*AUSTRALIA - MEASURES AFFECTING THE IMPORTATION OF APPLES FROM NEW ZEALAND*

**(WT/DS367)**

# THIRD PARTY SUBMISSION OF THE UNITED STATES OF AMERICA

**August 1, 2008**

**Table of Contents**

**Table of Reports Cited**

| | |
|---|---|
| *Australia – Salmon (Panel)* | Panel Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/R, adopted 6 November 1998, as modified by the Appellate Body Report, WT/DS18/AB/R |
| *Australia – Salmon (AB)* | Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, adopted 6 November 1998 |
| *EC – Asbestos (AB)* | Appellate Body Report, *European Communities – Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/AB/R, adopted 5 April 2001 |
| *EC – Bed Linen (Article 21.5) (AB)* | Appellate Body Report, *European Communities – Anti-Dumping Duties on Imports of Cotton-Type Bed Linen from India – Recourse to Article 21.5 of the DSU by India*, WT/DS141/AB/RW, adopted 24 April 2003 |
| *EC – Biotech* | Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, adopted 21 November 2006 |
| *EC – Hormones (Panel)* | Panel Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/R, WT/DS48/R, adopted 13 February 1998, as modified by the Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R |
| *EC – Hormones (AB)* | Appellate Body Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998 |
| *EC – Sardines (AB)* | Appellate Body Report, *European Communities – Trade Description of Sardines,* WT/DS231/AB/R, adopted 23 October 2002 |
| *EC – Tubes or Pipe Fittings (AB)* | Appellate Body Report, *European Communities – Anti-Dumping Duties on Malleable Cast Iron Tube or Pipe Fittings from Brazil,* WT/DS219/AB/R, adopted 18 August 2003 |

| | |
|---|---|
| *Japan – Agricultural Products (AB)* | Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R, adopted 19 March 1999 |
| *Japan – Alcohol (AB)* | Appellate Body Report, *Japan – Taxes on Alcoholic Beverages,* WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 1 November, 1996 |
| *Japan – Apples (Panel)* | Panel Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/R, adopted 10 December 2003, as modified by the Appellate Body Report, WT/DS245/AB/R |
| *Japan – Apples (AB)* | Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, adopted 10 December 2003 |
| *Japan – Apples (Article 21.5)* | Panel Report, *Japan – Measures Affecting the Importation of Apples – Recourse to Article 21.5 of the DSU by the United States*, WT/DS245/RW, adopted 20 July 2005 |
| *Korea – Alcohol (AB)* | Appellate Body Report, *Korea – Taxes on Alcoholic Beverages,* WT/DS75/AB/R, WT/DS84/AB/R, adopted 17 February 1999 |
| *Korea – Dairy (AB)* | Appellate Body Report, *Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products*, WT/DS98/AB/R, adopted 12 January 2000 |
| *US – Wheat Gluten (AB)* | Appellate Body Report, *United States – Definitive Safeguard Measures on Imports of Wheat Gluten from the European Communities*, WT/DS166/AB/R, adopted 19 January 2001 |

**Exhibit List**

| Exhibit Number | Title |
|---|---|
| US-1 | Taylor, R.K., Hale, C.N, Gunson, F.A., and Marshall, J.W., *Survival of the fire blight pathogen, Erwinia amylovora, in calyxes of apple fruit discarded in an orchard*, Crop Protection 22 (4): 603-608 (2003) |
| US-2 | Nichols, C.W. and Wilson, E.E., *An outbreak of European canker in California*, Plant Disease Reporter 40: 952-953 (1956) |
| US-3 | Dubin, H.J. and English, H., *Epidemiology of European Apple Canker in California*, Phytopathology: 65: 542-550 (1975) |
| US-4 | Biosecurity Australia Policy Memorandum 2005/20, Revised Draft Import Risk Analysis Report for Apples from New Zealand (December 1, 2005) |
| US-5 | Letter from Michael A. Guidicipietro to Louise Van Meurs (March 29, 2006) |
| US-6 | Dueck, J. and Morand, J.B., *Seasonal Changes in the Ephiphytic Population of Erwinia Amylovora on Apple and Pear*, Canadian Journal of Plant Science 55: 1007-1012 (1975) |

## I. Introduction

1. The United States welcomes the opportunity to provide the Panel with its views in this dispute, in which New Zealand challenges Australia's imposition of phytosanitary measures for the importation of its apples under the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement"). As the Panel is aware, the United States was the complaining party in *Japan – Apples*, a dispute that dealt with fire blight restrictions imposed by Japan for the importation of U.S. apples. In light of that experience, the United States considers it appropriate to offer its views on the scientific evidence and the merits of some of New Zealand's claims, particularly in relation to fire blight. The United States, as a major agricultural exporter and importer, has a strong interest in the proper interpretation and application of the SPS Agreement. It seeks to provide an unbiased view of the scientific evidence in this submission – a view that, with respect to fire blight, was confirmed by the panel and the Appellate Body in *Japan – Apples*.

2. In this submission, the United States first addresses the Panel's obligation under Article 11 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* ("DSU"). The United States then focuses the majority of its discussion on New Zealand's claims that Australia's measures are maintained without sufficient scientific evidence in violation of Article 2.2 and are not based on a risk assessment under Article 5.1 of the SPS Agreement. The United States also provides a short discussion of its understanding of Article 5.5 and offers its views on New Zealand's Article 5.6 claim for fire blight. Finally, the United States briefly highlights its own experience relevant to New Zealand's claim of undue delay pursuant to Article 8 and Annex C.

## II. The Panel Should Make An Objective Assessment of the Matter Before It Pursuant to Article 11 of the DSU

### A. The Applicable Standard of Review

3. In the view of the United States, Australia has failed to correctly set forth the applicable standard of review in this dispute. Although Australia recognizes that Article 11 of the DSU provides the standard of review for panels in disputes under the WTO covered agreements, including the SPS Agreement,[1] it then advances a view of the standard of review that is inconsistent with Article 11. Australia maintains that the Panel should provide it "considerable deference" in assessing the scientific basis of sanitary and phytosanitary ("SPS") measures evaluated in its risk assessment. But such an interpretation does not comport with Article 11.

4. Article 11 requires a panel to make "an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements." In *EC – Hormones*, the Appellate Body elaborated on the

[1] The United States notes that the *SPS Agreement*, like almost all other WTO agreements, does not prescribe a particular standard of review or include specific provisions addressing the review by a panel of a determination or examination conducted by a national authority. *EC – Hormones (AB)*, paras. 114-116.

meaning of Article 11 and the proper standard of review. It explained that the standard under Article 11, "is neither *de novo* review, as such, nor 'total deference,' but rather the 'objective assessment of the facts'. Many panels have in the past refused to undertake *de novo* review, wisely, since under current practice and systems, they are poorly suited to engage in such a review. On the other hand, 'total deference to the findings of national authorities', it has been well said, 'could not ensure an 'objective assessment' as foreseen by Article 11 of the DSU."[2]

5. The Appellate Body echoed these statements in *Japan – Apples*, regarding "the question of the standard of review that a panel should apply in the assessment of scientific evidence submitted in proceedings under the SPS Agreement."[3] The Appellate Body stated that "Article 11 of the DSU sets out the applicable standard, requiring panels to make an 'objective assessment of the facts'." It further explained that, "as regards fact-finding by panels and the appreciation of scientific evidence, total deference to the findings of the national authorities would not ensure an objective assessment as required by Article 11 of the DSU."[4]

6. Although Australia states that "total deference" is not required, it is difficult for the United States to see how the "considerable deference" that Australia advocates can be reconciled with a panel's obligation to make "an objective assessment of the facts" under Article 11. In Australia's view, when a Member has a comprehensive risk assessment, "it is incumbent on panels to accord considerable deference (but not total deference) to that assessment."[5] Likewise, "a panel should show considerable deference to the findings reflected in the risk assessment."[6] The Panel "must refrain from conducting a *de novo* review of the evidence (that is, to assess the evidence *anew*) or to re-do" Australia's risk assessment.[7] Australia further argues that there is no need for the Panel to conduct an "intense scrutiny of the scientific evidence" to satisfy its obligation to conduct an objective assessment of the facts unless New Zealand demonstrates a lack of "reasonable confidence in the risk assessment."[8] Australia then concludes that applying the appropriate standard of review "means that the Panel may not intervene in the findings or conclusions of the Final IRA Report unless New Zealand has established that it is so seriously flawed that the Panel cannot have reasonable confidence in it."[9]

---

[2] *EC – Hormones (AB)*, para. 117.

[3] *Japan – Apples (AB)*, para. 165.

[4] *Japan – Apples (AB)*, para. 165.

[5] Aus. First Written Submission ("FWS"), para. 191.

[6] Aus. FWS, para. 201.

[7] Aus. FWS, para. 196.

[8] Aus FWS, para. 206.

[9] Aus. FWS, para. 207.

7. Adopting the deferential standard of review advocated by Australia would be tantamount to making the same mistake that the Appellate Body cautioned against in *EC – Hormones* when the European Communities argued in favor of a "deferential 'reasonableness' standard."[10] In the words of the Appellate Body, "[t]o adopt a standard of review not clearly rooted in the text of the *SPS Agreement* itself, may well amount to changing that finely drawn balance [between the jurisdictional competences conceded by the Members to the WTO and the jurisdictional competences retained by the Members for themselves]; and neither a panel nor the Appellate Body is authorized to do that."[11] In the view of the United States, the Panel need not determine that Australia's risk assessment "is so seriously flawed that the Panel cannot have reasonable confidence in it" in order to make findings regarding its consistency with the SPS Agreement. Rather, the Panel should make an objective assessment of whether the scientific evidence presented in Australia's risk assessment support the conclusions of that risk assessment and whether Australia's measures based on that risk assessment are consistent with the SPS Agreement.

8. Finally, the United States notes that Australia also asserts that the requirement to have "an objective assessment of the facts" varies across the covered agreements, and even across particular obligations within the same agreement.[12] For instance, Australia argues for considerable deference on scientific issues, but maintains that only "a relatively low level of deference" is necessary for a Member's decisions pertaining to trade issues, such as whether a disguised restriction on trade exists under Article 2.3 or Article 5.5.[13] But, in the view of the United States, there is no support in the text of the SPS Agreement for what amounts to a "specifically applicable" standard of review for certain types of claims. The United States submits that proper standard of review is clearly articulated in Article 11 and requires the Panel to make "an objective assessment of the facts" regarding all of the claims brought by New Zealand in this dispute.

### B. The Relevance of Prior Panel and Appellate Body Reports

9. The United States considers that a panel's obligation to make "an objective assessment of the facts" pursuant to Article 11 is also important to understanding the relevance of reports by prior panels and the Appellate Body. The United States is of the view that adopted reports by prior panels and the Appellate Body should be considered for their persuasiveness, but they are not binding on subsequent panels and need not be followed.

---

[10] *EC – Hormones (AB)*, para. 113.

[11] *EC – Hormones (AB)*, para. 115.

[12] Aus. FWS, para. 176.

[13] Aus. FWS, paras. 189-190.

10. The nature of prior adopted panel reports was considered by the Appellate Body in *Japan – Alcohol (AB)*. There, the Appellate Body explained:

> Adopted panel reports are an important part of the GATT *acquis*. They are often considered by subsequent panels. They create legitimate expectations among WTO Members, and therefore, should be taken into account where they are relevant to any dispute. However, they are not binding, except with respect to resolving the particular dispute between the parties to that dispute. In short, their character and their legal status have not been changed by the coming into force of the *WTO Agreement*.[14]

11. In *Japan – Apples*, the panel and Appellate Body reports addressed issues and scientific evidence that are relevant to this dispute. The United States submits that the Panel in this dispute is not bound by the prior adopted reports in *Japan – Apples*. Although the United States encourages the Panel to consider the findings and conclusions of the panel and Appellate Body in that dispute to the extent that they are relevant and persuasive, particularly in relation to fire blight, the Panel must make its own "objective assessment of the matter before it." Australia appears to share this view in light of its statement that it is essential for the Panel "to fulfil its mandate to make an 'objective assessment' of the matter pursuant to Article 11 of the DSU, rather than adopting the findings of the *Japan – Apples* dispute as New Zealand suggests."[15]

## III. Article 2.2 of the SPS Agreement Requires Sufficient Scientific Evidence to Maintain a Measure

### A. Legal Standard

12. Article 2 of the SPS Agreement is entitled "Basic Rights and Obligations." Article 2.1 states that "Members have the right to take sanitary and phytosanitary measures necessary for the protection of . . . plant life or health, provided that such measures are not inconsistent with this Agreement." Article 2.2 requires WTO Members to "ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect . . . plant life or health, is based on scientific principles, and is not maintained without sufficient scientific evidence."

13. In this dispute, New Zealand claims that Australia's measures are maintained without sufficient scientific evidence, in violation of Article 2.2. In *Japan - Agricultural Products*, the panel and the Appellate Body examined the obligation not to maintain an SPS measure without sufficient scientific evidence. Both the panel and Appellate Body read this phrase in light of the ordinary meaning of the word "sufficient" ("of a quantity, extent, or scope adequate to a certain purpose or object") and in the context of Article 5.1 (there must be a rational relationship

---

[14] *Japan – Alcohol (AB)*, p. 14 (internal footnote omitted).

[15] Aus. FWS, para. 26.

between a risk assessment and an SPS measure), Article 3.3 (a scientific justification for an SPS measure exists if there is a rational relationship between the SPS measures and available scientific evidence), and Article 5.7 (providing a qualified exemption from Article 2.2 for provisional SPS measures where "relevant" scientific evidence is insufficient).[16] The Appellate Body affirmed the conclusion of the panel that the obligation in Article 2.2 not to maintain an SPS measure "without sufficient scientific evidence" requires that "there be a rational or objective relationship between the SPS measure and the scientific evidence."[17] Furthermore, "[w]hether there is a rational relationship between an SPS measure and the scientific evidence is to be determined on a case-by-case basis and will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence."[18] In *Japan – Apples*, the Appellate Body noted that Panel was correct in conducting its assessment of the scientific evidence on the basis of this interpretation of Article 2.2.[19]

### B. Article 2.2 is a Separate Obligation from Article 5.1

14. Australia maintains that because Article 5.1 may be viewed as a specific application of Article 2.2, "Article 5.1 and the associated provisions elaborate specific conditions which, if met, will *positively establish* consistency with Article 2.2."[20] Australia draws support for its contention from statements by the Appellate Body that Article 2.2 and Article 5.1 should "constantly be read together" and that the basic obligation set out in Article 2.2 imparts meaning to Article 5.1.[21] The United States agrees that Article 2.2 and Article 5.1 provide relevant context for each other, but that does not mean that a panel must first examine consistency with Article 5.1 rather than with Article 2.2. Rather, as in *Japan Apples*, it is possible to examine separately whether a measure is based on sufficient scientific evidence.

### C. There is No Scientific Evidence that Mature, Symptomless Apples Transmit Fire Blight or Serve as a Pathway for Disease

15. As the complaining party in *Japan – Apples*, the United States has significant experience with the extensive scientific evidence regarding fire blight. As was also case during that dispute, there is still no scientific evidence that mature, symptomless apples transmit fire blight disease.

---

[16] *Japan – Agricultural Products (AB)*, paras. 73-80.

[17] *Japan – Agricultural Products (AB)*, para. 84.

[18] *Japan – Agricultural Products (AB)*, para. 84.

[19] *Japan – Apples (AB)*, para. 162.

[20] Aus. FWS, para. 225 (emphasis original).

[21] Aus. FWS, para. 215 (citing *EC – Hormones*, *Australia – Salmon*, and *Japan – Agricultural Products*).

The scientific evidence further demonstrates that apples are not a pathway for the disease.[22] And Australia has provided no scientific evidence establishing either that mature, symptomless apples transmit fire blight disease or that they are a pathway for disease. Accordingly, the United States considers that the measures that Australia imposes on apples from New Zealand are maintained without sufficient scientific evidence, in violation of Article 2.2 of the SPS Agreement.

### 1. Mature, Symptomless Apples Do Not Transmit Fire Blight

16. The vast scientific literature on fire blight establishes that mature, symptomless apples have never transmitted fire blight, nor do they play a role in the transmission of the disease. The United States does not survey all of that evidence here, but instead focuses on two important studies that conducted a critical review of all published data on the presence of *Erwinia amylovora* (fire blight bacteria) on or in mature, export-quality apples and estimated the theoretical probability of transmission of the disease via those fruit. The first study, published by Roberts *et al.* in 1998, was the first of its kind to provide a quantitative estimate of the phytosanitary risks associated with the export of commercial apple fruit from countries where fire blight disease is known to occur to those countries where fire blight disease is not known to occur. This study conducted a thorough review of the scientific literature on fire blight disease in apples, and then incorporated data from that review in its risk analysis based on the relevance of the data to the specific steps in the pathway that must be completed for the spread and establishment of fire blight to countries where it does not exist. The second study, published by Roberts and Sawyer in 2008, updates the 1998 Roberts *et al.* study and re-estimates the likelihood of a fire blight outbreak in areas previously free of the disease, based on new and revised information.[23] Australia attempts to discredit this comprehensive and significant 2008 study because it contradicts the findings of Australia's risk assessment. But as the United States explains below, Australia's contentions lack merit.

17. The Roberts *et al.* (1998) study took into consideration three crucial facts about *Erwinia amylovora*: 1) the survival of epiphytic populations of *Erwinia amylovora* is very short; 2) there is a low incidence of viable populations of *Erwinia amylovora* on mature, symptomless apple fruit at harvest; and 3) there is a lack of a documented pathway by which susceptible host material could become inoculated and infected from fruit-borne inoculum.[24] The study "focuses

---

[22] The International Plant Protection Convention, which provides the framework within which international standards, guidelines, and recommendations for plant health are developed, defines a pathway as "[a]ny means that allows the entry or spread of a pest." International Plant Protection Convention, Glossary of Phytosanitary Terms, at 12 (2001) (International Standards for Phytosanitary Measures Publication No. 5).

[23] Roberts, R.G. and A.J., Sawyer, *An updated pest risk assessment for spread of Erwinia amylovora and fire blight via commercial apple fruit, Crop Protection* 27: 362-368 (2008) (Exhibit NZ-29).

[24] R.G. Roberts *et al.*, *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17: 19-28, 19 (1998) (Exhibit NZ-22).

on the probability of the disease becoming established, via shipments of apple fruit of export quality, in regions where the disease does not exist."[25]

18. To estimate the risk of entry and establishment, the 1998 study used a simple linear model that multiplied the number of fruit being exported[26] by the probability values for five separate steps in the pathway: 1) the probability that fruit is infected or contaminated with *Erwinia amylovora* ("P1"); 2) the probability that *Erwinia amylovora* survives storage, transport, and discard conditions ("P2"); 3) the probability that fruit is discarded or placed near a host ("P3"); 4) the probability that the host is at a receptive stage ("P4"); and 5) the probability that *Erwinia amylovora* is transferred to a new host, and infection occurs ("P5").[27] The figures for these five probabilities were based on data from published scientific studies, or when no data was available, on assumptions based on the documented biology of the disease.

19. Roberts *et al.* (1998) concluded, "[u]sing published data on the incidence of *E. amylovora* on mature, symptomless apple fruit and several conservative assumptions, we have estimated the risk of establishing new outbreaks of fire blight in previously blight-free areas, and found this risk to be extremely low."[28] Elsewhere, the study characterized this risk as "so small as to be insignificant."[29] By way of illustration, the study estimated that in the absence of phytosanitary controls for fire blight, the risk of an outbreak was only once every 11,364 years. The study further found "no evidence in the scientific literature that apple fruit in commercial shipments, whether contaminated with *E. amylovora* or not, have provided inoculum for an outbreak of fire blight. The extremely low probability of new fire blight outbreaks provided by the model is supported by the absence of new outbreaks of fire blight caused by inoculum from commercial fruit, in spite of billions of apples being shipped around the world over many years."[30]

20. Ten years later, the Roberts and Sawyer (2008) study updated the original study by removing inapplicable data, such as that from immature fruit, and adding new relevant data that was published post-1998. For instance, a 2002 paper by Taylor *et al.* reported field experiments

---

[25] R.G. Roberts *et al.*, *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17: 19-28, 20 (1998) (Exhibit NZ-22).

[26] This number was held constant at 20 million apple fruit.

[27] R.G. Roberts *et al.*, *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17: 19-28, 24 (1998) (Exhibit NZ-22).

[28] R.G. Roberts *et al.*, *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17: 19-28, 25 (1998) (Exhibit NZ-22).

[29] R.G. Roberts *et al.*, *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17: 19-28, 19 (1998) (Exhibit NZ-22).

[30] R.G. Roberts *et al.*, *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17: 19-28, 25 (1998) (emphasis added) (Exhibit NZ-22); *see also id.* at 22 (reviewing statements in literature – e.g., Lelliott (1959), Great Britain Ministry of Agriculture, Fisheries, and Food (1969), Schroth *et al.* (1974), and Thomson (1992) – that fruit are not involved in disease spread).

that demonstrated that cells of *Erwinia amylovora* did not move from discarded, contaminated apples to other orchard surfaces via insects, were not transferred to a susceptible host by any other means, and did not cause fire blight disease, even under fire blight conducive conditions extant in orchards.[31] These types of changes to the data significantly reduced two of the probabilities used in the model to estimate the risk of an outbreak of fire blight – the probability that apple fruit is infested with *Erwinia amylovora* (i.e. P1) and the probability that *Erwinia amylovora* survives storage, transport, and discard conditions (i.e. P2).

21. Based on revised data, the Roberts and Sawyer (2008) study explained that the "resulting estimates of the probability of an outbreak of fire blight due to trade in export-quality apple fruit were dramatically lower than those reported in the 1998 PRA [pest risk assessment], even at increased export levels. These changes also greatly enhanced our confidence in current estimates over those in the 1998 PRA because several of the most subjective estimates have been replaced with estimates based upon published data, and demonstrate that the estimated probabilities of spreading *E. amylovora* and fire blight on apple fruit in Roberts *et al.* (1998) were overestimated, even though extremely low." For example, the 1998 study estimated that the likelihood of a fire blight outbreak with no controls in place to be once in 11,364 years, but with the revised data, this estimated risk dropped significantly to only once every 217,926 years. The study further explained that the "new estimates strongly reinforce the conclusion drawn in the original 1998 PRA that international trade of commercial, export quality apple fruit poses a negligible risk of introducing fire blight to importing countries."[32] In describing the risk of transmission as "negligible" rather than "zero," the study merely reflects "the uncertainty that theoretically always remains [that an event may occur] since science can never provide absolute certainty" that an event may never occur.[33]

22. Australia makes three arguments in its effort to discredit Roberts and Sawyer (2008), none of which have any merit. First, Australia asserts that Roberts and Sawyer (2008) should be disregarded because it does not take into account an assessment of unrestricted risk.[34] To the contrary, the paper properly considers unrestricted risk by accounting for it in a manner that addresses the real world situation with apple orchards that may be affected by fire blight. The paper addresses three different scenarios that may occur in an orchard, originally set out in Roberts *et al.* (1998). Scenario 1 ("S1") is orchards with eight measures in place for fire blight. Scenario 2 ("S2") orchards have a few less requirements to protect against fire blight, and

---

[31] Roberts, R.G. and A.J. Sawyer, *An updated pest risk assessment for spread of Erwinia amylovora and fire blight via commercial apple fruit,* Crop Protection 27: 362-368, 363 (2008) (Exhibit NZ-29).

[32] Roberts, R.G. and A.J. Sawyer, *An updated pest risk assessment for spread of Erwinia amylovora and fire blight via commercial apple fruit,* Crop Protection 27: 362-368, 367 (2008) (Exhibit NZ-29).

[33] *EC – Hormones (AB)*, para. 186. Thus, the scientific conclusion that mature, symptomless apple fruit pose a "negligible" or "insignificant" risk of transmitting the disease reflects the scientific evidence that exported apples have never transmitted fire blight and are not a pathway for the disease.

[34] Aus. FWS, paras. 365-368.

Scenario 3 ("S3") orchards have no phytosanitary requirements for fire blight.[35] It is true that S3 includes data from S1 and S2, but this was proper because S3 represents all orchards in an exporting country without restriction. If the study had only considered all of the orchards meeting only the S3 criteria, it would have overestimated the level of apple fruit infestation because the data in the studies used for S3 were preferentially taken from orchards that had fire blight. But not all orchards in either North America or New Zealand have fire blight (many are free of the disease), and assuming that they do (as Australia does in its Importation Step 1 discussed below) biases the model and its application to the real world.[36] Furthermore, Roberts and Sawyer (2008) used a weighted average in including data from S1 and S2 orchards along with data purely from orchards that met the criteria of S3.[37] If the data for S1 and S2 was removed, the probability that apple fruit was infested with *Erwinia Amylovora* (P1) would actually decrease.[38] In other words, including the data from S1 and S2 orchards that had some measures in place for fire blight did not lower the estimate of the risk for S3 in any way.

23. Second, Australia asserts that Roberts and Sawyer (2008) is based on flawed experimental data because some of the studies on which it relied could not detect low numbers of fire blight bacteria on apple fruit.[39] But for the significant portion of the data for which Roberts himself was in control of the experimental methods and detection limits of fire blight bacteria, much lower detection limits were used and still no fire blight bacteria was found on or in mature apple fruit.[40] The basis of Australia's quibble with the data is unclear in light of its statement that

---

[35] R.G. Roberts *et al.*, *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17: 19-28, 19 (1998) (Exhibit NZ-22).

[36] Australia also argues that Roberts and Sawyer (2008) is not relevant to trade in apples between Australia and New Zealand because most of the data used in the paper was from North America rather than New Zealand. Aus. FWS, para. 366. But for fire blight, the location of the study is not relevant because the biology of the disease is the same regardless of location.

[37] "For P1, S3: P1 for S3 is estimated as 0.0013817. From nine trials marked S3 but not S2 or S1, 3,144 mature fruit were tested and 63 were found to be externally contaminated with Ea, giving a contamination rate of 0.0200382 for orchards meeting only S3 requirements (1455, 900, 400, 175, 60, 54, 40, 40, 20, Revised Table 1). As 95% of apples met either S1 or S2 requirements, 5% of the apples met only S3 requirements. Thus, a weighted average is calculated a follows:

5/100 x 0.0200383 = 0.0010019 (S3 orchards only)
95/100 x 0.0003988 = 0.0003798 (orchards meeting S1 and S2 requirements)
0.0013817"

Roberts, R.G. and A.J. Sawyer, *An updated pest risk assessment for spread of Erwinia amylovora and fire blight via commercial apple fruit, Crop Protection* 27: 362-368, 366 (2008) (Exhibit NZ-29).

[38] This is determined by subtracting 0.0003798 (S1and S2 orchards) from 0.0013817 (total estimate) to get 0.0010019, which is only the S3 orchards.

[39] Aus. FWS, para. 369.

[40] This data came primarily from Roberts et al. (1989). *See* Roberts, R.G., S.T. Reymond and R.J. McLaughlin, *Evaluation of mature apple fruit from Washington State for the presence of E. amylovora,* Plant Disease 73, 917-921 (1989) (Exhibit NZ-97). This study had the greatest effect on the numbers used in Roberts *et*

its risk assessment had a smaller lower value for the probability that fruit is contaminated with *Erwinia Amylovora* than Roberts and Sawyer (2008) estimated.[41]

24. Australia also seeks to have it both ways by questioning the data used in Roberts and Sawyer (2008), but then arguing that this data supports some of the findings of its risk assessment. Australia maintains that the maximum value in its risk assessment for the probability that *Erwinia amylovora* transfers to a new host and initiates infection is less than one-tenth the value for the same probability found in Roberts and Sawyer (2008) derived by multiplying P4 (the probability that the host is at a receptive stage) by P5 (the probability that *Erwinia amylovora* is transferred to a new host, and infection occurs).[42] But probabilities P4 and P5 were only estimates in Roberts *et al.* (1998) that were based on median distributions and given with "much uncertainty" because there was no data. Roberts and Sawyer (2008) then modified the value for P5 based on a 2002 study reporting no transfer of *Erwinia amylovora* from contaminated fruit to receptive hosts in field conditions. Although the 2002 study indicated that the value for P5 should have been zero, Roberts and Sawyer (2008) actually increased the estimate for P5 from 0.0001 to 0.0003, as a result of using the median for a binomial distribution with some data rather than no actual data. Accordingly, it is incorrect for Australia to suggest that these estimates support the figures in its risk assessment.

25. Third and finally, Australia asserts that Roberts and Sawyer (2008) do not justify the use of a 50 percent upper confidence level for some of the probabilities in the transmission scenario, which skews the estimate of the number of years before a fire blight outbreak occurs.[43] But a 50 percent upper confidence level was not improper, and the model used actually overestimated the likelihood of an outbreak. The issue of confidence levels can best be understood in relation to a specific example in the study – the probability that fire blight bacteria is transferred to a new host and infection occurs (P5). For P5, Roberts and Sawyer (2008) used a binomial distribution with a 50 percent upper confidence limit.[44] A binomial formula is most appropriate for an event that either does or does not occur; in this case, either fire blight bacteria can be transferred to a new host and cause infection or it cannot. Although fire blight bacteria has never been demonstrated in laboratory conditions or in nature to transfer to a new host that then becomes infected, the authors chose to assign a distribution value to this event, rather than assigning it a value of zero. Had the authors instead assigned a zero value to P5, as is properly indicated by the scientific

---

*al.* (1998) and Roberts and Sawyer (2008), and it specified a detection limit of approximately 20 and 30 bacterial cells per fruit for internal and external tests, respectively.

[41] Aus. FWS, para. 369.

[42] Aus. FWS, para. 370-371.

[43] Aus. FWS, paras. 372-375.

[44] Roberts, R.G. and A.J. Sawyer, *An updated pest risk assessment for spread of Erwinia amylovora and fire blight via commercial apple fruit*, Crop Protection 27: 362-368, 366 (2008) (Exhibit NZ-29).

data,[45] the value of the entire scenario of transmission of fire blight would have become zero because the various probabilities are multiplied together. In other words, by assigning a distribution value to P5, Roberts and Sawyer (2008) estimated some likelihood of an outbreak of fire blight, rather than dismissing the entire event as virtually impossible.

26. Furthermore, the limits of confidence (or confidence interval) applied to any distribution represents the proportion of samples that might represent the true value and must be a positive number (not zero). But for P5, the data indicates that the actual value based on 1,830 data points for the probability is likely to be zero or near zero. Applying 50 percent as the upper limit of the confidence interval means that fewer samples are needed for the results to reflect the true value. Roberts and Sawyer (2008) used the 50 percent upper limit because the events of P5 are not known to have ever occurred and are highly unlikely to ever occur, which means that this upper limit is adequately robust to estimate the risk of P5. Australia suggests that a higher confidence level is appropriate, requiring many more samples, which falsely increases the likelihood that the transmission scenario for fire blight would occur by reducing the value of the existing data to represent the true value of P5.

27. The key point regarding confidence limits is that Roberts and Sawyer (2008) actually *overestimates* the risk of an outbreak of fire blight through mature, symptomless apples. Even the highest estimates in that study overestimate this risk because the published scientific data indicates that P5 – the transfer of fire blight bacteria from discarded apples to a susceptible host and subsequent development of fire blight disease – does not occur. That Roberts and Sawyer (2008) included a positive value for this step, rather than using actual data (which indicates a zero value), indicates the strong bias towards overestimation of the risk in the binomial model used in the study.

28. The scientific evidence that mature symptomless apples do not transmit fire blight is further supported by U.S. data on trade in apples. The United States is a major exporter of apples, and fire blight has been geographically dispersed in the United States since at least the 1920s.[46] U.S. export statistics indicate that the United States has exported 14 million metric tons of apple fruit, or approximately 64.9 billion apples, over the last 41 years.[47] Nonetheless, there has not been a single instance of fire blight spread through exports of U.S. apple fruit during that time. Moreover, during that time, 7.1 million metric tons of apples, or approximately 32.9 billion apples, went to 18 countries that are identified as being either free of fire blight or from

---

[45] The data used had 1,830 samples in which there was no transmission of fire blight bacteria to a host.

[46] R.G. Roberts *et al.*, *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17: 19-28, 20 (1998) (Exhibit NZ-22).

[47] To estimate the number of fruit that have been exported, official U.S. export data, which is kept by volume, must be converted. Apple sizes range considerably, but assuming that the average exported apple was an "88" in size (88 apples per 42 lb. box), 14 million metric tons is equivalent to approximately 64.9 billion apples.

which no fire blight has been reported.[48] None of these countries impose measures for fire blight of the same variety as those that Australia imposes on apples from New Zealand, and yet none have reported transmission of fire blight through imports of U.S. apples.

### 2. Mature, Symptomless Apples are Not a Pathway for Fire Blight Disease

29. Mature, symptomless apples do not transmit fire blight because they are not a pathway for the disease, and Australia has provided no evidence that proves the contrary. As the United States explained in *Japan – Apples*, the scientific evidence indicates that: (1) *Erwinia amylovora* are not associated internally with mature, symptomless apple fruit; (2) *Erwinia amylovora* are rarely associated externally with mature, symptomless apple fruit, even when harvested from blighted trees and orchards; (3) even if a mature, symptomless apple were externally contaminated with *Erwinia amylovora*, such bacteria are unlikely to survive normal commercial handling, storage, and transport of fruit; and (4) even if the imported commodity were externally contaminated with *Erwinia amylovora*, there is no dispersal mechanism or vector to allow movement of such bacteria from the fruit to a suitable host.[49] Imported apples are not a means of transmission of fire blight bacteria because the chain of transmission – from association of bacteria with fruit to bacterial survival of handling, storage, and transport to vectoring of bacteria to a suitable host – is never completed.[50] Accordingly, the United States considers that Australia lacks a scientific basis to restrict imports of mature, symptomless apple fruit because they are not a pathway for the transmission of the disease.

30. The scientific evidence indicates that mature symptomless apples do not harbor fire blight bacteria internally and that external bacteria on mature, symptomless apples are rarely found. In a 1989 study, Roberts *et al.* found no internal or external bacteria either in or on the surface of 1,555 mature, symptomless apples harvested from blighted orchards in the State of Washington.[51] The Roberts (2002) study cited by New Zealand was a major investigation that sampled 30,900 apple fruit and also found no internal disease symptoms.[52] As part of that study, nine hundred fruit were sampled at harvest from trees that actually had fire blight disease, but no *Erwinia amylovora* were found when scientists from the Japanese and U.S. governments tested them

---

[48] These countries are Chinese Taipei, Hong Kong, Indonesia, Saudi Arabia, Thailand, the United Arab Emirates, Singapore, Malaysia, Venezuela, the Philippines, Colombia, India, Costa Rica, the Dominican Republic, Russia, Panama, Brazil, and China.

[49] *Japan – Apples (Panel)*, para. 4.82.

[50] *Japan – Apples (Panel)*, para. 4.83.

[51] R.G. Roberts *et al.*, *Evaluation of mature apple fruit from Washington State for the presence of Erwinia amylovora*, Plant Disease 73: 917-921 (1989) (Exhibit NZ-97).

[52] NZ FWS, para. 4.11 (citing R.G. Roberts, *Evaluation of buffer zone size on the incidence of* Erwinia amylovora *in mature apple fruit and associated phytosanitary risk*, Acta Horticulturae 590: 47-53 (2002) (Exhibit NZ-20)).

simultaneously. Moreover, the study evaluated an additional 30,000 apples harvested at various distances from these infected trees for the incidence of fire blight disease development during commercial storage, but not a single apple developed the disease.

31. Even in the rare event that mature, symptomless apples were externally contaminated with *Erwinia amylovora*, the bacteria would be unlikely to survive normal commercial handling, storage, and transport conditions. This is evidenced by the Hale and Taylor (1999) study cited by New Zealand, which examined the survival of *Erwinia amylovora* on apple fruit subject to normal commercial cooling and storing by surface-inoculating fruit with varying numbers of bacteria and measuring surviving bacteria after storage.[53] The study found that under both "commercial conditions" and "laboratory conditions," of 570 inoculated fruit, bacteria were eliminated on all but two fruit after storage for 25 days at cool temperatures and 14 days at room temperature. Bacteria were only isolated from some of the fruit that had been inoculated with extremely large numbers of bacteria, levels far higher than those that have been found on harvested mature, symptomless fruit.[54]

32. The scientific evidence further demonstrates that there is no documented vector or dispersal mechanism to transfer external fire blight bacteria from mature, symptomless apple fruit to a susceptible host. As the Roberts *et al.* 1998 literature review explained, "[t]here are no specific pathways recorded that document movement of *E. amylovora* from fruit, either imported or domestic in origin, to susceptible host tissues in an orchard or nursery."[55] This is true despite studies that attempted to vector the bacteria to susceptible hosts. For instance, New Zealand points to a study by Hale *et al.* (1996). In that study, heavily inoculated apple fruit were suspended in the canopy of apple trees "as close as possible to blossom clusters containing open flowers," but there "was no spread of *E. amylovora*" to "any of the immature or mature fruit [in such trees] sampled," and "[n]o symptoms were seen in any blossom clusters" in the immediate vicinity of the inoculated fruit.[56] In a 2003 study, Taylor and Hale placed 1,800 apple fruit that had been contaminated with a marked strain of fire blight bacteria into an orchard. Even under conditions conducive for fire blight development, the discard of contaminated fruit in an orchard led neither to lateral spread of the bacterium to new host material nor to the development of fire

---

[53] NZ FWS, para. 4.18 (citing C.N. Hale & R.K. Taylor, *Effect of cool storage on survival of Erwinia amylovora in apple calyxes*, Acta Horticulturae 489: 139-43, (1999) (Exhibit NZ-24)).

[54] Hale, C.N. and R.K. Taylor, *Effect of cool storage on survival of Erwinia amylovora in apple calyxes*, Acta Horticulturae 489: 139-43, 141 (1999) (Exhibit NZ-24).

[55] R.G. Roberts *et al.*, *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17: 19-28, 23 (1998) (Exhibit NZ-22).

[56] C.N. Hale *et al.*, *Ecology and epidemiology of fire blight in New Zealand*, Acta Horticulturae 411: 79-85, 83 (1996) (Exhibit NZ-27).

blight disease in surrounding trees that could be attributed to the marked strain.[57] Taken together, this scientific evidence indicates that mature, symptomless apples are not a pathway for fire blight disease.

### 3. The Findings of *Japan – Apples*

33. The scientific evidence that mature, symptomless apples do not serve as a pathway for disease was confirmed by the original panel in *Japan – Apples*, and reaffirmed by the compliance panel in that dispute. The *Japan – Apples* panel found that "there is not sufficient scientific evidence to conclude that mature symptomless apples would harbour endophytic populations of bacteria."[58] The panel also concluded that "that there is not sufficient scientific evidence to conclude that mature, symptomless apples are likely to harbour epiphytic populations of bacteria capable of transmitting *E. amylovora*."[59] Additionally, the panel found that "mature apples are unlikely to be *infected* by fire blight if they do not show any symptoms."[60]

34. The *Japan – Apples* panel further concluded that "it has not been established with sufficient scientific evidence that the last stage of the pathway (i.e. the transmission of fire blight to a host plant) would likely be completed."[61] The panel ultimately concluded that "there is not sufficient scientific evidence that apple fruit are likely to serve as a pathway for the entry, establishment or spread of fire blight."[62] In light of that conclusion, the Panel found that some elements of Japan's measure "are not supported by scientific evidence within the meaning of Article 2.2 of the *SPS Agreement*."[63] The Appellate Body upheld the Panel's conclusion.[64]

35. In the compliance proceeding in *Japan – Apples*, the panel recognized the findings of the original panel with respect to the scientific evidence regarding the entry, establishment, and spread of fire blight.[65] It also considered new studies relied upon by Japan that purported to prove that mature apple fruit may be infected by *Erwinia amylovora*, and that the pathway for

---

[57] Taylor, R.K., Hale, C.N, Gunson, F.A., and Marshall, J.W., *Survival of the fire blight pathogen, Erwinia amylovora, in calyxes of apple fruit discarded in an orchard*, Crop Protection 22 (4): 603-608 (2003) (Exhibit US-1).

[58] *Japan – Apples (Panel)*, para. 8.128.

[59] *Japan – Apples (Panel)*, para. 8.136.

[60] *Japan – Apples (Panel)*, para. 8.139 (emphasis original).

[61] *Japan – Apples (Panel)*, para. 8.168.

[62] *Japan – Apples (Panel)*, para. 8.176.

[63] *Japan – Apples (Panel)*, para. 8.199.

[64] *Japan – Apples (AB)*, para. 168.

[65] *Japan – Apples (Article 21.5)*, paras. 8.39-8.40.

transmission of the disease may be completed using common flies as a vector.[66] The panel concluded that these studies did not provide sufficient scientific evidence to establish, in natural conditions, the risks that "(a) mature and symptomless apples can nonetheless harbour endophytic bacteria (latent infection) and that; (b) the pathway would likely be completed between a discarded infested/infected apple and a host plant in Japan, so as to lead to the establishment and spread of fire blight in Japan."[67]

## 4. Australia's Measures for Apples from New Zealand

36. The United States considers particularly problematic some of the measures imposed by Australia that are the same or similar to those that the Dispute Settlement Body ("DSB") in *Japan – Apples (Article 21.5)* found were being maintained without sufficient scientific evidence. For instance, Australia requires apples to be sourced from areas free of fire blight symptoms, orchard inspections, and the suspension of an orchard/block if visual symptoms of fire blight are detected.[68] But the *Japan – Apples (Article 21.5)* panel found that requirements that an "orchard be free of apple trees or other plant infected with fire blight, that the orchard...be inspected once per year at the early fruitlet stage, and that detection of a blighted tree in this area by inspection will disqualify the orchard as a whole cannot be considered to be supported by sufficient scientific evidence."[69]

37. Australia further requires disinfection of apples at the packing house and cleaning and disinfecting of packing house equipment before each Australian packing run.[70] These requirements, however, are contrary to the conclusions of the *Japan – Apples (Article 21.5)* panel that "surface disinfection is not justified by scientific evidence" and that "the scientific evidence does not justify chlorine disinfection of packing facilities in order to prevent contamination of mature, symptomless apples by *E. amylovora*."[71] Australia also requires that packing houses registered for export source apple fruit only from registered orchards, which essentially imposes a separation requirement on apples exported to Australia.[72] But in *Japan – Apples (Article 21.5),* the panel concluded that "separation of fruit destined for Japan is not supported by sufficient scientific evidence."[73] In light of the findings of the *Japan – Apples*

---

[66] *Japan – Apples (Article 21.5)*, para. 8.42.

[67] *Japan – Apples (Article 21.5)*, para. 8.71.

[68] Final Import Risk Analysis Report for Apples from New Zealand ("IRA"), Part B, Biosecurity Australia (November 2006) pp. 106, 316, 318 (Exhibit NZ-1).

[69] *Japan – Apples (Article 21.5)*, para. 8.89.

[70] IRA, p. 318 (Exhibit NZ-1).

[71] *Japan – Apples (Article 21.5)*, paras. 8.97 and 8.102.

[72] IRA, p. 317 (Exhibit NZ-1).

[73] *Japan – Apples (Article 21.5)*, para 8.107.

*(Article 21.5)* with respect to the aforementioned measures, the United States is of the view that the similar measures imposed by Australia are also maintained without sufficient scientific evidence, in violation of Article 2.2 of the SPS Agreement.

### C. The Scientific Evidence on European Canker

38. New Zealand and Australia have set forth competing interpretations of the scientific evidence regarding whether mature, symptomless apples are a pathway for transmitting European canker. The United States does not address all of the scientific evidence in this debate, but instead offers its views below on three key factors necessary for the infection of apple fruit with European canker, in part based on its own experience. These three factors are: 1) conducive climatic conditions; 2) the presence of a susceptible host; and 3) a sufficient concentration of inoculum. Favorable occurrence of all three of these factors is necessary for infection of apple fruit to occur. In light of these three factors, and the U.S. knowledge of the disease, the United States does not consider that Australia has adduced sufficient scientific evidence to establish that apples will be latently infected with European canker and can transfer the disease to susceptible hosts.

39. Preliminary, the United States notes that it is important to distinguish between the infection of trees and the infection of fruit with European canker. Although trees may be infected with European canker, this does not necessarily mean that fruit will likewise become infected. For instance, during a 1956 outbreak of European canker in Sonoma County, California, wood canker was the only phase of the disease that was of concern, and no infection of fruit occurred during the outbreak.[74]

40. Conducive climatic conditions is the first factor that is needed for the infection of apple fruit with European canker. European canker has not been reported as present in the major apple producing regions of central Washington State. The United States believes that the absence of European Canker in these areas is because the climate is not suitable to the development of the disease. A range of factors is necessary for the climatic conditions to be conducive to the infection of apple fruit, including favorable temperatures and the timing, duration, and quantities of rainfall. During a 1965 outbreak of European canker in Sonoma County, California in which fruit were infected, rainfall above 100 centimeters per year, foggy weather, and moderate temperatures seemed to be the unifying factors that resulted in the appearance of the causal organism in the orchards. This outbreak was also the result of favorable epidemiological and biological conditions, such as leaf fall at the appropriate time and conidial production.[75]

---

[74] Nichols, C.W. and Wilson, E.E., *An outbreak of European canker in California*, Plant Disease Reporter 40: 952-953 (1956) (Exhibit US-2).

[75] Dubin, H.J. and English, H., *Epidemiology of European Apple Canker in California*, Phytopathology: 65: 542-550 (1975) (Exhibit US-3).

41. In terms of suitable climatic conditions, a 1975 study by Dubin and English found that several consecutive days of wetness, without a dry period, are necessary to achieve a high level of European canker infection. Conidia – the asexual fungal spores of *Nectria galligena* – are dispersed by water in liquid form and easily dry out, even at high levels of relative humidity. Dubin and English (1975) found that over 90 percent of conidia germinated in water in liquid form, but the ability of conidia to germinate dropped significantly in lower humidity. For instance, spore germination was reduced by half when conidia were subjected to high relative humidity of 100 percent, but with no free water, and temperatures of 19 degrees Celsius for 12 hours.[76] This study indicates that inoculum potential will be lower in periods without rain and when relative humidity falls below saturation.

42. The second factor that is necessary for the infection of apple fruit is the presence of a susceptible host. Although the infection of apple fruit with European canker in the United States is rare, the presence of a susceptible host has been studied in other countries, particularly in relation to the timing of fruit infection. Swinburne (1971) found that fruit in storage were more likely to develop rots if they had been infected on the tree late in the summer.[77] Fruit infected early in the season contained a natural resistance to European canker in the form of benzoic acid, which is toxic to the pathogen.[78]

43. The third factor necessary for infection of apple fruit is a high concentration of spores to serve as an inoculum. Dubin and English (1974) found that five conidia per leaf scar wound were not sufficient to cause infection, 50 conidia per leaf scar wound caused only 20 percent of the leaf scar wounds to be infected, and 500 conidia resulted in infection of 80 percent of the leaf scar wounds.[79] Furthermore, the susceptibility of leaf scar wounds to infection by *Nectria galligena* declines with time. Another study found that only 6 percent of the leaf scar wounds were infected after 28 days, as compared with a 20-percent rate of infection for fresh scar wounds.[80]

44. As for whether European canker infection could be transmitted to a host orchard, apple fruit has never been reported to be an important source of inoculum for the spread of European

---

[76] Dubin, H.J. and English, H., *Effects of Temperature, Relative Humidity, and Dessication on Germination of Nectria Galligena Conidia*, Mycologia: 67: 83-88 (1975) (Exhibit NZ-12).

[77] Swinburne, T.R., *The Seasonal Release of Spores of Nectria Galligena from Apple Cankers in Northern Ireland*, Annuals of Applied Biology. 69: 97-104 (1971) (Exhibit Aus-76).

[78] Swinburne, T.R., *European canker of Apple (Nectria galligena)*, Review of Plant Pathology. 54: 787-799 (1975) (Exhibit NZ-9).

[79] Dubin, H. J. and English, H., *Factors affecting apple scar infection by Nectria galligena conidia*, Phytopathology 64: 1201-1203 (1974) (Exhibit Aus-67).

[80] Wilson, E. E., *Development of European canker in a California apple district*, Plant Disease Reporter. 50:182-186 (1966) (Exhibit NZ-64).

canker. Individual apple fruits that have been discarded on the ground will most likely either decompose or be consumed by animals before any latent infection that might exist would have a chance to cause decay, and the fungus can sporulate. In the unlikely event of an apple fruit producing spores, these spores will be unlikely to cause an infection of European canker in trees because lengthy wet periods, as well as high levels of inoculum, are needed.

45. Furthermore, in the unlikely event that a sporulating apple is discarded on the ground, it would be a poor source of inoculum for trees in an apple orchard because conidia are dependent on splashing rain drops for dissemination, and the concentration of spores a few meters from the sporulating fruit will likely be well below the threshold required for infection. And spores that are dispersed by air will be subject to even greater dilution than spores dispersed by rain. Australia also posits that birds and insects may be a possible means for European canker to be transmitted from a sporulating apple on the orchard floor to a host tree.[81] But there is no scientific evidence that supports this proposition.

46. In closing, the United States notes that Australia's risk assessment acknowledges that fruit are unlikely to spread European canker. The risk assessment states that "[n]o studies exist in the literature to demonstrate long-distance disease spread from fruit infections...."[82] Later, the risk assessment recognizes that, "[t]here is no evidence in the literature that indicates that long-distance spread of the disease is due to movement of fruit." Rather, the risk assessment explains that, "[l]ong-distance movement of European canker is primarily the result of movement of infected nursery stock."[83]

### D. Apple Leafcurling Midge and U.S. Inspection Levels

47. Australia has provided New Zealand with the option of either of two measures to address apple leafcurling midge (ALCM). These options are: 1) inspection of 3,000 fruit sample with application of a suitable treatment or rejection of any lots where ALCM is found, or 2) inspection of a 600 fruit sample with mandatory treatment of all lots for ALCM.[84] In Australia's discussion regarding whether these measures are consistent with Articles 2.2 and 5.1 of the SPS Agreement, it notes that the United States has a regulatory program in place for the export of apples from New Zealand to the United States.[85] The United States makes one point of clarification regarding its regulatory program.

---

[81] Aus. FWS, para. 615.

[82] IRA, p. 142 (Exhibit NZ-1).

[83] IRA, p. 142 (Exhibit NZ-1).

[84] Aus. FWS, para. 954; IRA, pp. 319-322 (Exhibit NZ-1).

[85] Aus. FWS, para. 848.

48. The inspection levels that the United States uses for apples from New Zealand are not targeted to ALCM, but a different pest – light brown apple moth. The United States requires a biometric sampling level for light brown apple moth based on the determination that this moth is a high risk pest with a high likelihood of introduction in the United States, particularly because many different plants may serve as a host for it. The United States determined that a biometrically designed inspection was necessary to provide an adequate level of confidence in detecting light brown apple moth.

## IV. Article 5.1 Requires that SPS Measures Be Based on a Risk Assessment

### A. Legal Standard

49. Article 5.1 of the SPS Agreement provides that "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal, or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations." Article 5.1 may "be viewed as a specific application of the basic obligations contained in Article 2.2 of the SPS Agreement."[86] Thus, reading Article 5.1 in the context of Article 2.2, the obligation that an SPS measure be "based on" a risk assessment "requires that the results of the risk assessment must sufficiently warrant – that is to say, reasonably support – the SPS measure."[87]

50. Paragraph 4 of Annex A (Definitions) of the SPS Agreement provides further context for Article 5.1. Paragraph 4 defines two types of risk assessments. The definition that is relevant in this dispute defines a risk assessment as: "The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences." Thus, as the Appellate Body stated in *Australia–Salmon*, to be consistent with Article 5.1, a risk assessment must:

> (1) *identify* the diseases whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases;
>
> (2) *evaluate the likelihood* of entry, establishment or spread of these diseases, as well as the associated potential biological and economic consequences; and

[86] *EC – Hormones (AB)*, para. 180.

[87] *EC – Hormones (AB)*, para. 193.

> (3) evaluate the likelihood of entry, establishment or spread of these diseases *according to the SPS measures which might be applied*.[88]

51. The Appellate Body further explained in *Australia – Salmon* that "for a risk assessment to fall within the meaning of Article 5.1 and the first definition in paragraph 4 of Annex A, it is not sufficient that a risk assessment conclude that there is a *possibility* of entry, establishment or spread of diseases and associated biological and economic consequences." Rather, a risk assessment "must evaluate the 'likelihood', i.e., the 'probability' of entry, establishment or spread of diseases and associated biological and economic consequences as well as the 'likelihood', i.e., the 'probability' of entry, establishment or spread of diseases *according to the SPS measures which might be applied*."[89] Additionally, in *EC – Hormones*, the Appellate Body noted that a Member should be evaluating ascertainable risk in a risk assessment and that "theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed."[90]

52. In *Japan – Apples*, the Appellate Body determined that the third step of the risk assessment requires an evaluation of SPS measures that might be applied, not simply those that are already in place. According to the Appellate Body:

> The definition of "risk assessment" in the *SPS Agreement* requires that the evaluation of the entry, establishment or spread of a disease be conducted "according to the sanitary or phytosanitary measures which might be applied." We agree with the Panel that this phrase "refers to the measures *which might* be applied, not merely to the measures which *are being* applied." The phrase "which might be applied" is used in the conditional tense. In this sense, "might" means: "were or would be or have been able to, were or would be or have been allowed to, were or would perhaps". We understand this phrase to imply that a risk assessment should not be limited to an examination of the measure already in place or favoured by the importing Member. In other words, the evaluation contemplated in paragraph 4 of Annex A to the *SPS Agreement* should not be distorted by preconceived views on the nature and the content of the measure to be taken; nor should it develop into an exercise tailored to and carried out for the purpose of justifying decisions *ex post facto*.[91]

53. The United States considers that Australia's interpretation of the third step of a risk assessment is not supported by the text of the SPS Agreement or by findings in the Appellate

---

[88] *Australia – Salmon (AB)*, para. 121 (emphasis original).

[89] *Australia – Salmon (AB)*, para. 123 (emphasis original).

[90] *EC – Hormones* (AB), para. 186.

[91] *Japan – Apples (AB)*, para. 208 (emphasis original) (internal footnotes omitted).

Body report that it cites. Australia attempts to draw a distinction between "principal measures" and "ancillary measures," and then argues that there is "no obligation to evaluate every single requirement that is actually imposed, whether it is a principal measure or merely an ancillary requirement."[92] But the text of the SPS Agreement makes no such distinctions. Rather it plainly states that a risk assessment must evaluate the likelihood of entry, establishment, and spread "according to the sanitary or phytosanitary measures which might be applied." There is simply no textual basis for Australia's claim that it need only evaluate "the principal risk reduction measures," that it applies.[93] Not only must Australia evaluate all of the measures that it actually applies, the SPS Agreement requires it to evaluate alternative measures that might be applied.[94]

54. Australia attempts to find support for its position in *Australia – Salmon (AB)* by focusing on the phrase "total risk", and arguing that the Appellate Body's use of this phrase means that a risk assessment must only evaluate the "principal risk reduction measures."[95] But the Appellate Body made no such statement, nor can this interpretation be properly inferred from its language. Rather, in mentioning "total risk," the Appellate Body was simply noting that the Panel made factual findings regarding "the quarantine policy options considered to reduce the total risk associated with all of the diseases of concern."[96] And the Appellate Body found that "*some* evaluation" of the risk reduction factors at issue was insufficient to fulfill the third requirement of a risk assessment.[97]

### B. General Concerns with the IRA

55. Australia's risk assessment is set forth in the document entitled "Final Import Risk Analysis for Apples from New Zealand" ("IRA").[98] New Zealand contends that Australia did not conduct a proper risk assessment for its apples because it failed to evaluate the "likelihood" of entry, establishment, and spread of the diseases at issue. Australia responds that its IRA is

---

[92] Aus. FWS, para. 857. The United States sees no distinction for purposes of the SPS Agreement between principal risk reduction measures and ancillary measures, which Australia states "do not actually reduce the risks themselves, but are required to simply to support, verify, and operationalize the principal risk reduction measures." Aus. FWS, para. 859. For instance, Australia maintains that for fire blight, the requirement that an orchard/block be suspended for the season on the basis of evidence of pruning or other activities that could be an attempt to remove or hide symptoms of fire blight is only an ancillary measure. But to the extent that Australia's view of the science is correct (and the United States maintains that it is not), the suspension of orchards where fire blight may exist could reduce the risk of the spread of the disease.

[93] Aus. FWS, para. 859.

[94] *Japan – Apples (AB)*, para. 208.

[95] Aus. FWS, para. 858.

[96] *Australia – Salmon (AB),* para. 133.

[97] *Australia – Salmon (AB),* para. 134 (emphasis original).

[98] IRA (Exhibit NZ-1).

consistent with Article 5.1 of the SPS Agreement. The United States does not analyze Australia's IRA in full, but instead outlines some of its concerns with the IRA. Some of these concerns relate to the general methodology adopted by Australia, and other concerns are specific to Australia's evaluation of the scientific evidence, particularly with respect to fire blight and European canker.

56. Australia emphasizes that the SPS Agreement does not prescribe a particular methodology for risk assessments and that Members are entitled to determine their own risk assessment methodology.[99] Accordingly, Australia maintains that its use of the semi-quantitative approach to its IRA was appropriate. The United States does not disagree that the choice of a risk assessment methodology is left to individual Members,[100] but notes that Australia has not been consistent regarding its methodological approach – both within the IRA and with respect to other risk assessments that it has conducted for other products. Australia employs a semi-quantitative model in its IRA to estimate the likelihood of entry, establishment, and spread of certain pests – namely fire blight, European canker, apple scab, apple leafcurling midge, and garden featherfoot. Yet, for other pests identified in the IRA, Australia evaluated the risk of entry, establishment, and spread using the qualitative approach that it has primarily employed in past risk assessments. These pests include grey-brown cut worm, leafrollers, codling moth, mealybugs, Oriental fruit moth, and oystershell scale. Australia indicated in its IRA that for this latter category of pests, it was extending the analysis and policy used for these pests for stone fruit from New Zealand.[101] Although Australia's use of a qualitative risk assessment methodology for some pests appears to be based on a prior risk assessment, it is unclear why Australia did not extend that methodology to the new diseases and pests that it was evaluating, such as fire blight and European canker.

57. Australia's semi-quantitative approach to its IRA for apples from New Zealand is also inconsistent with the vast majority of its other publicly available risk assessments. To date, Australia has published 15 final risk assessments and 7 draft risk assessments.[102] Of these 22

---

[99] *See, e.g.,* Aus. FWS, paras. 282, 286.

[100] The United States notes, however, that Article 5.1 states that Members should take "into account risk assessment techniques developed by the relevant international organizations," and the guidelines of the International Plant Protection Conventions are relevant in this dispute.

[101] IRA, p. 12 (Exhibit NZ-1).

[102] Australia's published final import risk assessments have been for Fuji apples from Japan (December 1998), ya pears from China (December 1998), apples from New Zealand (December 1998), mangoes from the Philippines (February 1999), pears from Korea (March 1999), durian from Thailand (November 1999), grapes from the United States (June 2000), sweetcorn seed from the United States (April 2002), pineapples from the Philippines and Thailand (July 2002), maize from the United States (October 2002), mangosteens from Thailand (February 2004), longans and lychees from China and Thailand (February 2004), Tahitian limes from New Caledonia (May 2006). Its published draft risk assessments are for flower bulbs from the Netherlands (November 2000), citrus fruit from Florida, United States (July 2003), grapes from Chile (September 2005), bananas from the Philippines (July 2007), mangoes from India (May 2008), capsicum from Korea (May 2008), stone fruit from the United States (June

risks assessments, in addition to apples from New Zealand, only one other – for bananas from the Philippines – has employed a semi-quantitative model. All of the others have used a qualitative approach. Again, Australia's rationale for generally adopting a qualitative assessment, but using the semi-quantitative approach in limited instances is unclear.

58. In general, a qualitative risk assessment involves identifying the quarantine pests associated with a commodity and likely to follow the pathway of the imported commodity, and then qualitatively assessing the likelihood and consequences of pest introduction. Qualitative assessments are based on available scientific literature, as well as expert opinion.

59. Australia's semi-quantitative approach to the IRA for apples from New Zealand diverges from the qualitative approach. There, Australia sets forth multiple importation steps and multiple distribution points and pathways for the introduction and spread of a pest. It also assigns probabilities to extremely unlikely events that would normally be considered "negligible" in a qualitative assessment or "practically zero" in a quantitative assessment. Because the probabilities for events leading to the introduction of a pest have a multiplicative relationship (that is, the various probabilities are multiplied together), any event that is negligible or zero effectively eliminates the pathway. But by including values for these probabilities, as well as using uniform distributions (which imply no knowledge about the likelihood of a certain event except at the extremes) and large estimates of the volume of trade, Australia reaches exaggerated conclusions regarding the probability of a pathway. Contrary to Australia's view that negligible events should not be treated as a rupture in the pathway, it is impractical and unproductive to consider pathways with events that approach a probability of zero. This is particularly true because estimates are generally based on conservative assumptions in the absence of or with unclear data, which means that the actual conditions are more likely to be closer to zero.

60. The U.S. concerns with Australia's IRA for apples from New Zealand are not new. In December 2005, Australia released a draft of the IRA for apples from New Zealand for public comment.[103] In March 2006, the United States submitted comments to Australia as part of this process that expressed its concerns, particularly with respect to fire blight. In its comments, the United States explained that it considered the draft IRA "severely flawed, particularly for fire blight and the other diseases for which [Biosecurity Australia] developed semi-quantitative models."[104] The United States also addressed some more general concerns and provided specific information on particular problems with Australia's analysis. For instance, the United States explained that Australia "should clearly and transparently present the final assumptions on which the statistical ranges are based for each variable of the model and the final calculations" because

---

2008), and unshu mandarins from Japan (July 2008). *See* http://www.daff.gov.au/ba (last visited July 30, 2008).

[103] Biosecurity Australia Policy Memorandum 2005/20, Revised Draft Import Risk Analysis Report for Apples from New Zealand (December 1, 2005) (Exhibit US-4).

[104] Letter from Michael A. Guidicipietro to Louise Van Meurs (March 29, 2006) (Exhibit US-5).

in many cases, the defined statistical range is not supported by the scientific evidence.[105] Based on the U.S. review of Australia's final IRA for apples from New Zealand, it does not appear that Australia revised its IRA in a manner that addresses the problems identified by the United States. Although the United States does not repeat all of those concerns here, they remain.

## C. Fire Blight

### 1. Difficulties with the Semi-Quantitative Model

61. The United States has some specific concerns regarding Australia's IRA for fire blight. As explained above, a risk assessment requires an evaluation of the likelihood of entry, establishment, or spread of a disease within the territory of the importing Member. But the semi-quantitative model that Australia adopted with regard to fire blight contributed to a flawed risk assessment, as evidenced, in part, by the various values that it assigns to different steps in its analysis.

62. Australia's semi-quantitative model suffers from several difficulties. First, the statistical estimates are not clearly linked to the scientific evidence presented and in many places, even contradict the evidence. Second, Australia defines and estimates variables for the model that are not supported by scientific evidence. Third, the additive nature of the model builds on the faulty estimates. And fourth, the mapping of unsupported quantitative estimates to volumes of trade that appear to be overestimated affects the credibility of the model as a determinant of unrestricted risk and the establishment of risk mitigations.

### 2. Importation Steps for the Likelihood of Entry

63. The difficulties with Australia's semi-quantitative approach to the risk assessment for fire blight are well illustrated by its eight step analysis of the likelihood of entry of fire blight, in which it failed to properly evaluate the risk of entry. In several instances, Australia extrapolates values for risk levels in the absence of, or contrary to, the scientific evidence. In the view of the United States, Australia commits errors in its IRA by, in different instances, ignoring the most relevant studies and instead citing literature that is not relevant or has disputed findings and providing misleading interpretations of the data or conclusions found in the literature. The United States does not catalogue all of those errors below, but instead selects certain examples to illustrate the flaws in Australia's approach. A more detailed list of the errors in each of these eight steps is set forth in Exhibit US-5, which, as explained above, is the U.S. comments on Australia's draft IRA.

[105] Letter from Michael A. Guidicipietro to Louise Van Meurs, p. 1 (March 29, 2006) (Exhibit US-5).

64. To begin, in Importation step 1, Australia's IRA concludes that the likelihood of fire blight bacteria in the source orchards is 100%.[106] But, as is also true of the United States, fire blight bacteria are not present in all orchards in New Zealand. Thus, Australia significantly overestimates the risk.[107] Moreover, it was not necessary for Australia to even include this first step in its analysis because the relevant issue is whether the apple fruit that is being exported contains *Erwinia amylovora*, and not whether the bacteria exists in the orchards.[108]

65. In Importation step 2, Australia assigns a most likely value of 3% to the likelihood that fruit picked from an orchard would be infected or infested with *Erwinia amylovora*.[109] But Australia relies on non-definitive studies, such as van der Zwet (1990) and others pertaining to immature fruit and seeks to extrapolate results to assess the risk for mature fruit, while ignoring highly relevant published data on this issue. The Roberts *et al.* (1998) study estimated this risk to be significantly lower – at 0.35% (or 0.003502) when no fire blight control measures were in place.[110] This risk was further reduced to 0.14% (or 0.0013817) in the Roberts and Sawyer (2008) study, when updated and revised data was included.[111] In other words, by using published data that was also available to Australia, Roberts and Sawyer (2008) estimated the likelihood for this step that ranged from $1.4 \times 10^{-3}$ to $4 \times 10^{-4}$, which is orders of magnitude smaller than those used in Australia's IRA. Furthermore, Australia introduced bias into its analysis by giving "'much less weight' to studies that found no evidence of *E. amylovora* on mature apples."[112] The

---

[106] IRA, p. 53 (Exhibit NZ-1).

[107] Thomson, S.V. and Hale, C.N., *A comparison of fire blight incidence and environment between New Zealand and Western United States*, Acta Horticulturae 217, 93-98 (1987) (Exhibit NZ-94). This initial overestimation biases the overall risk found by Australia, since the various probabilities are multiplied together.

[108] In Roberts (2002), mature, export quality apples from trees and orchards with fire blight disease were preferentially sampled to provide a worst case scenario for the estimation of risks of contaminated fruit being exported. The scientific data in that study indicated an extremely low risk of fruit infestation or fire blight disease occurring in export quality apple fruit. *See* R.G. Roberts, *Evaluation of buffer zone size on the incidence of Erwinia amylovora in mature apple fruit and associated phytosanitary risk*, Acta Horticulturae 590: 47-53 (2002) (Exhibit NZ-20).

[109] IRA, p. 55 (Exhibit NZ-1).

[110] R.G. Roberts *et al.*, *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17: 19-28, 19 (1998) (Exhibit NZ-22). The United States notes that higher risk found in the 1998 study was the result of inaccurate and inapplicable data from the 1990 van der Zwet study.

[111] Roberts, R.G. and A.J. Sawyer, *An updated pest risk assessment for spread of Erwinia amylovora and fire blight via commercial apple fruit,* Crop Protection 27: 362-368, 367 (2008) (Exhibit NZ-29) (emphasis supplied). The United States notes that in both the 1998 and 2008 studies, the data sets are skewed in favor of higher estimates of risk because they are from apple fruit harvested from orchards or trees with fire blight disease. Accordingly, they do not represent the likelihood of fruit being infested with *Erwinia amylovora* from the total population of apple fruit destined for export.

[112] Aus. FWS, para. 385 (citing IRA, p. 65).

United States submits that Australia's approach in this step undermines the quality of its analysis and the validity of its derivative conclusions.

66. Australia's analysis in Importation step 3 – the likelihood that clean fruit will be contaminated by *Erwinia amylovora* during picking and transport to the packing house – provides an example of how its fails to focus on the relevant scientific literature, and instead either ignores this literature or cites peripheral studies. For instance, the IRA notes that "[f]ew studies have tested *E. amylovora* populations on leaves around the time apples are harvested."[113] While this may be true, Australia still chose to ignore the studies that had been published. For instance, the IRA does not cite to Dueck and Morand (1975) or include data from that study. But Dueck and Morand found that by late August, when apple harvest would typically begin in North America, they did not isolate epiphytic *E. amylovora* from leaves in an orchard with fire blight, indicating these populations are in decline after their summer peak.[114] Furthermore, the IRA cited a peripheral study by Calzolari *et al.* (1982) on the diagnosis of fire blight using immunofluroescence staining,[115] but it did not cite a much more relevant study by Dueck (1974) finding that "[m]ature apples did not support a detectable resident population of *E. amylovora*."[116]

67. In importation step 4 – the likelihood that *E. amylovora* survives routine processing procedures in the packing house, Australia fails to consider relevant scientific evidence and draws incorrect inferences from the scientific literature on which it relies. A study by Hale and Taylor (1999), discussed in more detail in Section III.C.2 above, demonstrated that cold storage significantly decreased populations of fire blight bacteria on mature apple fruit.[117] Australia cites Temple *et al.* (2007) for the proposition that cold storage helps fire blight bacteria survive better than at room temperatures.[118] Yet Australia failed to recognize the most relevant portion of the

---

[113] IRA, p. 66 (Exhibit NZ-1). This statement reflects Australia's confusion of the relevant issue because the product being exported is not apple leaves, but apple fruit. Thus, Australia should have focused on the presence of *Erwinia amylovora* on apple fruit and not leaves.

[114] Dueck, J. and Morand, J.B., *Seasonal Changes in the Ephiphytic Population of Erwinia Amylovora on Apple and Pear*, Canadian Journal of Plant Science 55: 1007-1012 (1975) (Exhibit US-6). Australia sought to rely on a study by Ockey and Thomas (2006). *See* Aus. FWS, para. 416 (citing Exhibit NZ-26). But the experimental design of this study clearly indicates that the sampling occurred in May and June, during active fire blight season, rather than late August or September when fruit harvest occurs. As such, it is not reasonable to conclude, as Australia does, that the hands of fruit pickers would be heavily contaminated because the period of heavy contamination would have already passed.

[115] IRA, p. 67 (Exhibit NZ-1).

[116] Dueck, J., *Survival of E. amylovora in association with mature apple fruit,* Canadian Journal of Plant Science 54, 349-351, 350 (1974) (Exhibit NZ-96).

[117] Hale, C.N. and R.K. Taylor, *Effect of cool storage on survival of Erwinia amylovora in apple calyxes*, Acta Horticulturae 489: 139-143 (1999) (Exhibit NZ-24).

[118] Aus. FWS, para. 424.

study, which found that "as in the field, incidence of detection and population size declined with time, *with no detection of the pathogen after 56 days*, *regardless of the storage environment.*"[119] In this regard, Australia misstates the finding of the literature to support its position that fire blight bacteria could survive cold storage, when that literature actually concludes that populations of *E. amylovora* could no longer be detected after a period of time.

68. Importation step 5 – the likelihood that clean fruit is contaminated by *E. amylovora* during processing in the packing house – suffers from similar defects. Although the IRA cites multiple papers as providing evidence or support for the assessment of risk at this stage, none of the papers cited deal with the relevant commodity – mature, symptomless fruit. Furthermore, none of the studies cited provide any direct evidence of contamination of mature apple fruit by packing shed machinery.

69. Importation step 6 – the likelihood that *E. amylovora* survives palletization, quality inspection, containerization, and transportation to Australia – provides an example of Australia assigning a value to a risk in the absence of scientific evidence. The IRA assigns a value of 0.8 to this risk,[120] which is a very high level of risk for a series of events for which there is no supporting scientific evidence, but only circumstantial extrapolation. Here again, Australia relies on Temple *et al.* (2007) to argue that cold storage can prolong the life of *E. amylovora* on apples, without mentioning that the study found that regardless of storage conditions, the populations of the bacteria become undetectable after a number of days.[121]

70. In Importation step 7 – the likelihood that clean fruit is contaminated by *E. amylovora* during palletization, quality inspection, containerization, and transportation, Australia relies on flawed scientific evidence. Citing a 1990 study by van der Zwet, the IRA states that internally infected fruit may ooze bacteria that may contaminate clean fruit.[122] But any fruit that oozes bacteria must be immature, and therefore would not occur on an export packing line. It was confirmed during the *Japan – Apples* dispute that van der Zwet's work on this issue dealt with immature apple fruit.[123] Thus, in importation step 7, Australia presumes a commodity that does not exist – mature and symptomless, but oozing apple fruit. Moreover, Australia points to no scientific data that supports the conclusion that this step in the pathway has ever occurred because no such data exists.

---

[119] Temple, T.N., V.O. Stockwell, P.L. Pusey and K.B. Johnson, *Evaluation of Likelihood of Co-Occurrence of E. amylovora with Mature Fruit of Winter Pear*, Phytopathology 97(10), 1263-1273 (2007) (Exhibit NZ-98) (emphasis supplied).

[120] IRA, p. 79 (Exhibit NZ-1).

[121] Aus. FWS, para. 435.

[122] IRA, p. 79 (Exhibit NZ-1).

[123] *Japan – Apples (Panel)*, para. 4.94.

### 3. The Likelihood of Entry, Establishment, and Spread

71. Australia's evaluation of the likelihood of establishment or spread of fire blight into its territory is also flawed. Australia relies heavily on the van der Zwet (1990) study for the proposition that fire blight bacteria can rapidly multiple on fruit and allow for a sufficient dose of inoculum.[124] But, as the panel in *Japan – Apples* noted, the experimental design of that study suffered from difficulties that rendered its conclusions "relatively confused", "difficult to interpret", and "even unconvincing."[125] Australia also asserts that *E. amylovora* may be transferred from apple fruit to susceptible hosts.[126] But the United States considers that it is important to recognize that there is no scientific evidence demonstrating completion of the pathway. Thus, it is a purely hypothetical risk that should be treated accordingly.

72. In estimating the overall probability of entry, establishment, and spread of fire blight, Australia also fails to consider the relevant scientific evidence. Australia estimates that the overall risk is 4.5%.[127] As New Zealand explains, this figure means that a fire blight outbreak will occur in Australia due to imported apples from New Zealand approximately once every 22 years.[128] But based on the 1998 study by Roberts *et al.* that surveyed all of the relevant scientific literature (discussed in detail in Section III.C above), the likelihood of a fire blight outbreak in an area where the disease was not present with no measures to protect against fire blight is only once every 11,364 years.[129] After this study was updated in 2008 with new and revised data, Roberts and Sawyer found that the risk of a fire blight outbreak dropped dramatically to once every 217,925 years.[130] Thus, it is difficult to reconcile Australia's IRA, which predicts a fire blight outbreak once every 22 years, with a recent study that conducted a comprehensive review of the scientific literature and estimated the likelihood of an outbreak to be only once every 217,925 years.

73. Finally, the United States notes that Australia has not evaluated the likelihood of entry, establishment, and spread of fire blight according to the SPS measures that might be applied, in accordance with the SPS Agreement's definition of a risk assessment. Australia appears to concede that it did not evaluate three of the measures that it imposes for fire blight, which pertain

---

[124] Aus. FWS, paras. 463-469.

[125] *Japan – Apples (Panel)*, para. 8.127.

[126] Aus. FWS, paras. 472-475.

[127] IRA, p. 104 (Exhibit NZ-1).

[128] NZ FWS, para. 4.249.

[129] R.G. Roberts *et al.*, *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17: 19-28, 25 (1998) (Exhibit NZ-22).

[130] Roberts, R.G. and A.J. Sawyer, *An updated pest risk assessment for spread of Erwinia amylovora and fire blight via commercial apple fruit,* Crop Protection 27: 362-368, 367 (2008) (Exhibit NZ-29).

to the suspension of an orchard/block on the basis of pruning, the requirement to clean packing equipment, and the requirement that packing houses only source apples from registered orchards. Australia justifies its decision on the ground that these were not principal measures that operate in their own right.[131] But, as the United States explained above, the SPS Agreement makes no distinctions between principal and ancillary measures. Thus, Australia has failed to properly evaluate all of the measures that it actually applies, let alone other SPS measures that might be applied.

### D. European Canker

74. The United States also has concerns regarding Australia's application of a semi-quantitative model to its European canker analysis. Australia determined that 95 percent of New Zealand apple production comes from orchards in areas where either the disease has never been recorded or occurs only sporadically in very wet seasons.[132] It is unclear to the United States why the IRA chooses to represents this conclusion with a distribution ($10^{-2}$ to 6 X $10^{-2}$ with a most likely probability of 3 X $10^{-2}$) when Australia's conclusion regarding this key factor appears to indicate a ranking of Negligible, Low or Very Low ($10^{-3}$ to 5 X $10^{-2}$).[133]

75. In assessing the risk of European canker, it has been well documented that the disease expression will only occur where rainfall is greater than 1000 millimeters annually. For instance, this was found in a study by Dubin and English (1975).[134] But apple production areas of New Zealand, as well as the major apple producing regions in the U.S. States of Washington, Oregon and Idaho, do not have the moisture required for the establishment of European canker and are therefore very likely to be free of this disease.

76. The United States has further concerns that the transfer scenario for European canker from mature, export quality apples set forth in the IRA is also highly unlikely. For successful infection from mature, export quality apple fruit, there must be a coincidence of a sporulating apple, a certain duration of wetness, and a susceptible host. The United States considers this an unlikely event that should have been treated as such in the IRA.

77. As was the case with fire blight, the United States also notes that Australia has failed to evaluate the likelihood of entry, establishment, and spread of European canker according to the SPS measures that might be applied, as required by the SPS Agreement's definition of a risk

---

[131] Aus. FWS, paras. 864-865.

[132] IRA, p. 119 (Exhibit NZ-1).

[133] IRA, p. 121 (Exhibit NZ-1).

[134] Dubin, H.J. and H. English, *Effects of temperature, relative humidity, and desiccation on germination of Nectria Galligena Conidia*, Mycologia 67, 83-88 (1975) (Exhibit NZ-12); Dubin, H.J. and English, H., *Epidemiology of European Apple Canker in California*, Phytopathology: 65: 542-550 (1975) (Exhibit US-3).

assessment. Australia appears to concede that it did not evaluate its requirement that all new planting stock be examined and treated for European canker, but maintains that this measure was only imposed to support its principal measure that fruit be sourced only from pest-free places of production.[135] Again, Australia has not even evaluated all of the SPS measures that it applies, let alone evaluating other possible measures that might be applied.

## V. Arbitrary or Unjustifiable Distinctions in the Level of Protection Under Article 5.5

78. Article 5.5 of the SPS Agreement provides, in part, as follows: "[w]ith the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade." In understanding Article 5.5, the United States considers it important to recognize that the SPS Agreement allows each Member to establish its own appropriate level of protection and that Article 5.5 does not prohibit a Member from having different appropriate levels of protection in different situations.

79. The SPS Agreement protects the right of each WTO Member to establish the level of protection from sanitary and phytosanitary risks at the level that it deems appropriate. This is evidenced by the preamble to the SPS Agreement and the definition of "appropriate level of sanitary or phytosanitary protection." Other provision of the SPS Agreement support this right, for example Article 3.3. The sixth preambular clause of the SPS Agreement makes clear that commitments to harmonize measures based on international standards, guidelines, and recommendations are undertaken "without requiring Members to change their appropriate level of protection of human, animal, or plant life or health." Furthermore, the SPS Agreement defines "appropriate level of sanitary or phytosanitary protection" as the "level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory."[136] And Article 3.3 permits Members to depart from international standards where they have a different level of protection than the one that the international standard would achieve.

80. Not only does the SPS Agreement permit Members to set own their appropriate levels of protection, Article 5.5 does not require that the levels of protection set by Members be consistent. This is evidenced by the language of Article 5.5, which states that "each Member *shall avoid* arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different

---

[135] Aus. FWS, paras. 866-867.

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

situations."[137] It is significant that Article 5.5 uses the phrase "shall avoid" rather than "shall not have" because the latter phrase would indicate a *prohibition* on different levels of protection, while the former does not. Although consistency in a Member's level of protection is an objective of Article 5.5, it is not an absolute requirement. Article 5.5 recognizes the need for guidelines to help with the practical implementation of that provision, as well as recognizing that there may be a number of relevant factors, such as voluntary exposure to risk.

81. In *EC – Hormones*, the Appellate Body provided its interpretation of Article 5.5, which is consistent with the view of the United States. The Appellate Body explained:

> The objective of Article 5.5 is formulated as the "achieving [of] consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection". Clearly, the desired consistency is defined as a goal to be achieved in the future. To assist in the realization of that objective, the Committee on Sanitary and Phytosanitary Measures is to develop *guidelines for the practical implementation of Article 5.5*, bearing in mind, among other things, that ordinarily, people do not voluntarily expose themselves to health risks. Thus, we agree with the Panel's view that the statement of that goal [consistency] does not establish a *legal obligation* of consistency of appropriate levels of protection. We think, too, that the goal set is not absolute or perfect consistency, since governments establish their appropriate levels of protection frequently on an *ad hoc* basis and over time, as different risks present themselves at different times. It is only arbitrary or unjustifiable inconsistencies that are to be avoided.[138]

82. The United States has no independent knowledge of the facts surrounding the importation of Nashi pears from Japan into Australia and takes no position on whether Australia has arbitrary and unjustifiable distinctions in its level of protection between Nashi pears from Japan and apples from New Zealand.

## VI. Article 5.6 Requires that SPS Measures Not Be More Trade Restrictive Than Necessary to Meet a Member's Appropriate Level of Protection

### A. Legal Standard

83. Article 5.6 of the SPS Agreement imposes an obligation on each WTO Member not to establish or maintain SPS measures that are more trade-restrictive than required to achieve its appropriate level of protection. The provision states:

---

[137] SPS Agreement, Art. 5.5 (emphasis supplied).

[138] *EC – Hormones (AB)*, para. 213 (emphasis original).

> Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.

The footnote to Article 5.6 clarifies:

> For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

84. In *Australia – Salmon,* the Appellate Body agreed with the Panel that, reading Article 5.6 together with its footnote, there were three elements necessary "to establish a violation of Article 5.6." First, there must be a measure that "is reasonably available taking into account technical and economic feasibility." Second, the measure must achieve "the Member's appropriate level of sanitary or phytosanitary protection." Third, the measure must be "significantly less restrictive to trade than the SPS measure contested." The three elements are applied cumulatively – i.e., if the complaining party fails to establish any one of the three elements, "the measure in dispute would be consistent with Article 5.6."[139]

### B. Fire Blight

85. In the view of the United States, there is an alternative measure for fire blight that is reasonably available, achieves Australia's appropriate level of protection, and is significantly less restrictive to trade than Australia's fire blight measures: restricting importation to mature, symptomless apple fruit. This measure follows from the scientific evidence that mature, symptomless apple fruit are not a pathway for the disease and thus will not result in transmission of fire blight to Australia. In the absence of any evidence that mature, symptomless apples transmit the disease, the United States submits that Australia has imposed fire blight measures that are more trade-restrictive than required to achieve its appropriate level of protection.

86. Restricting the importation of apples to mature, symptomless apple fruit is a reasonably available measure. As New Zealand has explained, such a measure is technically and economically feasible because its pipfruit industry already has pre-harvest and post-harvest

---

[139] *Australia – Salmon (AB)*, para. 194; *see Australia – Salmon (Panel)*, para. 8.167.

quality control measures in place to ensure that exported apple fruit meet certain standards for maturity, and are symptomless.[140] In *Japan – Apples (Article 21.5)*, the panel found similar quality control measures by the U.S. industry "could provide sufficient guarantees to reasonable ensure that the product exported is mature, symptomless apples."[141] The panel thus concluded that "the requirement that apples imported into Japan be mature and symptomless is an alternative measure that is reasonably available taking into account technical and economic feasibility."[142]

87. A measure that restricts exports of apple fruit to mature, symptomless apples also achieves Australia's appropriate level of protection. Australia describes its appropriate level of protection as a "high level of sanitary or phytosanitary protection aimed at reducing risk to a very low level, but not to zero."[143] But there is no evidence that mature, symptomless apple fruit have ever transmitted fire blight or are a pathway for the disease. Thus, restricting importation to mature, symptomless apple fruit would achieve Australia's appropriate level of protection. This conclusion is reinforced by the panel's finding in *Japan – Apples (Article 21.5)*. There, Japan's appropriate level of protection was the equivalent of an import ban – arguably a higher level of protection than Australia has set, and the panel determined that a requirement for mature, symptomless apples "is an alternative measure that could meet Japan's ALOP [appropriate level of protection]."[144]

88. Limiting the export of apples to mature, symptomless apples would also be significantly less trade restrictive than Australia's current scheme, which requires eight separate measures for fire blight.[145] As New Zealand notes, exporters could find some of these measures, such as annual inspections,[146] to be particularly onerous and not worth the risk to their investment.[147] In *Japan – Apples (Article 21.5)*, the panel found that a "requirement to import only mature,

---

[140] NZ FWS, paras. 4.492-4.493.

[141] *Japan – Apples (Article 21.5)*, para. 8.177.

[142] *Japan – Apples (Article 21.5)*, para. 8.181.

[143] IRA, p. 4 (Exhibit NZ-1).

[144] *Japan – Apples (Article 21.5)*, paras. 8.193, 8.196. *See also* para. 8.74 ("Both the relevant scientific evidence and the opinions of the experts consulted by the Panel support the view that limiting exports of apples from the United States to mature, symptomless fruits would ensure that such shipments do not contaminate host plants in Japan.").

[145] NZ FWS, para. 3.83.

[146] IRA, p. 316 (Exhibit NZ-1).

[147] NZ FWS, para. 4.507.

symptomless apples would be 'significantly less trade restrictive'" than the nine-part import regime that Japan had instituted.[148]

## VII. Undue Delay Under Article 8 and Annex C

89. Article 8 of the SPS Agreement provides that "Members shall observe the provisions of Annex C in the operation of control, inspection, and approval procedures... and otherwise ensure that their procedures are not inconsistent with provisions of this Agreement." Paragraph 1(a) of Annex C further states that "Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that: (a) such procedures are undertaken and completed without undue delay."

90. In *EC – Biotech*, the panel offered an interpretation of Annex C(1)(a). The panel explained that "[t]he verb undertake makes clear that Members are required to begin, or start, approval procedures after receiving an application for approval."[149] The panel also stated that based on the ordinary meaning of the phrase "without undue delay," that "Annex C(1)(a), first clause, requires that approval procedures be undertaken and completed with no unjustifiable loss of time."[150] The panel further noted that "a determination of whether a particular approval procedure has been undertaken and/or completed 'without undue delay' must be made on a case-by-case basis, taking account of relevant facts and circumstances."[151] The panel also explained that it viewed "Annex C(1)(a), first clause, essentially as a good faith obligation requiring Members to proceed with their approval procedures as promptly as possible, taking into account of the need to check and ensure the fulfillment of their relevant SPS requirements."[152]

91. The United States shares New Zealand's concerns about undue delay by Australia regarding its import risk assessments for foreign apples. As Australia has done with apples from New Zealand, it continues to block access to its market for U.S. apples due to longstanding quarantine restrictions. The United States suffered a long delay in the commencement of a risk assessment for U.S. apples, which was further compounded by the lengthy delays in Australia's IRA for apples from New Zealand.

92. The United States first formally requested access to Australia's market for U.S. apples and provided Australia with a pest list to facilitate commencement of the risk assessment in June 1999. Yet, Australia waited until March 17, 2008 to announce the commencement of a risk

---

[148] *Japan – Apples (Article 21.5)*, para. 8.188.

[149] *EC – Biotech*, para. 7.1494.

[150] *EC – Biotech*, para. 7.1495.

[151] *EC – Biotech*, para. 7.1497.

[152] *EC – Biotech*, para. 7.1498.

assessment for U.S. apples – a delay of almost nine years. During those nine years, the United States made multiple requests for access to the Australian market and emphasized the importance of beginning and completing the risk assessment. In response, at various times throughout that period, Australia informed the United States that it would consider the U.S. request for market access only after it had completed the IRA for New Zealand apples. In other words, Australia chose to put the U.S. risk assessment on hold until it had completed the IRA for New Zealand. Essentially, Australia linked the timing of the U.S. risk assessment to the completion of the IRA for New Zealand and delayed commencement of the U.S. risk assessment due to delays in the IRA for New Zealand. The Panel will appreciate the concerns that these facts raise.

## VIII. Conclusion

93. The United States thanks the Panel for providing an opportunity to comment on the issues at stake in this proceeding, and hopes that its comments will prove to be useful.