Set Forth in the U.S. Other Appellant's Submission, the Panel Erred in Including Immature Fruit Within the Scope of the Dispute.

6. For the reasons set forth in the U.S. Other Appellant's Submission, the Panel erred in

^{4/} Panel Report, para. 8.157.

^{5/} Panel Report, para. 8.161.

including immature fruit within the scope of this dispute. As explained in that submission, the Panel's error goes beyond that which Japan asserts. While Japan seeks only to reverse findings unfavorable to it, the Panel had no authority to examine claims which the United States did not pursue, or to relieve *either party* of its burden of presenting facts and argumentation. Thus, the Appellate Body should conclude not only that the Panel's conclusion in paragraph 8.166 should not be read to extend to immature fruit, but also that the Panel erred in offering the reasoning and conclusions in paragraphs 7.30-32, 8.32, 8.34, 8.119-121 and 8.154-8.162.

7. For these reasons, the Panel's findings and conclusions in connection with immature apples should therefore be reversed. If, on the other hand, the Appellate Body were to conclude that the Panel had the independent authority to undertake an analysis of immature fruit, then the Appellate Body should also conclude that the Panel's conclusion in paragraph 8.166 should also extend to immature fruit. The United States demonstrated that there was no scientific evidence supporting the existence of a vector from any apples, whether mature or immature. The experts supported this. Dr. Geider stated that, even in the case of an apple "which shows fire blight symptoms" [*i.e.*, is infected], "I am not convinced that this automatically implies that fire blight will come up in that country where the apples are finally on the market so I think even that risk of heavily infected apples it must be a lot of additional circumstances that fire blight get established in the environment of this apple so I would say it is still negligible that this event can occur."^{6/} Thus, to the extent that the Panel was correct in offering views with respect to immature apples, its conclusion that there is no vector for either immature or mature apples was correct.

2. The Panel's Conclusion in Paragraph 8.166 is Correct, and Should be Upheld With Respect to the Subject of the Dispute – Mature, Symptomless Apples.

8. While the United States agrees with Japan that the Panel's findings and conclusions with respect to immature apples should be reversed, it does not agree that paragraph 8.166 should also

^{6/} Panel Report, Annex 3, para. 393.

be reversed, except to the extent that it and the finding that follows purport to apply to immature apples, for the reasons already described. The structure of Japan's argument (the fact that it is included in a section on "infected" fruit) and several of its statements suggest in fact that it is only challenging the Panel's conclusion with respect to immature apples. To the extent that Japan contends that paragraph 8.166 should be reversed with respect to mature apples, therefore the United States disagrees.

9. In paragraphs 8.163-8.168, the Panel examined whether the final step in the pathway proposed by Japan for transmitting fire blight to a host plant in Japan could be completed. This step involved transmission of bacteria from discarded fruit. The Panel correctly concluded in paragraph 8.166 that this stage of the pathway would not be completed because, in part, of the absence of a vector to transmit any hypothetically surviving bacteria to a host plant.

10. Japan criticizes the Panel's fact finding in paragraph 8.166, alleging that it reflects the Panel's failure to discharge its functions under Article 11 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* ("DSU") and elaborating on this argument over several pages.^{7/} However, it is clear that Japan's complaint lies in the Panel's assessment of the facts before it and the weight it accorded those facts, and that there is no basis to disturb this finding. By now it is well-established that a breach of Article 11 with respect to fact finding requires something more than the fact that a Panel declined to accept a particular party's arguments or its views on the conclusions to be drawn from the available evidence. Establishing a breach of Article 11 requires a showing that the Panel showed "deliberate disregard" for evidence or "refuse[d] to consider," "willfully distort[ed]" or misrepresent[ed]" evidence.^{8/} This is a high standard, and Japan has not met it here. In paragraph 8.166, the Panel cited several studies that found no vector for calyx-infested discarded apples, notwithstanding their proximity

^{7/} Japan's Appellant's Submission, paras. 47-71.

^{8/} Appellate Body Report, *EC – Measures Affecting Meat and Meat Products (Hormones)*, adopted 13 February 1998, WT/DS26/AB/R ("*EC – Hormones*"), para. 133.

to host plants, as well as statements by the experts on the absence of evidence for the proposition that several hypothetical candidates could actually serve as vectors (birds, rain splash, bees).^{9/} Japan offered no contrary evidence.

11. To the extent Japan is referring to mature apples, Japan posits the spurious suggestion that the Panel engaged in “independent fact finding,”^{10/} and that the United States failed to raise a presumption on completion of the last stage of the pathway.^{11/} Contrary to Japan’s suggestion, the Panel’s analysis was made in response to the clear and repeated argumentation of the United States that there was no evidence of a vector to complete the pathway,^{12/} including the request of the United States in its comments on the interim report that such a finding be made.^{13/}

12. Japan also suggests the existence of legal standards that have no basis in the text of the DSU. For example, Japan posits that “independent factual determinations” by panels may only be made if “there is overwhelming evidence supporting that conclusion.”^{14/} There is nothing in the DSU to suggest such a standard. Likewise, Japan resurrects arguments made and rejected in the context of the *Japan Varietals* dispute with respect to a “precautionary principle,” suggesting that such a principle required the Panel to conduct its fact finding so as to find for Japan on the existence of a vector to complete the pathway, notwithstanding the absence of any scientific

^{9/} Japan criticizes the Panel for also referring to the absence of contamination in studies even when ooze was reported to exist. Inasmuch as this situation could only occur in the case of immature, infected apples, the accuracy or otherwise of this statement is irrelevant to the Panel’s conclusion as it relates to mature, symptomless apples, which might, at most, have small populations of *E. amylovora* in their calyxes. Japan does not contest the Panel’s citation to studies on this situation.

^{10/} Japan’s Appellant’s Submission, para. 48.

^{11/} Japan’s Appellant’s Submission, para. 56.

^{12/} E.g., U.S. First Written Submission, paras. 44-45; U.S. Second Written Submission, paras. 12-14.

^{13/} U.S. Comments on the Interim Panel Report, at 2-3.

^{14/} Japan’s Appellant’s Submission, paras. 48-49.

evidence of such a vector, and the existence of contrary evidence.^{15/} Japan quotes the Appellate Body report in *Hormones* on the topic of precaution, but only selectively. The Appellate Body noted, *inter alia*,

[T]he [precautionary] principle has not been written into the *SPS Agreement* as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement. . . . [T]he precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the *SPS Agreement*.^{16/}

Japan ignores these statements and in no way succeeds in demonstrating any textual directive which would have compelled the Panel to find evidence of a vector where such evidence did not exist. Japan cites to several statements made by the experts which “emphasized the need for caution,”^{17/} but itself acknowledges that “these expressions do not identify a concrete path of the dissemination of the disease . . .”^{18/} Japan would have the Panel use generalized statements of “caution” to infer the existence of evidence. That evidence, however, does not exist. Japan then argues that this hypothetical, non-existent evidence trumps very specific evidence on the issue at hand. The Panel correctly declined to follow Japan’s approach, relying instead on the actual evidence presented by the United States and supported by the experts. For example, the Panel refers in paragraph 8.166 to specific answers of the experts with respect to the hypothetical vectors,^{19/} and the experts also directly addressed the issue in response to U.S. questions.^{20/}

13. Japan also seeks to argue that a statement made by the Panel in its interim report

^{15/} Japan’s Appellant’s Submission, paras. 64-70.

^{16/} *EC – Hormones*, para. 124.

^{17/} Japan’s Appellant’s Submission, para. 67.

^{18/} Japan’s Appellant’s Submission, para. 67.

^{19/} The Panel cites paragraphs 241 and 263 of Annex 3 of the Panel Report.

^{20/} Panel Report, Annex 3, paras. 171-181.

concerning “theoretical risk” somehow should have led the Panel to disregard scientific evidence specifically relating to the issue before it on the absence of a vector.^{21/} Again, Japan appears to suggest a mode of fact finding that requires panels to disregard the facts before them. In this case, Japan relies on a Panel statement not included in the final report, or a revised version of the statement in the final report,^{22/} which is at best ambiguous and in any event irrelevant to the issue of the existence of a vector.^{23/}

14. Again, to the extent that Japan is merely arguing that the conclusion in paragraph 8.166 should not be read to apply to infected fruit, the United States does not disagree, although not for the reasons Japan presents, and notwithstanding the fact that the conclusion is correct in the case of infected fruit.^{24/} However, to the extent Japan is seeking to reverse the Panel's conclusion in

^{21/} Japan's Appellant's Submission, para. 57

^{22/} See Japan's Appellant's Submission, paras. 60-61.

^{23/} Japan also attempts to infer from the Panel's use of the term “unlikely” in paragraph 8.166 that the Panel considered the risk of completion of the pathway to be more than theoretical. Japan's Appellant's Submission, para. 50. However, here as elsewhere, the Panel used the term “unlikely” merely to reflect a proper, scientific approach to risk, given that science can never state with absolute certainty that an event will not occur. See *EC Hormones*, para. 186. This approach is reflected throughout the discussions of the parties and Panel with the experts, including on the topic of completion of the pathway. In that connection, Dr. Geider stated that the probability of vectoring of fire blight from a calyx-infested apple “is close to zero but of course *in theory* it cannot be excluded, but I still would say it's almost zero.” Panel Report, Annex 3, para. 372 (emphasis added). Dr. Hale then stated, “We have no scientific evidence from the work that we have done that there is any transmission, but as Dr. Geider has pointed out, *as scientists*, it is very difficult to say that it is totally impossible.” Panel Report, Annex 3, para. 376 (emphasis added). Likewise, Dr. Smith stated, “there is no evidence of [transmission] and in any case it appears exceedingly *unlikely*.” Panel Report, Annex 3, para. 381 (emphasis added). Indeed, in the absence of any evidence that bacteria could be vectored, any discussion of the “likelihood” of this occurring can only be theoretical.

^{24/} In this regard, at the experts' session, Dr. Geider observed, “even in this case [of an infected apple entering a country], I am not convinced that this automatically implies that fire blight will come up in that country . . . so I think even that risk of heavily infected apples it must be a lot of additional circumstances that fire blight [will] get established in the environment of this apple so I would say it is still negligible that this event can occur.” Panel Report, Annex 3, para. 393.

paragraphs 8.166 and 8.168 on the absence of a vector with respect to mature apples, the Appellate Body should reject Japan's arguments and uphold the Panel's findings.

B. The Panel Correctly Found That Japan's Fire Blight Measure Is Maintained Without Sufficient Scientific Evidence, in Breach of Article 2.2.

15. Japan also seeks reversal of the Panel's finding, with respect to mature apples, that Japan, in breach of SPS Agreement Article 2.2, has not ensured that its fire blight measure is not maintained without sufficient scientific evidence.^{25/} Again, Japan's arguments largely amount to efforts to reweigh the evidence before the Panel, and to suggest legal standards that not only are not found in the SPS Agreement, but that would – if accepted – eviscerate the Agreement. Specifically, Japan takes issue with the fact that, based on the arguments of the United States, the scientific record, and the views of the experts on the scientific record, the Panel reached a different conclusion with respect to the meaning of the one and only study Japan has been relying on for over ten years to justify its fire blight measure.^{26/} Japan appears to suggest that, in a case involving the SPS Agreement, a responding Member's evaluation of the scientific evidence may not be questioned. Japan also appears to posit that, in disputes under Article 2.2 of the SPS Agreement, the complaining party has the unscientific and impossible burden of proving the absence of any evidence that, examined in isolation, leaves any issue relating to a product unresolved, however immaterial.

1. Japan Objects to How the Panel Weighed the Evidence, Which is Beyond the Scope of Appellate Review, Absent a Breach of DSU Article 11.

16. Japan has not, with respect to mature apples, argued that the Panel's fact finding is in

^{25/} Article 2.2 provides, in relevant part:

Members shall ensure that any sanitary or phytosanitary measure ... is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

^{26/} Japan's Appellant's Submission, paras. 75-80.

breach of DSU Article 11.^{27/} Under the circumstances, review of the Panel's fact finding on mature apples is beyond the scope of appellate review.^{28/} Thus, Japan's objections to how the Panel weighed the significance of the van der Zwet (1990) study, the history of trans-oceanic dissemination of fire blight, and Japan's continued, unsupported assertions of the possibility of infection of mature, symptomless apples^{29/} should, for this reason alone, be rejected, and the Panel's finding that Japan breached Article 2.2 of the SPS Agreement should be affirmed.

2. The Appellate Body Should Also Reject Japan's Argument on How Panels Should Review a Member's Assessment of the Evidence.

17. To the extent that Japan is considered to have raised legal arguments on Panel fact finding and not simply a reconsideration of that fact finding, the Appellate Body also should reject Japan's arguments that the Panel somehow erred by not giving sufficient weight to Japan's own interpretation of the evidence and by not requiring the United States to prove the absence of scientific evidence.

18. Japan argues that Article 2.2 should be interpreted to allow an importing Member "a certain degree of discretion, within the requirements of a risk assessment under Articles 5.1 and

^{27/} See Japan's Appellant's Submission, paras. 71-91.

^{28/} DSU Article 17.6. In *EC – Hormones*, the Appellate Body explained,

Under Article 17.6 of the DSU, appellate review is limited to appeals on questions of law covered in a panel report and legal interpretations developed by the panel ... Determination of the credibility of the weight properly to be ascribed to (that is, the appreciation of) a given piece of evidence is part and parcel of the fact finding process and is, in principle, left to the discretion of the panel as the trier of facts ... Whether or not a panel has made an objective assessment of the facts before it, as required by Article 11 of the DSU, is ... a legal question which, *if properly raised on appeal*, would fall within the scope of appellate review.

para. 132 (emphasis added).

^{29/} Japan's Appellant's Submission, paras. 78-80, 86-87, 88-89.

5.2, . . . to determine the value of the evidence to it and to introduce a particular measure thereon.”^{30/} According to Japan, the Panel failed to respect this discretion, based on the fact that, “the Panel evaluated the scientific evidence in accordance with the experts’ view, despite the contrary view of an importing Member (Japan).”^{31/}

19. For Japan, apparently, the “discretion” of importing Members precludes panels from disagreeing with a Member’s judgments that are unsupported by scientific evidence, as occurred here. However, as the Appellate Body explained in *Australia Salmon* in response to a similar argument by Australia, under the standard set forth in DSU Article 11 to make “an objective assessment of the facts of the case,” panels “are not required to accord to factual evidence of the

^{30/} Japan’s Appellant’s Submission, paras. 76-77.

^{31/} Japan’s Appellant’s Submission, para. 78. Japan cites as an example that the Panel found that mature apples are unlikely to be infected, notwithstanding Japan’s discredited interpretation of van der Zwet (1990). See Panel Report, paras. 7.6, 8.127. In this connection, Japan incorrectly asserts, without citation, that the United States “did not deny that surface infection was identified as fire blight.” As an initial matter, the parties addressed the phenomenon of surface *presence* of bacteria, and not surface infection, a concept for which there is no evidence. Bacterial presence on the surface of fruit does not constitute an “infection.” See Panel Report, paras. 2.12-2.13. Further, the context in which the U.S. discussed surface presence was to explain that surface bacteria typically die out quickly. See U.S. First Written Submission, para. 37; U.S. Comments on the Experts’ Answers, para. 34. Japan also asserts that a shipment could include physiologically, but not commercially mature apples, and it is not known at which point prior to commercial maturity an apple loses its susceptibility to harboring *E. amylovora*. Japan’s Appellant’s Submission, para. 80. In fact, there is no evidence whatsoever for the proposition that physiologically mature apples are “still susceptible” to *E. amylovora*, and it is illogical and scientifically improper to infer otherwise from the mere fact that the precise point at which an apple loses its susceptibility is not known. Further, Japan’s argument disregards the fact that even if, contrary to commercial practice, a physiologically mature apple were harvested before it was commercially mature, and were not filtered out through the control process which ensures compliance with U.S. laws on grading standards, the apple would be commercially mature by the time of shipment. By definition, a physiologically mature apple will continue to ripen to commercial maturity, a process taking less time than the period required to sort, grade and treat apples prior to shipment.

parties the same meaning and weight as do the parties.”^{32/} Further, Japan’s argument that Article 2.2 of the SPS Agreement should be read to preclude panels from disagreeing with a responding Member’s evaluation of the facts echoes Japan’s unsuccessful argument in *Japan Varietals* that Article 2.2's application is limited to situations in which the scientific evidence is “patently” insufficient.^{33/} As in that case, there is no support in Article 2.2 or any other provision of the SPS Agreement for Japan’s position. As it did in *Australia Salmon* and *Japan Varietals*, the Appellate Body should reject the unsupported suggestion that panels are barred from examining the facts presented to them. Members may not disregard their obligations under Article 2.2 based on this non-existent bar.

20. Japan also argues that the Panel erred because it should have found that the United States failed to “prove absence of scientific evidence in other material aspects.”^{34/} In so arguing, Japan appears to suggest that it was incumbent upon the United States as complaining party to foreclose any and all speculation on hypothetical risks in order to meet its burden under Article 2.2. Japan itself recognizes the impossibility of this task: “In fact, since there is no closed boundary with regard to ‘other aspects,’ it is impossible to prove absence of *relevant* scientific evidence by accumulating the dissected pieces of evidence.”^{35/} Japan cites as examples of such “relevant evidence” its discredited (as being unfounded and without a factual basis) speculation that apple fruit *may have been* the cause of trans-oceanic dissemination of fire blight, since the actual cause is unknown, and its discredited (through both U.S. evidence and the unanimous opinion of the experts) interpretation of the van der Zwet (1990) study which, in Japan’s view, provides evidence that mature harvested apple fruit will be subsequently infected.^{36/}

^{32/} Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, adopted 6 November 1998, WT/DS18/AB/R (“*Australia Salmon*”), para. 267.

^{33/} *Japan Varietals*, para. 82.

^{34/} Japan’s Appellant’s Submission, para. 85.

^{35/} Japan’s Appellant’s Submission, para. 85.

^{36/} Japan’s Appellant’s Submission, paras. 86-88.

21. Japan is simply seeking to reweigh the Panel's evaluation of the evidence under the pretext of arguing a misapplication of the burden of proof. Furthermore, Japan is incorrect as to the applicable burden of proof. Japan both distorts the applicable burden – in Japan's characterization, complaining parties must "prove the absence of scientific evidence," rather than "raise a presumption" that there was no relevant scientific evidence supporting the measure – and considers that complaining parties must disprove any and all speculation based on any uncertainties in the scientific record.

22. With regard to Japan's characterization of the burden of proof, Japan itself acknowledges that it would impose on complaining parties an "impossible" task, as mentioned above, which is a proposition that can not be seriously entertained if Article 2.2 is to hold any meaning. Indeed, while a complaining party can be expected to address the scientific evidence of which it (and the panel) is aware, once it has adequately done so, it is incumbent upon the responding Member to present evidence to rebut the presumption of a breach. In fact, given that the SPS Agreement cannot be read to place the "impossible" burden of proving a negative on the complaining Member, it must be possible for the complaining Member to raise the necessary presumption when there is no evidence which is even arguably relevant. The Appellate Body suggested a means by which this might be achieved in *Japan Varietals*, when it pointed out that a complaining Member can establish a strong indication of the absence of relevant evidence if, following a request to the responding Member to provide the scientific basis for a measure pursuant to SPS Agreement Article 5.8, the responding Member fails to do so. This is only logical, for while the burden in a dispute lies with a complaining party to establish a breach of an agreement obligation, Article 2.2 ultimately imposes on the Member imposing the SPS measure an obligation to ensure that the measure is not maintained without sufficient scientific evidence.^{37/} The Panel noted this distinction in its report.^{38/} The Panel also correctly assigned the

^{37/} *Japan Varietals*, para. 137.

^{38/} Panel Report, para. 8.41. And indeed, the United States on April 4, 2002, made an SPS Agreement Article 5.8 request regarding the measure at issue. The United States therefore has addressed all of the evidence on which Japan claimed to have relied on in this dispute.

burden of proof in this dispute, and the United States carried its burden.

3. The Appellate Body Should Reject Japan's Argument on "Uncertainty."

23. Likewise, it would not be a plausible interpretation to read Article 2.2 as requiring a complaining Member to disprove any speculative scenario that a responding Member suggests. Japan suggests at various times in its submission that it may maintain its measure based on "uncertainty." It is therefore important to recall the fundamental point that Article 2.2, and the SPS Agreement generally, speaks not of "uncertainty," but of "scientific evidence." Article 2.2 requires that measures not be maintained "without sufficient scientific *evidence*," not "without sufficient uncertainty." It will always be true that not every aspect of, or issue relating to, a product will be known with scientific certainty. However, this lack of certainty cannot serve as the basis for a measure. Otherwise the SPS Agreement would be meaningless. The Appellate Body has addressed this issue, explaining in *EC – Hormones*,

In one part of its Reports, the Panel opposes a requirement of an "identifiable risk" to the uncertainty that theoretically always remains since science can *never* provide *absolute* certainty that a given substance will not *ever* have adverse health effects.[footnote omitted] We agree with the panel that this theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed.^{39/}

24. Contrary to this guidance, Japan suggests that it may base its measure on speculation that apple fruit *may have been* the means by which trans-oceanic dissemination of fire blight occurred in the past, based only on the fact that the cause "is still unknown;"^{40/} and on speculation that *E. amylovora* bacteria *may* be present in physiologically mature apples, based only on the fact that the precise point prior to commercial maturity at which apples lose their susceptibility to

^{39/} *EC – Hormones*, para. 186 (emphasis in original).

^{40/} Japan's Appellant's Submission, para. 86.

presence of bacteria is not known.^{41/} Japan would have the Panel find this speculation to be sufficient *scientific evidence* to maintain Japan's measure notwithstanding extensive, direct scientific research supporting the conclusion that mature apples will not be infected with fire blight,^{42/} endophytically infested with *E. amylovora* bacteria^{43/} or epiphytically infested with populations capable of transmitting the bacteria.^{44/} Moreover, as the Panel noted,^{45/} the United States addressed Japan's arguments with respect to trans-oceanic transmission of fire blight,^{46/} and 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."^{47/} Under the circumstances, it would indeed require an extreme view of the burden on complaining parties in SPS disputes to conclude that the Panel erred in finding that the United States met its burden in this dispute.

25. For the above reasons, Japan has failed to demonstrate any error with respect to the Panel's finding that Japan's fire blight measure is consistent with Article 2.2 of the SPS Agreement.

C. The Panel Correctly Found that Japan's Measure Does Not Meet the Requirements of Article 5.7.

26. Japan again suggests that "uncertainty" may trump voluminous, relevant evidence in arguing that the Panel erred in finding that Japan's fire blight measure failed to meet the

^{41/} Japan's Appellant's Submission, para. 88.

^{42/} See Panel Report, paras. 8.137-8.139.

^{43/} See Panel Report, paras. 8.123-8.128.

^{44/} See Panel Report, paras. 8.129-8.136.

^{45/} Panel Report, para. 8.145

^{46/} See Panel Report, paras. 4.68-4.72.

^{47/} Panel Report, para. 8.149, *citing* paras. 6.20-6.23.

requirements of Article 5.7 of the SPS Agreement. Further, Japan seeks to interpret the requirements of the first sentence of Article 5.7 so as to authorize its incorrect approach, mischaracterizing the Panel's explanation of these requirements in order to argue that the Panel erred. Finally, Japan offers disturbing arguments with respect to "new uncertainty" which suggest that, even if the DSB were to find Japan's measure inconsistent with the SPS Agreement in this dispute, Japan would still not comply with its SPS Agreement obligations. The Appellate Body should reject Japan's arguments and uphold the Panel findings.

1. The Panel Did Not Err in Describing the Requirements of Article 5.7.

27. Japan argues at paragraphs 93-94 of its Appellant's Submission that the Panel erred in concluding from the first clause of the first sentence of Article 5.7 that, "Article 5.7 was obviously designed to be invoked in situations where little, or no, reliable evidence was available on the subject matter at issue,"^{48/} and that such a situation is not occurring in the present dispute because, among other reasons, there is available "a wealth of information" – a "large amount of relevant scientific evidence" – accumulated for the past 200 years through scientific studies and practical experience.^{49/} According to Japan, the Panel's approach is "too narrow" because, even in the face of generally available literature, there may be "segments of issues where evidence is not available" involving "unresolved uncertainty."^{50/} "Article 5.7 should not be interpreted to be inapplicable as long as there is unresolved uncertainty."^{51/} Further, according to Japan, the Panel's approach does not consider the applicability of Article 5.7 to different types of situations, and suggests that the Panel's approach would somehow preclude a measure from meeting Article 5.7's requirements if based on "new uncertainty."^{52/}

^{48/} Panel Report, para. 8.219.

^{49/} Panel Report, paras. 8.216, 8.219.

^{50/} Japan's Appellant's Submission, paras. 94, 98.

^{51/} Japan's Appellant's Submission, para. 109.

^{52/} Japan's Appellant's Submission, paras. 96, 100-101.

28. Japan's arguments amount to a misrepresentation of the Panel's analysis, designed to justify Japan's position that it is entitled to maintain its fire blight measure so long as it can identify any speculative uncertainty in the evidence, however irrelevant or peripheral, and to support a reading of Article 5.7 apparently designed to justify Japan's non-compliance in this dispute should the DSB find Japan's measure to be WTO-inconsistent. In fact, the Panel largely addressed Japan's arguments in the interim review section of its report, emphasizing – as Japan pointedly does not – that Article 5.7 speaks of “relevant” scientific evidence:

It is possible that, in a given situation, a lot of scientific research may have been carried out on a particular issue without yielding sufficiently “relevant” – within the meaning of Article 5.7 – or reliable evidence. In such a case, however, there is little or no reliable evidence on the subject matter at issue. What Japan addresses in its comment on paragraph 8.219 is, in fact, a question of weighing the evidence before the Panel. We have carefully reviewed the material submitted in this case and found that the present situation was one where a lot of “relevant scientific evidence” had already been accumulated. Our assessment was not simply quantitative; it was also qualitative, as demonstrated by the position we have taken on van der Zwet *et al.* (1990) on the basis, *inter alia*, of the opinion of experts consulted by the Panel.[footnote omitted]^{53/}

29. In other words, the Panel's approach more than accommodates the scenarios Japan posits, including multiple risks and newly discovered risks. The mere fact that some uncertainty exists in the material before a panel, whether so-called “unresolved” or “new,”^{54/} cannot justify the

^{53/} Panel Report, para. 7.9. Japan also argues that it is somehow “[e]qually important[.]” that the United States did not specifically refer to the “200 years of studies and practical experience” noted by the Panel in connection with its arguments relating to Article 5.7. Japan's Appellant's Submission, para. 97. While the United States did not cite the 200 year figure, which Dr. Geider used at the experts' session (Panel Report, Annex 3, para. 336), the United States did emphasize the extensive research which has been conducted on these issues over a number of years (*see* U.S. Answers to Questions from the Panel (Nov. 13, 2002), para. 103), and finds it unlikely that the conclusion of the Panel, or any other rational observer, would change had only 100, or 50, or 5 years of study produced the extensive record of scientific evidence which exists.

^{54/} It is difficult to understand what Japan means when it calls some uncertainty “new.” Japan does not appear to be claiming that what was certain has somehow become uncertain. Rather, Japan appears to consider that each area where Japan can point out that there is not yet

conclusion that relevant scientific evidence is insufficient. Such a conclusion must be based on an assessment of the evidence itself. For example, as discussed above, the fact that there is no conclusive evidence as to the means by which prior cases of trans-oceanic dissemination occurred cannot be considered relevant to the question of whether mature apple fruit transmit fire blight in the face of specific, direct, and voluminous evidence that mature apple fruit do not transmit it. That evidence is based – among other reasons – on the demonstrated lack of susceptibility of mature apple fruit to fire blight infection, to the endophytic presence of *E. amylovora* bacteria, or to the epiphytic presence in populations capable of transmitting the bacteria.^{55/}

30. Further, it is worth recalling the context provided by the remainder of Article 5.7 and by Article 5 when examining the concept of “sufficiency.” Article 5 is captioned, “Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection.” The second sentence of Article 5.7 indicates that this paragraph does, in fact, relate to the assessment of risk. The second sentence requires that Members adopting provisional measures must seek to “obtain *additional* information necessary for a more objective assessment of risk.” The negative implication is that, at the time the provisional measure is adopted, the information necessary for an objective assessment of risk is lacking.

31. This is only logical. If there were sufficient information to conduct a risk assessment and that information supported a measure, there would be no need to adopt a measure “provisionally,” since it could be adopted “based on” the risk assessment pursuant to Article 5.1. Likewise, if there were sufficient information to conduct a risk assessment and that assessment

sufficient scientific experiments or other evidence is somehow “new” uncertainty, rather than uncertainty that has always existed.

^{55/} Further, the Panel points out that, as noted by Dr. Smith, “not only was there no evidence that fruits had ever introduced fire blight to an area, but there was also no necessity to invoke such an improbable pathway since there were much more probable alternatives.” Panel Report, para. 8.149, *citing* para. 6.31. The Panel further notes in footnote 310 that, “The most probable route identified by the experts was the entry of infected planting materials.”

indicated that a measure were *not* justified, a Member which would not be able to adopt a measure under Article 5.1 should not then be free to adopt a measure “provisionally” under Article 5.7. Otherwise, the obligation in Article 5.1 would become meaningless.

32. The conclusion that sufficiency in the first sentence of Article 5.7 should be understood to relate to the information available for a risk assessment is also supported by the language of the second clause of that sentence: “In cases where relevant scientific evidence is insufficient,” provisional measures may be adopted “on the basis of available pertinent information including that from the relevant international organizations as well as from ... phytosanitary measures applied by other Members.” It would not be necessary to adopt a measure “on the basis of” such “available pertinent information” if the measure could be “based on” a risk assessment (which presupposes that there is sufficient scientific information to conduct the risk assessment).^{56/}

33. Thus, the Panel correctly identified its task as determining whether the “relevant scientific evidence” before it was sufficient, based on a consideration of all of the evidence, regardless of which position it favors,^{57/} and regardless of whether that evidence resolves every speculative uncertainty, of new or long-standing provenance. Japan’s argument that the Panel misstated the first requirement under Article 5.7 is incorrect, and the Appellate Body should reject it.

2. Japan’s “Unresolved Uncertainty” Does Not Change the Panel’s Conclusion That Japan Has Not Met the Requirements of Article 5.7.

34. As discussed above, the mere existence of uncertainty in the scientific evidence before a

^{56/} The United States wishes to note that a Member wishing to adopt a measure is always obligated to attempt to assess the risks to which the measure is addressed, regardless of whether the measure is permanent or provisional. The need for a “*more* objective assessment of risk” set forth in the second sentence of Article 5.7 indicates that an attempt must still be made to assess risks on the basis of available pertinent information, even if the assessment does not otherwise meet the requirements of Article 5.1.

^{57/} See Panel Report, paras. 8.216, 8.220.

Panel has no necessary bearing on whether the relevant scientific evidence is insufficient for purposes of Article 5.7. For this reason alone, Japan's suggestion that relevant evidence cannot be sufficient if there is uncertainty with respect to a measure or risk is incorrect. In addition, however, the examples of "unresolved uncertainty" cited by Japan in support of its Article 5.7 argument do not even constitute relevant scientific evidence.

35. For example, Japan refers to expressions by the experts on the need for caution, alleging that they "acknowledg[ed] that the requirement of a fire-blight free orchard was reasonable," and that they "voiced a strong reservation about the possibility that Japan is forced to remove all measures in one step."^{58/} However, by the experts' own admission, these statements were not based on scientific, but on policy, judgments. According to Dr. Smith, "I am not sure this is something that has to be argued in scientific terms. It is a matter of public policy."^{59/} Indeed, Dr. Hayward was struck by the contradiction between Dr. Smith's suggestion that fruits continue, for some period, to be exported from a fire-blight free orchard with Dr. Smith's scientific observation that, despite the fact that apple fruits in Europe have been traded completely freely between European countries – with "no orchard inspections, no registration of orchards, no phytosanitary certificates, no interference of plant health authorities in any way at all in the trade in apples" – "nobody can cite an instance when fruits have transmitted fire blight."^{60/} 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

^{58/} Japan's Appellant's Submission, para. 107.

^{59/} Panel Report, Annex 3, para. 423.

^{60/} Panel Report, Annex 3, para. 411.

blight.^{61/}

36. Dr. Smith's answer is revealing, for, in addition to making the unremarkable observation that "it is impossible to say that it has never happened," he states that he was offering his interpretation not of what the science would support, but what, in his view, is permitted under the SPS Agreement. He 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.^{62/} 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."^{63/}

37. Dr. Geider, as well, indicates that his observations on post-dispute settlement measures arise from non-scientific considerations. In response to a request from Japan on what might occur over "the next 25 years," Dr. Geider expressed his discomfort ("[y]ou are asking us a little bit too much"), then queried, if fire blight were introduced to Japan through a means other than

^{61/} Panel Report, Annex 3, para. 415.

^{62/} Panel Report, Annex 3, para. 416. Dr. Smith stated:

In my written replies, I used the wording "appropriate level of protection" because the Members of the WTO have the possibility of deciding on different measures on the basis of the same scientific evidence if they choose to do so. Although from a scientific point of view it might appear to us as experts that there was inconsistency in the approaches of the authorities in different countries, countries have the sovereign right to decide that they will take more stringent measures in the face of the same risk.

The Panel Chair followed up this statement with the observation, ". . . Subject to the provisions of the SPS Agreement." Panel Report, Annex 3, para. 417.

^{63/} Panel Report, Annex 3, para. 419.

apple fruit at the same time fruit were being imported, "Would you blame us that we were not strict enough to seize that situation and that this is the situation which cannot be foreseen?"^{64/} Likewise, Dr. Geider responded to a Japanese question on whether all measures 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."^{65/}

38. It is understandable that the experts, believing they were being asked to decide on how Japan should implement DSB recommendations and rulings in this dispute should the DSB find against Japan, would be uncomfortable with this role, and might, out of this discomfort or their own sense of policy (or WTO legal) considerations, suggest a "compromise." However, the role of experts in a dispute is to assist the Panel with its understanding of the scientific evidence, and not to suggest implementation compromises or the proper interpretation of the SPS Agreement. The experts' statements in this connection were not scientific evidence, which the Panel correctly defined as "evidence gathered through scientific methods," and which "excludes in essence not only insufficiently substantiated information, but also such things as a non-demonstrated hypothesis."^{66/}

39. When offering their views on the scientific record, the experts were clear and unequivocal, concluding that there is no evidence that mature apple fruit will be infected,^{67/} no convincing evidence that mature fruit will harbor endophytic populations of bacteria,^{68/} no

^{64/} Panel Report, Annex 3, para. 398.

^{65/} Panel Report, Annex 3, para. 409.

^{66/} Panel Report, paras. 8.92-8.93.

^{67/} Panel Report, Annex 3, paras. 355-58.

^{68/} Panel Report, Annex 3, paras. 360-63.

evidence that epiphytic calyx populations in mature fruit can infect a mature apple,^{69/} and no evidence that a hypothetically surviving epiphytic calyx population of bacteria would be vectored to a susceptible host.^{70/} This is scientific evidence, whereas compromise solutions inspired by policy or legal judgements from which “uncertainties” are inferred are not scientific evidence and so cannot form the basis of an evaluation of whether the relevant scientific evidence is sufficient.

40. Japan also describes an unpublished study it presented shortly before the experts session^{71/} as “novel,” with the suggestion that this novelty creates uncertainty justifying a conclusion that relevant scientific evidence is insufficient.^{72/} However novel the effort, the conclusion of the experts on this study is that the study did not demonstrate the conclusions Japan ascribed to it, namely that there had been movement of fire blight bacteria into the cortex of mature fruit.^{73/} Likewise, Japan mischaracterizes a statement by the Panel that the prudence displayed by the experts should not be “completely assimilated” to a “theoretical risk” as reflecting a Panel finding that “there still remained unresolved, scientific uncertainty over the risk of shipment of infected apple.”^{74/} Neither of these so-called “uncertainties” alters the Panel’s correct conclusion that as a result of the extensive, direct evidence on fire blight disease created through studies and experience, this is not a case in which “relevant scientific evidence” is insufficient under Article 5.7.

3. Japan’s Conception of “New Uncertainty” Cannot Justify a Measure Under Article 5.7.

^{69/} Panel Report, Annex 3, paras. 365-70.

^{70/} Panel Report, Annex 3, paras. 372-81.

^{71/} The United States notes ironically that, at the interim review stage, Japan argued that scientific evidence which has become available after the date of entry into force of the WTO Agreement should not be included in an assessment under Article 5.7. *See* Panel Report, para. 7.10.

^{72/} Japan’s Appellant’s Submission, para. 108.

^{73/} Panel Report, para. 8.117, *citing* Annex 3, paras. 178, 180, 181,182.

^{74/} Japan’s Appellant’s Submission, para. 106.

41. Japan also suggests, in what appears to be a veiled attempt to justify future non-compliance should the DSB find against it in this dispute, that the very act of removing its current measures creates “uncertainty” justifying continued imposition of the current measures, or some other measure, pursuant to Article 5.7. Japan draws this conclusion from the suggestions of the experts regarding staged removal of the current measures, which, as discussed above, stemmed from their concern over Japan’s “comfort” and from other policy considerations, and not from consideration of the scientific evidence. Japan states that it is not arguing that “a measure, once found inconsistent with the SPS Agreement, could be maintained indefinitely. Under this interpretation, needless to say, the measure could be maintained only as far as it meets the requirements of Article 5.7.”^{75/} Apparently then, Japan considers that it would be entitled to maintain its current measure for some time after adoption of adverse DSB recommendations and rulings in this dispute, through the circular argument that the uncertainties associated with future removal of the measure render the “relevant scientific evidence” insufficient under Article 5.7.

42. There are not yet adopted recommendations and rulings in this dispute, let alone implementation measures, and it would thus be premature to opine on the WTO-compliance of any such hypothetical measures, even if they were within the terms of reference. However, to the extent that Japan is arguing that its current fire blight measure meets the requirements of Article 5.7 by virtue of this “new uncertainty,” it cannot be correct. Hypothetical speculation about the impact of removal of Japan’s measure, any more than other speculation concerning theoretical (and in this case, unspecified) risks, cannot serve as the basis for arguing that a measure meets the requirements of Article 5.7, any more than such speculation can serve as the basis for a risk assessment under Article 5.1.^{76/} Were it otherwise, the exception in Article 5.7 would swallow the whole of the SPS Agreement. In any event, as already discussed, Japan’s discussion of so-called “uncertainty” does not change the record of this dispute, which is an extensive record of

^{75/} Japan’s Appellant’s Submission, paras. 112-115.

^{76/} See *EC – Hormones*, para. 186.

numerous scientific studies and decades of experience with trade in mature apple fruit. That relevant scientific evidence is more than sufficient to undertake an objective assessment of the risks associated with trade in mature apple fruit, and thus the first requirement of Article 5.7 has not been met.

4. Japan Also Failed to Meet the Other Requirements of Article 5.7.

43. As the Panel correctly explained, Article 5.7 sets out four requirements which have to be met for a measure to be justified as a provisional measure:

- (i) The measure is imposed in respect of a situation where “relevant scientific evidence is insufficient”;
- (ii) the measure is adopted on the basis of “available pertinent information”;
- (iii) the Member “seek[s] to obtain the additional information necessary for a more objective assessment of risk; and
- (iv) the Member “review[s] the . . . measure accordingly within a reasonable period of time.”^{77/}

44. The requirements of Article 5.7 are cumulative, and all must be met.^{78/} In addition to the requirements of the first clause of the first sentence of Article 5.7, Japan has not met the other three requirements.

45. As outlined in more detail in the U.S. Answers to Questions from the Panel, paras. 104-109, there is no “available pertinent information” on which its fire blight measure is based, because Japan has cited no specific “available pertinent information” as the basis for its measure. Indeed, there is no such “pertinent information” upon which a measure can be based because

^{77/} Panel Report, para. 8.123, *citing Japan Varietals*, para. 89.

^{78/} Panel Report, para. 8.213, *citing Japan Varietals*, para. 89.

none of the information presented by Japan suggests that mature apple fruit can serve as a pathway for fire blight. Japan's "available pertinent information," like its "scientific evidence," is thus either not "pertinent" to exported apple fruit, or, with respect to its suggested pathway, is little more than speculative.^{79/}

46. Likewise, Japan has not been seeking to obtain the additional information necessary for a more objective assessment of risk. To the contrary, Japan has disregarded multiple pieces of evidence before it concerning the lack of susceptibility of mature apple fruit to fire blight infection and bacterial presence, even when that evidence was compiled in cooperation with Japanese scientists.^{80/}

47. Finally, Japan has not reviewed the measure within a reasonable period of time, since Japan has not examined, let alone sought, information or evidence on critical elements of the pathway for transmission of fire blight. To conclude, Japan's argument that Article 5.7 must be applicable so long as there is any uncertainty highlights its hope that the fire blight measure will be anything but provisional.

48. Thus, Japan meets none of the requirements set forth under Article 5.7. Inasmuch as Japan's failure to meet even one requirement renders Article 5.7 inapplicable, the Appellate Body should uphold the Panel's finding that Japan has failed to establish that its fire blight measure is a provisional measure justified under Article 5.7.

D. *The Panel Correctly Found that Japan's Risk Assessment Did not Meet the Requirements of Article 5.1.*

49. Japan's challenge to the Panel's Article 5.1 finding consists largely of a cursory repetition

^{79/} See U.S. Answers to Questions from the Panel (November 13, 2002), paras. 104-105; U.S. Answers to Additional Panel Questions (January 28, 2003), para. 32.

^{80/} See U.S. Answers to Questions from the Panel (November 13, 2002), paras. 106-107.

of objections which Japan raised at the interim review stage of the Panel proceedings, and which the Panel correctly rejected. In addition, however, Japan also lays bare that to which it alluded in the context of its Article 5.7 argument, namely, that it considers that it would have the right to maintain its fire blight measure even if the DSB were to find Japan's measure inconsistent in this dispute. The Appellate Body should affirm the Panel's Article 5.1 finding, and reject Japan's spurious legal theories on the proper interpretation of Article 5.1.

1. The Panel Was Correct in its Identification of Deficiencies In Japan's Risk Assessment Which Rendered it Inconsistent With the Requirements of Article 5.1.

50. Japan revives criticisms it made at the interim review stage which the Panel properly rejected. For example, Japan criticizes the Panel's conclusion that, although Japan's Pest Risk Assessment ("PRA") addressed general risks from fire blight, it did not address the specific risks, if any, associated with imported apple fruit. Japan admits that the PRA "did not specifically focus on a particular commodity,"^{81/} but argues that this is not necessary, since it is only a "matter of methodology," and under the IPPC Guidelines Japan was free to consider multiple vectors.^{82/}

51. However, as the Panel correctly explained at the outset of its discussion on "specificity," a risk assessment conducted under Article 5.1 of the SPS Agreement should be sufficiently specific to the risk at issue.^{83/} Indeed, it is difficult to conceive how a measure imposed on a particular product could rationally relate to, and thus be based on, an assessment of risks that "did not specifically focus on" that product. The Panel explains in the interim review section of its report that while the IPPC Guidelines do not limit consideration in a risk assessment to just one particular host of a kind of bacteria, "they do require that the risk relating to the particular commodity to be imported be evaluated. In its 1999 PRA, Japan evaluated the risks associated

^{81/} Japan's Appellant's Submission, para. 128.

^{82/} Japan's Appellant's Submission, paras. 127-28.

^{83/} Panel Report, para. 8.267.

with all possible hosts taken together, not sufficiently considering the risks specifically associated with the commodity at issue: US apple fruit exported to Japan.”^{84/}

52. Japan also criticizes the Panel's conclusion that the PRA was deficient because it identifies mere possibilities rather than probabilities. As the Panel explained, Annex A, paragraph 4 of the SPS Agreement requires a risk assessment to contain an evaluation of the “likelihood of entry, establishment or spread of a disease.”^{85/} The Panel noted that the Appellate Body had clarified that an evaluation of likelihood “involves more than a mere identification of ‘possibilities’”. It requires an assessment of *probability* of entry, and in the words of the Appellate Body, ‘probability implies a higher degree or a threshold of potentiality or possibility.’”^{86/} The Panel concluded that Japan's PRA does not meet this requirement, either failing to evaluate the likelihood of entry through apple fruit, or not offering “any precise evaluation of the ‘degree of potentiality’ or probability for the occurrence of the event.”^{87/}

53. Japan suggests that the Panel breached DSU Article 11 by failing to refer to clarifying statements by Japan regarding terms used in the PRA, statements which Japan itself does not refer to in its Appellant's Submission. Likewise, Japan argues that the Panel failed to make an objective assessment under Article 11 with respect to the PRA's examination of pathways. First of all, it appears that Japan has failed to raise its Article 11 claim with respect to the Panel's findings regarding Article 5.1 of the SPS Agreement, in accordance with the Appellate Body's guidance concerning Rule 20(2)(d) of the *Working Procedures for Appellate Review*.^{88/}

^{84/} Panel Report, para. 7.14.

^{85/} Panel Report, para. 8.273.

^{86/} Panel Report, para. 8.273, *citing EC – Hormones*, para. 184 (emphasis in original).

^{87/} Panel Report, para. 8.274.

^{88/} The Appellate Body has recently made clear that an appellant wishing to claim on appeal that a panel has failed to comply with its obligations under DSU Article 11 must include that claim in its notice of appeal. The Appellate Body suggested that a notice of appeal may do so through explicit reference to Article 11, through reference to the language of that article, or through an allegation that the panel “failed to make an objective assessment of the matter before

Notwithstanding this fact, Japan again fails to demonstrate that the Panel's fact finding in its examination of Japan's risk assessment was marked by "egregious errors" of the sort necessary to establish that a Panel failed to make an objective assessment of the facts as required by Article 11.^{89/} Indeed, Japan has no response to the list of deficiencies in Japan's risk assessment confirmed by Dr. Hale and included in the Panel's analysis at paragraph 8.279, which included Japan's failure to address the probability of several steps in the pathway occurring.^{90/} Further, while Japan focuses its criticisms on the Panel's examination of terms used in Japan's risk assessment, the Panel's concerns were broader: "It is not merely the use of some terms that is at issue here, it is the whole approach followed by Japan in undertaking the PRA."^{91/}

54. Japan also faults the Panel for concluding from the PRA's failure to consider alternative measures to those being applied that the PRA failed to meet the requirement in Article 5.1, and in Annex A, paragraph 4, of the SPS Agreement that the evaluation of risk be conducted "according to the sanitary or phytosanitary measures which might be applied." Japan asserts that it performs this assessment in connection with a proposal from an exporting country, but in fact, it failed to do even that, as the United States had proposed alternative measures prior to when Japan performed its PRA in 1999. Even had the United States not done so, as the Panel correctly responded in the interim review section of the report, "nothing in the text of Article 5.1 and Annex A, paragraph 4 suggests that alternative options have to be proposed by the exporting Member."^{92/} The Panel notes that paragraph 4 of Annex A refers to "'the SPS measures which might be applied', thus making it clear that a Member has an obligation to consider other

it, or an objective assessment of the facts of the case." See Appellate Body Report, *United States – Countervailing Measures Concerning Certain Products from the European Communities*, adopted 8 January 2003, WT/DS212/AB/R, paras. 72-75. In the present appeal, Japan's Notice of Appeal does none of these with respect to the Panel's finding regarding SPS Agreement Article 5.1.

^{89/} See *Japan Varietals*, para. 141.

^{90/} Panel Report, para. 8.279.

^{91/} Panel Report, para. 7.16.

^{92/} Panel Report, para. 7.18.

measures than those it actually applies.”^{93/}

55. As Dr. Hale and Dr. Smith observed, the 1999 PRA “appeared to prejudge the outcome of its risk assessment” and that “it was principally concerned to show that each of the measures already in place was effective in some respect, and concluded that all should therefore be applied.”^{94/} The Panel was entirely correct to conclude that the PRA failed to meet the requirements of a risk assessment within the meaning of Article 5.1, for any of the several reasons cited by the Panel.

2. Japan's Stated Intention Not to Comply Should Its Measure be Found Inconsistent Emphasizes the Importance of Clear *Legal* Findings.

56. After discussing, in the context of Article 5.7, one rationale seemingly directed towards retaining its fire blight measure even if the DSB were to find the measure inconsistent with Japan's WTO obligations, Japan offers a second rationale, along with an explicit statement that it intends no change. After arguing over the course of this dispute that its 1999 risk assessment must be evaluated against the information available at the time, an argument it reiterates in its Appellant's Submission, Japan now indicates that it has conducted “an informal risk assessment” on mature, symptomless apples “through argumentation in the course of this proceeding.”^{95/} Japan explains that it “has taken into account the latest data submitted by the United States or New Zealand during the Panel proceeding, and has concluded that they are not yet sufficient to warrant a modification of the current phytosanitary requirements.”^{96/} According to Japan, its informal risk assessment “has substantively fulfilled the risk assessment requirements of Article 5.1 of the SPS Agreement.”^{97/}

^{93/} Panel Report, para. 7.19.

^{94/} Panel Report, para. 8.289, *citing* paras. 6.177, 6.180.

^{95/} Japan's Appellant's Submission, para. 124.

^{96/} Japan's Appellant's Submission, para. 137.

^{97/} Japan's Appellant's Submission, para. 137.

57. It is rare in dispute settlement that a responding Member so clearly illustrates during the proceedings why dispute settlement was necessary in the first place. In its first submission, the United States laid out the history of bilateral discussions with Japan on the issue of fire blight and apples. As that history and Japan's arguments in this proceeding illustrate, the quantity or quality of evidence presented to Japan have been largely irrelevant to its ultimate judgement of that evidence, which has been to offer shifting and scientifically unsound technical reasons for rejection. The only constant has been Japan's refusal to relax its unsupported restrictions preventing imports of apples.

58. Japan has now indicated that it intends to take the same approach with respect to the legal findings which result from this dispute. Japan's position makes it even more essential than usual that those findings be clear, and be clearly grounded in the *legal* rights and obligations of the parties under the SPS Agreement. The role of dispute settlement is "to secure a positive solution to a dispute,"^{98/} and it helps do so by stating clearly the legal rights and obligations of each party.

59. Japan now argues that it not only should have the opportunity to phase out its fire blight measure if the DSB finds that the measure is inconsistent with the SPS Agreement, but that in fact it has a right to continue to maintain this measure, based on spurious legal theories developed from some comments from the experts that did not involve a scientific assessment. It is important that Japan understand that its legal theories are not valid. The mere existence of unspecified and irrelevant "uncertainty" may not substitute for the scientific evidence required under *both* Article 2.2 and Article 5.1 of the SPS Agreement, nor may it serve to justify a measure under Article 5.7. The SPS Agreement, while not standing in the way of legitimate SPS measures, must not be read to provide a loophole to block the market access for which Members have negotiated.

^{98/} Article 3.7 of the DSU.

60. The Panel was correct to find that Japan failed to meet the requirements of Article 5.1, and could have reached that conclusion on the even more fundamental basis that, given the close relationship of Articles 5.1 and 2.2, in the absence of sufficient scientific evidence to maintain a measure under Article 2.2, a measure will lack the rational relationship to a risk assessment required for it to be “based on” that risk assessment under Article 5.1. Such scientific evidence has been lacking since well before Japan imposed its fire blight measures, and nothing which has arisen in the course of this dispute can change that conclusion, notwithstanding Japan’s claims to have conducted a new risk assessment.

III. CONCLUSION

61. Japan’s arguments in its Appellant’s Submission have a common thrust – they are designed to reinterpret the SPS Agreement so as to remove from it any constraints on Members wishing to exclude foreign products without cause. Without such reinterpretations, Japan’s fire blight measure cannot stand under the SPS Agreement: it is maintained without scientific evidence and is not based on a proper risk assessment. Further, the relevant scientific information is not insufficient such that Japan might, had it met other requirements, have justified its measure under Article 5.7 of the SPS Agreement.

62. For the reasons set forth in this submission, the United States therefore respectfully requests that the Appellate Body:

- uphold the Panel’s finding that Japan is maintaining its fire blight measure without sufficient scientific evidence, in violation of Article 2.2 of the SPS Agreement;
- uphold the Panel’s finding that Japan has not met the obligations imposed in the first sentence of Article 5.7 of the SPS Agreement;

- find that Japan has not met the requirements of the remainder of Article 5.7 of the SPS Agreement; and

- uphold the Panel's finding that Japan's fire blight measure is inconsistent with Article 5.1 of the SPS Agreement.

EXECUTIVE SUMMARY

1. The U.S. argued, the experts confirmed, and the Panel concluded that there is not sufficient scientific evidence to conclude, with respect to exported apples – that is, apples which are mature and therefore symptomless – (1) that such apples would harbor endophytic populations of bacteria; (2) that such apples would harbor epiphytic populations of bacteria capable of transmitting *E. amylovora*; (3) that such apples would be infected by fire blight; and (4) that the last stage of the pathway (transmission of fire blight to a host plant) would likely be completed. Accordingly, after also concluding that the wealth of information available on fire blight means that Article 5.7 is not available as justifying Japan's measures under it, the Panel concluded that Japan has breached its obligation under Article 2.2 not to maintain its measure without sufficient scientific evidence. Further, the Panel examined Japan's asserted risk assessment, and found that it failed to meet Article 5.1 requirements on a number of counts.

2. The United States in its Other Appellant's Submission discussed why the Panel erred in extending its analysis to immature fruit, an issue which overlaps with Japan's appeal. With the exception of that issue, however, Japan in its Appellant's Submission fails to identify any legal error justifying reversal of the Panel's findings. Rather, Japan reintroduces discredited evidence and takes issue with how the Panel weighs the evidence, and argues for legal standards rejected in previous SPS disputes that would eviscerate the disciplines of the SPS Agreement. It also misrepresents both the Panel's findings and conclusions and the arguments of the United States. The Appellate Body should reject Japan's efforts and uphold all Panel findings relating to mature fruit, while reversing Panel conclusions relating to immature fruit, as set forth in the U.S. Other Appellant's Submission. To the extent the Appellate Body considers that the Panel was correct to examine immature fruit, all findings relating to that product should stand.

3. Japan fundamentally misunderstands the scientific method and scientific evidence. A consistent theme runs through Japan's Appellant's Submission. For Japan, a Member may stop or restrict imports unless there is total scientific certainty about every conceivable aspect of a

product. In other words, under the SPS Agreement, mere speculation and conjecture are sufficient foundation for a measure. Japan's approach would stand the SPS Agreement on its head. Rather than requiring that a Member not maintain a measure without sufficient scientific evidence, a Member could maintain a measure unless there is absolute scientific certainty. Of course, this also requires standing the scientific method on its head. Science is not about certainty, and cannot provide certainty, as the experts confirmed during the Panel hearings. Science is about testing hypotheses using real data and evidence. Japan's approach is fundamentally flawed and should be rejected.

4. In its Appellant's Submission, Japan argues that the Panel erred in offering findings on infected apples, with respect to which the United States presented no claims. While this argument distorts the U.S. argument – the United States presented no claims with respect to immature apples, the only apples which might be infected – the United States agrees that the Panel should not have issued conclusions and findings with respect to immature, potentially infected, apples. However, as explained in the U.S. Other Appellant's Submission, the United States considers that the Panel error identified by Japan requires that *all* Panel conclusions with respect to immature and/or infected apples be reversed or considered without effect, including its discussion of whether infected apples themselves are capable of harboring populations of bacteria which could survive commercial handling, storage and transportation, and that errors of handling or illegal actions are risks that may, "in principle," legitimately be considered by Japan. In this regard, it is important to bear in mind that while the United States put forward no claims with respect to these topics, *Japan* also put forward no scientific evidence on these topics. However, the United States notes that reversal of Panel findings with respect to immature and infected apples should not affect the Panel's conclusion in paragraph 8.166 on completion of the pathway as it relates to mature fruit, with respect to which the United States fully met its burden. Further, to the extent that the Appellate Body concludes that the Panel did not err in examining immature fruit, all of its findings with respect to that fruit should stand.

5. If the Appellate Body were to conclude that the Panel had the independent authority to

undertake an analysis of immature fruit, then the Appellate Body should also conclude that the Panel's conclusion in paragraph 8.166 should also extend to immature fruit. There was no scientific evidence supporting the existence of a vector from any apples, whether mature or immature.

6. While the United States agrees with Japan that the Panel's findings and conclusions with respect to immature apples should be reversed, it does not agree that paragraph 8.166 should also be reversed, except to the extent that it and the finding that follows purport to apply to immature apples, for the reasons already described. The structure of Japan's argument (the fact that it is included in a section on "infected" fruit) and several of its statements suggest in fact that it is only challenging the Panel's conclusion with respect to immature apples. To the extent that Japan contends that paragraph 8.166 should be reversed with respect to mature apples, the United States disagrees.

7. Japan criticizes the Panel's fact finding in paragraph 8.166, alleging that it reflects the Panel's failure to discharge its functions under DSU Article 11, and elaborating on this argument over several pages. However, it is clear that Japan's complaint lies in the Panel's assessment of the facts before it and the weight it accorded those facts, and that there is no basis to disturb this finding. By now it is well-established that a breach of Article 11 requires something more than the fact that a Panel declined to accept a particular party's arguments or its views on the conclusions to be drawn from the available evidence.

8. Japan also suggests the existence of legal standards with no basis in the text of the DSU. For example, Japan posits that "independent factual determinations" by panels may only be made if "there is overwhelming evidence supporting that conclusion." There is nothing in the DSU to suggest such a standard. Likewise, Japan resurrects arguments made and rejected in the context of the *Japan Varietals* dispute with respect to a "precautionary principle," suggesting that such a principle required the Panel to conduct its fact finding so as to find for Japan on the existence of a vector to complete the pathway, notwithstanding the absence of any scientific evidence of such

a vector, and the existence of contrary evidence. Japan quotes the Appellate Body report in *Hormones* on the topic of precaution, but only selectively.

9. Japan also seeks to argue that a statement made by the Panel in its interim report concerning “theoretical risk” somehow should have led the Panel to disregard scientific evidence specifically relating to the issue before it on the absence of a vector. Again, Japan appears to suggest a mode of fact finding that requires panels to disregard the facts before them. In this case, Japan relies on a Panel statement not included in the final report, or a revised version of the statement in the final report, which is at best ambiguous and in any event irrelevant to the issue of the existence of a vector.

10. Japan also seeks reversal of the Panel’s finding, with respect to mature apples, that Japan, in breach of SPS Agreement Article 2.2, has not ensured that its fire blight measure is not maintained without sufficient scientific evidence. Again, Japan’s arguments largely amount to efforts to reweigh the evidence before the Panel, and to suggest legal standards that not only are not found in the SPS Agreement, but that would – if accepted – eviscerate the Agreement.

11. Japan has not, with respect to mature apples, argued that the Panel’s fact finding is in breach of DSU Article 11. Under the circumstances, review of Panel fact finding on mature apples is beyond the scope of appellate review. Thus, Japan’s objections to how the Panel weighed the significance of the van der Zwet (1990) study, the history of trans-oceanic dissemination of fire blight, and Japan’s continued, unsupported assertions of the possibility of infection of mature, symptomless apples should, for this reason alone, be rejected, and the Panel’s finding that Japan breached Article 2.2 of the SPS Agreement should be affirmed.

12. To the extent that Japan is considered to have raised legal arguments on Panel fact finding and not simply a reconsideration of that fact finding, the Appellate Body also should reject Japan’s arguments that the Panel somehow erred by not giving sufficient weight to Japan’s own interpretation of the evidence and by not requiring the United States to prove the absence of

scientific evidence.

13. For Japan, the “discretion” of importing Members precludes panels from disagreeing with their judgments, even when unsupported by scientific evidence, as occurred here. However, as the Appellate Body explained in *Australia Salmon* in response to a similar argument by Australia, under the standard set forth in DSU Article 11 to make “an objective assessment of the facts of the case,” panels “are not required to accord to factual evidence of the parties the same meaning and weight as do the parties.”

14. Japan also argues that the Panel erred because it should have found that the United States failed to “prove absence of scientific evidence in other material aspects.” In so arguing, Japan appears to suggest that it was incumbent upon the United States as complaining party to foreclose any and all speculation on hypothetical risks in order to meet its burden under Article 2.2.

15. Leaving aside that Japan seeks to reweigh the Panel’s evaluation of the evidence under the pretext of arguing a misapplication of the burden of proof, Japan is incorrect as to the applicable burden of proof. Japan both distorts the applicable burden – in Japan’s characterization, complaining parties must “prove the absence of scientific evidence,” rather than “raise a presumption” that there was no relevant scientific evidence supporting the measure – and also considers that complaining parties must disprove any and all speculation based on any uncertainties in the scientific record. With regard to Japan’s characterization of the burden of proof, Japan itself acknowledges that it would impose on complaining parties an “impossible” task, a proposition that can not be seriously entertained if Article 2.2 is to hold any meaning. The Panel noted this distinction in its report. The Panel correctly assigned the burden of proof in this dispute, and the United States carried its burden.

16. Likewise, it would not be a plausible interpretation to read Article 2.2 as requiring a complaining Member to disprove any speculative scenario that a responding Member suggests. Japan, at various times in its submission, suggests that it may maintain its measure based on

“uncertainty.” It is therefore important to recall the fundamental point that Article 2.2, and the SPS Agreement generally, speaks not of “uncertainty,” but of “scientific evidence.” The Appellate Body has addressed this issue, explaining in *EC – Hormones*,

In one part of its Reports, the Panel opposes a requirement of an “identifiable risk” to the uncertainty that theoretically always remains since science can *never* provide *absolute* certainty that a given substance will not *ever* have adverse health effects.[footnote omitted] We agree with the panel that this theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed.

17. Japan has failed to demonstrate any error with respect to the Panel’s finding that its fire blight measure is inconsistent with Article 2.2 of the SPS Agreement.

18. Japan again suggests that “uncertainty” may trump voluminous, relevant evidence in arguing that the Panel erred in finding that Japan’s fire blight measure failed to meet the requirements of Article 5.7. Further, Japan seeks to interpret the requirements of the first sentence of Article 5.7 so as to authorize its incorrect approach, mischaracterizing the Panel’s explanation of these requirements in order to argue that the Panel erred. Finally, Japan offers disturbing arguments with respect to “new uncertainty” which suggest that, even if the DSB were to find Japan’s measure inconsistent with the SPS Agreement in this dispute, Japan would still not comply with its SPS Agreement obligations. The Appellate Body should reject Japan’s arguments and uphold the Panel.

19. Japan’s arguments amount to a misrepresentation of the Panel’s analysis, designed to justify Japan’s position that it is entitled to maintain its fire blight measure so long as it can identify any speculative uncertainty in the evidence, however irrelevant or peripheral, and to support a reading of Article 5.7 apparently designed to justify Japan’s non-compliance in this dispute should the DSB find Japan’s measure to be WTO-inconsistent. In fact, the Panel largely addressed Japan’s arguments in the interim review section of its report, emphasizing – as Japan pointedly does not – that Article 5.7 speaks of “relevant” scientific evidence.

20. The Panel's approach more than accommodates the scenarios Japan posits, including multiple risks and newly discovered risks. The mere fact that some uncertainty exists in the material before a panel, whether so-called "unresolved" or "new," cannot justify the conclusion that relevant scientific evidence is insufficient. Such a conclusion must be based on an assessment of the evidence itself.

21. Thus, the Panel correctly identified its task as determining whether the "relevant scientific evidence" before it was sufficient, based on a consideration of all of the evidence, regardless of which position it favors, and regardless of whether that evidence resolves every speculative uncertainty, of new or long-standing provenance. Japan's argument that the Panel misstated the first requirement under Article 5.7 is incorrect, and the Appellate Body should reject it.

22. In addition, the examples of "unresolved uncertainty" cited by Japan in support of its Article 5.7 argument do not even constitute relevant scientific evidence.

23. For example, Japan refers to expressions by the experts on the need for caution, alleging that they "acknowledg[ed] that the requirement of a fire-blight free orchard was reasonable," and that they "voiced a strong reservation about the possibility that Japan is forced to remove all measures in one step." However, by the experts' own admission, these statements were not based on scientific, but on policy, judgments. According to Dr. Smith, "I am not sure this is something that has to be argued in scientific terms. It is a matter of public policy." Dr. Geider queried, if fire blight were introduced to Japan through a means other than apple fruit at the same time fruit were being imported, "Would you blame us that we were not strict enough to seize that situation and that this is the situation which cannot be foreseen?"

24. It is understandable that the experts, believing they were being asked to decide on how Japan should implement DSB recommendations and rulings in this dispute should the DSB find against Japan, would be uncomfortable with this role, and might, out of this discomfort or their

own sense of policy (or WTO legal) considerations, suggest a “compromise.” However, the role of experts in a dispute is to assist the Panel with its understanding of the scientific evidence, and not to suggest implementation compromises or the proper interpretation of the SPS Agreement. The experts’ statements in this connection were not scientific evidence, which the Panel correctly defined as “evidence gathered through scientific methods,” and which “excludes in essence not only insufficiently substantiated information, but also such things as a non-demonstrated hypothesis.”

25. Japan also describes an unpublished study it presented shortly before the experts session as “novel,” with the suggestion that this novelty creates uncertainty justifying a conclusion that relevant scientific evidence is insufficient. However novel the effort, the conclusion of the experts on this study is that the study did not demonstrate the conclusions Japan ascribed to it, namely that there had been movement of fire blight bacteria into the cortex of mature fruit. Likewise, Japan mischaracterizes a statement by the Panel that the prudence displayed by the experts should not be “completely assimilated” to a “theoretical risk” as reflecting a Panel finding that “there still remained unresolved, scientific uncertainty over the risk of shipment of infected apple.” Neither of these so-called “uncertainties” alters the Panel’s correct conclusion that as a result of the extensive, direct evidence on fire blight disease created through studies and experience, this is not a case in which “relevant scientific evidence” is insufficient under Article 5.7 of the SPS Agreement.

26. Japan also suggests, in what appears to be a veiled attempt to justify future non-compliance should the DSB find against Japan in this dispute, that the very act of removing its current measures creates “uncertainty” justifying continued imposition of the current measures, or some others, pursuant to Article 5.7. To the extent that Japan is arguing that its current fire blight measure currently meets the requirements of Article 5.7 by virtue of this “new uncertainty,” it cannot be correct. Hypothetical speculation about the impact of removal of its measure, any more than other speculation concerning theoretical (and in this case, unspecified) risks, cannot serve as the basis for arguing that a measure meets the requirements of Article 5.7,

any more than such speculation can serve as the basis for a risk assessment under Article 5.1. Were it otherwise, the exception in Article 5.7 would swallow the whole of the SPS Agreement.

27. In addition to the requirements of the first clause of the first sentence of Article 5.7, Japan has not met the other three requirements. As outlined in more detail in the U.S. Answers to Questions from the Panel, paras. 104-109, there is no “available pertinent information” on which its fire blight measure is based, because Japan has cited no specific “available pertinent information” as the basis for its measure. Likewise, Japan has not been seeking to obtain the additional information necessary for a more objective assessment of risk. Finally, Japan has not reviewed the measure within a reasonable period of time, since Japan has not examined, let alone sought, information or evidence on critical elements of the pathway for transmission of fire blight.

28. Japan's challenge to the Panel's Article 5.1 finding consists largely of a cursory repetition of objections which Japan raised at the interim review stage of the Panel proceedings, and which the Panel correctly rejected. In addition, however, Japan also lays bare that to which it alluded in the context of its Article 5.7 argument, namely, that it considers that it would have the right to maintain its fire blight measure even if the DSB were to find Japan's measure inconsistent in this dispute. The Appellate Body should affirm the Panel's Article 5.1 finding, and reject Japan's spurious legal theories on the proper interpretation of Article 5.1.

29. Japan criticizes the Panel's conclusion that its Pest Risk Assessment (“PRA”) addressed general risks from fire blight, but not the specific risks, if any, associated with imported apple fruit. However, as the Panel correctly explained at the outset of its discussion on “specificity,” a risk assessment conducted under Article 5.1 of the SPS Agreement should be sufficiently specific to the risk at issue. Indeed, it is difficult to conceive how a measure imposed on a particular product could rationally relate to, and thus be based on, an assessment of risks that “did not specifically focus on” that product.

30. Japan also criticizes the Panel's conclusion that the PRA was deficient because it identifies mere possibilities rather than probabilities. As the Panel explained, Annex A, paragraph 4 of the SPS Agreement requires a risk assessment to contain an evaluation of the "likelihood of entry, establishment or spread of a disease." The Panel noted that the Appellate Body had clarified that an evaluation of likelihood "involves more than a mere identification of 'possibilities.'"

31. Japan also faults the Panel for concluding from the PRA's failure to consider alternative measures to those being applied that the PRA failed to meet the requirement in Article 5.1, and in Annex A, paragraph 4, of the SPS Agreement that the evaluation of risk be conducted "according to the sanitary or phytosanitary measures which might be applied." As the Panel correctly responded in the interim review section of the report, "nothing in the text of Article 5.1 and Annex A, paragraph 4 suggests that alternative options have to be proposed by the exporting Member." The Panel notes that paragraph 4 of Annex A refers to "'the SPS measures which might be applied', thus making it clear that a Member has an obligation to consider other measures than those it actually applies."

32. After discussing, in the context of Article 5.7, one rationale seemingly directed towards retaining its fire blight measure even if the DSB were to find the measure inconsistent with Japan's WTO obligations, Japan offers a second rationale, along with an explicit statement that it intends no change. After arguing over the course of this dispute that its 1999 risk assessment must be evaluated against the information available at the time, an argument it reiterates in its Appellant's Submission, Japan now indicates that it has conducted "an informal risk assessment" on mature, symptomless apples "through argumentation in the course of this proceeding."

33. Japan's position makes it even more essential than usual that the findings in this dispute be clear, and be clearly grounded in the *legal* rights and obligations of the parties under the SPS Agreement. The role of dispute settlement is "to secure a positive solution to a dispute," and it helps do so by stating clearly the legal rights and obligations of each party.

34. Japan now argues that it not only should have the opportunity to phase out its fire blight measures if the DSB finds against it, but that in fact it has a right to continue to maintain those measures, based on spurious legal theories developed from some comments from the experts that did not involve a scientific assessment. It is important that Japan understand that its legal theories are not valid. The mere existence of unspecified and irrelevant “uncertainty” may not substitute for the scientific evidence required under *both* Article 2.2 and Article 5.1 of the SPS Agreement, nor may it serve to justify a measure under Article 5.7. The SPS Agreement, while not standing in the way of legitimate SPS measures, must not be read to provide a loophole to block the market access for which Members have negotiated.

35. The Panel was correct to find that Japan failed to meet the requirements of Article 5.1, and could have reached that conclusion on the even more fundamental basis that, given the close relationship of Articles 5.1 and 2.2, in the absence of sufficient scientific evidence to maintain a measure under Article 2.2, a measure will lack the rational relationship to a risk assessment required for it to be “based on” that risk assessment under Article 5.1.

36. Japan’s arguments in its Appellant’s Submission have a common thrust – they are designed to reinterpret the SPS Agreement so as to remove from it any constraints on Members wishing to exclude foreign products without cause. Without such reinterpretations, Japan’s fire blight measure cannot stand under the SPS Agreement: it is maintained without scientific evidence and is not based on a proper risk assessment. Further, the relevant scientific information is not insufficient such that Japan might, had it met other requirements, have justified its measure under Article 5.7.

37. For the reasons set forth in this submission, the United States therefore respectfully requests that the Appellate Body reject Japan’s arguments in their entirety.