

*Japan – Measures Affecting the Importation of Apples*

(WT/DS245)

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

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## TABLE OF CONTENTS

I.	INTRODUCTION .....	1
II.	PROCEDURAL BACKGROUND .....	3
III.	FACTUAL BACKGROUND .....	3
	A. Fire Blight Disease and the Fire Blight Bacterium, <i>Erwinia amylovora</i> .....	3
	1. Biology and the Disease Cycle .....	4
	2. Host Plants .....	5
	3. Geographical Distribution .....	5
	B. The Japanese Fire Blight Measures .....	6
IV.	LEGAL ARGUMENTS .....	9
	A. Japan's Measures on U.S. Apples Are Inconsistent with Article 2.2 of the SPS Agreement Because They Are Maintained Without Sufficient Scientific Evidence .....	9
	1. Introduction: Japan Must Have Sufficient Scientific Evidence to Maintain its Measures .....	9
	2. The Scientific Evidence Establishes That Mature, Symptomless Apple Fruit Have Never Transmitted Fire Blight and Do Not Transmit the Disease .....	11
	3. The Scientific Evidence Underlying the Fact That Mature, Symptomless Apples Do Not Serve As a Pathway for the Disease .....	14
	A. <i>Mature, Symptomless Apples Do Not Harbor Fire Blight Bacteria Internally</i> .....	17
	B. <i>External Bacteria on Mature, Symptomless Apple Fruit Are Found Very Rarely</i> .....	19
	C. <i>Bacteria Are Highly Unlikely to Survive Commercial Handling, Storage, and Transport of Fruit</i> .....	23
	D. <i>There Is No Vector to Transfer External Bacteria from an Imported Fruit to a Susceptible Host</i> .....	25
	4. The Japanese Measures Impose Restrictions Unsupported by Any Scientific Evidence .....	27
	A. <i>Prohibition of Imported Apples from Orchards in Which Any Fire Blight Is Detected</i> .....	28
	B. <i>Prohibition of Imported Apples from Any Orchard Should Fire Blight Be Detected Within a 500 Meter Buffer Zone Surrounding Such Orchard</i> .....	28
	C. <i>Inspection of Export Orchards Three Times Yearly for the Presence of Fire Blight</i> .....	30
	D. <i>Prohibition of Imported Apples Unless Treated With Chlorine</i> ..	31
	E. <i>Prohibition of Imported Apples from U.S. States Other than Washington or Oregon</i> .....	32

	<i>F. Prohibition of Imported Apples Unless Other Production, Harvesting, and Importation Requirements Met</i> . . . . .	33
B.	Japan's Measures on U.S. Apples Are Inconsistent with Articles 5.1 of the SPS Agreement Because They Are Not Based on a Risk Assessment . . . . .	33
	1. Introduction: Japan's Fire Blight Measures Must Be Based on a Risk Assessment . . . . .	33
	2. Japan Does Not Evaluate the Likelihood of Entry, Establishment, or Spread as well as Potential Associated Biological and Economic Consequences . . . . .	36
	<i>A. Japan Did Not Evaluate the Likelihood of Entry and Ignored Key Evidence</i> . . . . .	37
	<i>B. By Ignoring Key Steps, Japan Failed to Evaluate the Likelihood of Entry</i> . . . . .	40
	<i>C. Japan Failed to Evaluate the Likelihood of Establishment and Spread</i> . . . . .	41
	<i>D. Conclusion</i> . . . . .	42
	3. Japan Did Not Evaluate the Likelihood of Entry, Establishment, or Spread According to the SPS Measures Which Might Be Applied . . . . .	43
	4. The Japanese Pest Risk Analysis Does Not Reasonably Support the Measures Taken . . . . .	47
	5. Japan Has Acted Inconsistently With Article 5.1 and Therefore With Article 2.2 . . . . .	49
	6. Conclusion: Japan Has Acted Inconsistently with Article 5.1 of the SPS Agreement . . . . .	49
C.	By Failing to Take Into Account Certain Information in Its Assessment of Risks, Japan Has Acted Inconsistently with Article 5.2 of the SPS Agreement . . . . .	50
D.	Japan's Measures Are Inconsistent with Article 5.6 of the SPS Agreement Because They Are More Trade-Restrictive than Required to Achieve Japan's Appropriate Level of Protection . . . . .	52
	1. Introduction and Legal Standard . . . . .	52
	2. Japan's Appropriate Level of Protection . . . . .	53
	3. Japan May Restrict Importation to Mature, Symptomless Apple Fruit . . . . .	54
	<i>A. The Measure Is Reasonably Available</i> . . . . .	54
	<i>B. The Measure Achieves Japan's Appropriate Level of Protection</i> . . . . .	55
	<i>C. The Measure Is Significantly Less Trade-Restrictive</i> . . . . .	55
	<i>D. Conclusion</i> . . . . .	56
E.	Japan Has Failed to Notify Changes to Its Fire Blight Measures and to Provide Information as Required by Article 7 and Annex B of the SPS Agreement . . . . .	57
V.	CONCLUSION . . . . .	58

## I. INTRODUCTION

1. This dispute is, we hope, the beginning of the end of 20 years of U.S. efforts to export apple fruit to Japan free of restrictions not based on science. During that period, on tens of occasions, the United States has corresponded and held bilateral meetings with Japan to discuss the scientific evidence that imported U.S. apples do not transmit fire blight (a bacterial disease affecting plant health and life) and to propose an easing of Japan's restrictions. As recently as 2001, the United States still believed it would be possible to resolve this issue bilaterally. At Japan's request, the United States had agreed to participate in a joint Japanese-U.S. research project – with the understanding that Japan would make changes to its fire blight restrictions should the joint research results confirm the scientific evidence. The joint research, in fact, produced exactly the predicted results, but the expected changes in the Japanese restrictions were not made. The United States does not take dispute settlement lightly nor enter into such proceedings hastily, but, in light of the extensive U.S. efforts to resolve this issue bilaterally,<sup>1</sup> the United States reluctantly concluded that WTO dispute settlement was warranted.

2. Japan prohibits the importation of apple fruit unless such apples are produced, treated, and imported in accordance with Japan's highly-restrictive fire blight measures. For example, fruit is prohibited unless produced within the U.S. States of Washington or Oregon. Fruit is prohibited unless the export orchard and a 500-meter buffer zone surrounding the export orchard are free of fire blight. Fruit is prohibited unless these orchards and buffer zones are inspected three times yearly for the presence of fire blight. Fruit is prohibited unless treated post-harvest with chlorine. Fruit is prohibited unless specified production requirements are met, such as chlorine treatment of containers for harvesting, chlorine treatment of the interior of the apple packing facility, and post-harvest separation of apples for Japan from other fruit. Finally, fruit is prohibited unless U.S. officials certify or declare that the fire blight measures have been met and unless Japanese officials, in turn, certify that the U.S. certification was made properly and that the fire blight measures have been met.

3. The United States does not question that fire blight is a plant disease of serious biological and economic consequences. Neither does the United States question Japan's determination – as is its right – to enact measures to protect against the risks arising from transmission of fire blight disease within its territory. However, consistent with the *Agreement on the Application of Sanitary and Phytosanitary Measures* (“SPS Agreement”), the United States and other WTO Members may expect that Japan will not restrict the importation of apples without scientific evidence that exported apples transmit the disease.

4. Billions of apples have been exported worldwide, most of which without *any* measures being imposed to protect against transmission of fire blight, yet there is *no evidence* that such

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<sup>1</sup> For further background on efforts to achieve access to the Japanese market for U.S. apples, see Exhibit USA-1.

apples have ever transmitted the disease. As the most recent comprehensive review of the scientific evidence on fire blight summarizes: “[I]t has *never been demonstrated* that mature fruit are involved in dissemination of [fire blight bacteria] and serve as a source of new infections in orchards. It would be extremely unlikely that contaminated fruit could be responsible for establishing new outbreaks of fire blight.”<sup>2</sup> Thus, while Japan may impose measures to guard against transmission of the disease into its territory, it may not restrict imports of a commodity that are *not in any way implicated* in transmitting the disease.

5. The United States proceeds in this submission as follows:

First, the United States presents the scientific evidence that mature, symptomless apples have never transmitted and do not transmit the fire blight disease. Because there is no evidence, let alone sufficient evidence, for Japan to maintain its fire blight measures, Japan has acted inconsistently with Article 2.2 of SPS Agreement.

Second, the United States demonstrates that Japan’s assessment of risks does not evaluate the likelihood of entry, establishment, or spread of fire blight. Japan fails to identify and evaluate evidence relevant to the exported commodity and relevant to key steps that must be completed for disease transmission. Thus, Japan has failed to ensure that its fire blight measures are based on an assessment of the risks to plant life or health, inconsistent with Article 5.1 of the SPS Agreement;

Third, the United States shows that, in its assessment of risks, Japan has failed to take into account available scientific evidence, relevant ecological and environmental conditions, and quarantine or other treatment and therefore has acted inconsistently with Article 5.2 of the SPS Agreement;

Fourth, the United States establishes that restricting importation of apples to mature, symptomless fruit is a measure that is reasonably available, achieves Japan’s appropriate level of protection, and is significantly less restrictive to trade than Japan’s fire blight measures. Thus, Japan’s measures are inconsistent with Article 5.6 of the SPS Agreement; and

Fifth, the United States notes that, despite the extensive attention given to these restrictions over the years, Japan has failed to notify changes in and information on its fire blight measures and therefore has acted inconsistently with Article 7 and Annex B of the SPS Agreement.

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<sup>2</sup> S.V. Thomson, *Epidemiology of Fire Blight*, in *Fire Blight: The Disease and Its Causative Agent, Erwinia Amylovora*, at 17 (2000) (J.L. Vanneste, ed.) (emphasis added) (Exhibit USA- 2).

6. In sum, the various inconsistencies of Japan’s fire blight measures flow from one essential fact: mature, symptomless apples, the exported commodity, have never transmitted and do not transmit fire blight. Given their fundamental lack of supporting evidence, Japan’s fire blight measures cannot be applied to imported U.S. apples consistent with the SPS Agreement, as outlined above. The United States respectfully requests that the Panel make findings to this effect and recommend that Japan bring its measures into conformity with its obligations under the SPS Agreement.

## II. PROCEDURAL BACKGROUND

7. On March 1, 2002, the United States requested consultations with Japan regarding its fire blight measures pursuant to Articles 1 and 4 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (“DSU”), Article XXIII of the *General Agreement on Tariffs and Trade 1994* (“GATT 1994”), Article 11 of the SPS Agreement, and Article 19 of the *Agreement on Agriculture*.<sup>3</sup> Consultations were held on April 18, 2002, but failed to resolve the matter.

8. On May 7, 2002, the United States requested the Dispute Settlement Body (“DSB”) to establish a panel pursuant to Article 6 of the DSU, with standard terms of reference as set out in Article 7.1 of the DSU.<sup>4</sup> On May 22, 2002, the United States requested the formation of a panel a second time. On June 3, 2002, the DSB established the Panel with standard terms of reference.<sup>5</sup> Australia, Brazil, Chinese Taipei, the European Communities, and New Zealand have reserved third-party rights.<sup>6</sup>

## III. FACTUAL BACKGROUND

### A. Fire Blight Disease and the Fire Blight Bacterium, *Erwinia amylovora*

9. Because fire blight has been intensely studied over the years, the main features of the disease cycle and the biology of the fire blight bacterium (*Erwinia amylovora*) are well

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<sup>3</sup> WT/DS245/1.

<sup>4</sup> WT/DS245/2.

<sup>5</sup> WT/DS245/3.

<sup>6</sup> *Id.*

understood and consequently should not be at issue in this dispute.<sup>7</sup> In this section, the United States briefly describes the fire blight disease cycle, host range, and geographic dispersal.<sup>8</sup>

## 1. Biology and the Disease Cycle

10. Fire blight bacteria overwinter exclusively in infected host plants. In the presence of warm, wet conditions in spring, the disease cycle commences when cankers on infected hosts exude a bacterial-laden ooze or inoculum. This inoculum is transmitted primarily through rain, but also via insects, to open flowers on the same or new host plants. The bacteria multiply externally on the stigmas of these open flowers and enter the plant through stomata (openings through which the plant breathes), nectaries (plant glands that secrete nectar), or wounds. The bacteria may spread within the host plant, infecting blossoms, fruiting spurs, twigs, branches, and leaves, and form new cankers (sunken areas surrounded by cracked bark) on infected branches or twigs. With appropriate environmental conditions, inoculum may then be exuded from infected shoots, cankered bark, and infected fruit and blossoms. Another means of infection may occur when fire blight plant hosts produce sporadic, late blossoms (so-called ‘rattail blossoms’) or become wounded, for example, through pruning, hail, or insect injury.

11. Cankers become inactive or less active during the growing season, especially in warmer, drier months or areas, resulting in declining epiphytic (external) counts of bacteria; by the time of fruit harvest in the fall, epiphytic bacteria are extremely rare. Cankers generally cease ooze production during the hot summer months and remain inactive until the following spring when they may reactivate and begin the disease cycle anew.

12. Symptoms of infection of host plants depend on the parts infected. Infected flowers droop, wither, and die, becoming dry and darkened in color. Infected shoots and twigs wither, darken, and die; as shoots and twigs wither, they bend downwards resembling a shepherd’s crook. Infected leaves take on a curled, scorched appearance. Infected fruit fail to develop fully, turning brown to black, shriveling, and becoming mummified, frequently remaining attached to

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<sup>7</sup> The United States notes that the 1999 Japanese Pest Risk Analysis on Fire Blight contains a largely accurate portrayal of the biology of the disease. 1999 Japanese Pest Risk Analysis § I-1, at 4-9 (U.S. translation) (Exhibit USA-3). However, as discussed in more detail later in this submission, Japan’s discussion of the “Possibility of Transmission by Apple Fruit,” *id.* at 9-10, is deeply flawed as there is no evidence that fruit have ever served as a source of bacterial inoculum for new infections and Japan cites evidence that is irrelevant to the exported commodity (mature, symptomless apple fruit). See *infra* §§ IV.A, B (claims under Article 2.2 and 5.1 of the SPS Agreement).

<sup>8</sup> This discussion of the biology of the disease is drawn principally from the following sources, which are typical of the scientific literature: S.V. Thomson, *Epidemiology of Fire Blight*, in *Fire Blight: The Disease and Its Causative Agent, Erwinia Amylovora* (2000) (J.L. Vanneste, ed.) (Exhibit USA- 2); R.G. Roberts, et al. *The potential for spread of Erwinia amylovora and fire blight*, *Crop Protection* 17: 19-28, 20-24 (1998) (Exhibit USA-4); European and Mediterranean Plant Protection Organization (EPPO), *Data Sheet on Quarantine Pests: Erwinia amylovora*, *Quarantine for Europe*, at 1-4 (1997) (Exhibit USA-5). The Thomson (2000) review appears in a recent reference work on fire blight and presents a comprehensive description of the epidemiology of the disease.

the limb. Limbs and trunks of trees may also develop cankers, which, if disease development is severe, may result in plant death.

## 2. Host Plants

13. The fire blight disease affects numerous host plants of the Rosaceae family, including both cultivated and native wild plants. Fruit tree hosts include pears (genus *Pyrus*), apples (genus *Malus*), quince (genus *Cydonia*), and loquats (genus *Eriobotrya*). Important host plants used in hedges and gardens include genera *Cotoneaster*, *Crataegus* (hawthorn), *Pyracantha* (firethorn), and *Sorbus* (mountain ash), although individual species may not serve as hosts.<sup>9</sup>

## 3. Geographical Distribution

14. It is believed that the fire blight bacterium (*Erwinia amylovora*) is native to North America as the earliest known observation and description of the disease was reported in New York State, U.S.A. By the early 1900s, fire blight had been reported in Canada from Ontario to British Columbia, in northern Mexico, and in the United States from the East Coast to California and the Pacific Northwest. Fire blight was reported in New Zealand in 1919, Great Britain in 1959, and Egypt in 1964. The disease has spread across northern and western Europe although Portugal and Finland remain fire blight-free, and it remains localized in France and Switzerland and restricted to certain spots in Spain, Italy, and Austria. Norway has reported eradication of the disease. Independently, fire blight has spread across the Mediterranean region, including Greece, Turkey, Israel, Lebanon, Iran, and several Central European countries.<sup>10</sup> Latin America and substantial parts of Africa and Asia apparently remain fire blight-free.

15. The United States notes that Japan claims to be free of fire blight, despite numerous scientific reports in the Japanese literature that document the occurrence and identification of the pathogen in Japan, describe disease symptoms and fulfillment of Koch's postulates (a method to prove that a particular microorganism is the cause of a disease)<sup>11</sup> with pure cultures of the

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<sup>9</sup> European and Mediterranean Plant Protection Organization (EPPO), *Data Sheet on Quarantine Pests: Erwinia amylovora*, Quarantine for Europe, at 1-2 (1997) (listing exceptions) (Exhibit USA-5).

<sup>10</sup> For more detail, see Commonwealth Agriculture Bureau International (CABI), *Crop Protection Compendium: Data Sheet on Erwinia amylovora* (2002) (Notes on Distribution) (Exhibit USA-6).

<sup>11</sup> Koch's postulates (as applied to plants) set out a four-step procedure by which a particular microorganism can be shown to be the cause of a disease. First, the specific organism should be shown to be present in all cases of plants suffering from a specific disease but should not be found in healthy plants. Second, the specific microorganism should be isolated from the diseased animal and grown in pure culture on artificial laboratory media. Third, this freshly isolated microorganism, when inoculated into a healthy laboratory plant, should cause the same disease seen in the original plant. Fourth, the microorganism should be reisolated in pure culture from the experimental infection. See E.W. Nester et al., *Microbiology* at 497 (3rd ed. 1983).



bacterium, and recommend control measures.<sup>12</sup> Japan's more recent claim to be fire blight-free has not been independently confirmed. Furthermore, a plant pathogenic bacterium closely related to *Erwinia amylovora* was reported in the 1980s to cause a fire blight-like disease of pear on Hokkaido; a subsequent study considered the causal agent of the Hokkaido fire blight-like disease to be *Erwinia amylovora*.<sup>13</sup> The Japanese claim that this shoot blight disease has been eradicated has also not been independently verified.<sup>14</sup> Despite substantial evidence to the contrary, the United States assumes for purposes of this submission that Japan is, as it claims, free of fire blight and fire blight bacteria.

## B. The Japanese Fire Blight Measures

16. When asked at consultations to specify the means by which Japan maintains its fire blight measures, Japan identified four distinct measures: (1) Plant Protection Law No. 151 (May 4, 1950), Article 7; (2) Plant Protection Law Enforcement Regulations (June 3, 1950), Article 9 and Annexed Table 2; (3) Ministry of Agriculture, Forestry and Fisheries (MAFF) Notification No. 354 (dated March 10, 1997), and (4) MAFF "Detailed Rules for U.S. Apples."<sup>15</sup> The United States briefly explains each of these measures.

17. Plant Protection Law No. 151 sets out Japan's general plant protection authority. Article 7, paragraph 1, states that "[n]o person shall import any article specified in each of the following items," which include "[p]lants designated by the Ministerial Ordinance."<sup>16</sup> Ministerial Ordinance No. 73, Japan's Plant Protection Law Enforcement Regulations, states in Article 9:

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<sup>12</sup> E. Uyeda, *The causal bacterium of apple blight*, Dai Nippon Nokaiho 260: 1-3 (1903) (in Japanese); M. Kazui, *Fire blight of pear and apple*, Byochugai Zassi, Journal of Plant Protection 9: 545-49 (1922) (in Japanese); M. Kazui, *Fire blight of pear and apple*, Byochugai Zassi, Journal of Plant Protection 9: 594-99 (1922) (in Japanese); K. Hara, *Sukamotsu byorigaku*, Pathology of Crop Plants, pp. 266-67 (1928) (in Japanese); T. Hemni, *Shokubutu chibyogaku hanron*, General discourse on remedies for plant diseases, pp. 146-47, 162 (1926) (in Japanese); H. Shiraishi, *On fire blight of pear*, Byochugai Zassi, Journal of Plant Protection 17: 655-58 (1930) (in Japanese); I. Kawai, *Garden Plant Protection*, pp. 294-95 (1954) (in Japanese).

<sup>13</sup> S.V. Beer et al., *Characterization of bacteria that cause "bacterial shoot blight of pear" in Japan*, Acta Horticulturae 411: 179-81 (1996) (concluding that the pathogenic bacterium was *E. amylovora* and infects apple trees); see Commonwealth Agriculture Bureau International (CABI), *Crop Protection Compendium: Data Sheet on Erwinia amylovora* (2002) (Notes on Distribution) ("The case of Japan is specific, where the causal agent of a 'shoot blight' of Asian pear (*Pyrus pyrifolia*) was shown to belong to *E. amylovora*, while it is claimed that the country is free of fire blight. The isolates from Japan show a host range which seems to be restricted, compared to standard isolates (Beer et al., 1996).") (Exhibit USA-6).

<sup>14</sup> See R.G. Roberts, et al. *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17, at 20-21 (1998) (reviewing literature relating to Japanese situation) (Exhibit USA-4).

<sup>15</sup> See U.S. Consultation Question 2 (Exhibit USA-7).

<sup>16</sup> Plant Protection Law No. 151, Art. 7, para. 1 (May 4, 1950) (Japan Plant Quarantine Association translation) (Exhibit USA-8).

“The districts and plants specified in article 7, paragraph 1, Item (1) of the Law shall be designated as follows. (1) The districts and plants specified in the Annexed Table 2.”<sup>17</sup> Item 16 of Annexed Table 2, in turn, designates “Live plants and plant parts (including fruit, flower and pollen, other than seed” of apple (genus *Malus*), “excluding those listed in Annexed List 24, 25, and 31” as prohibited to protect against “Fire blight (*Erwinia amylovora*).”<sup>18</sup>

18. Paragraph 25 of the Annexed List to Table 2 of the Plant Protection Law Enforcement Regulations sets out conditions under which U.S. apples may be imported into Japan: “Fresh fruit of apple of Golden Delicious variety and Red Delicious variety which are shipped from the United States of America directly to Japan without calling at any port and which conforms to the standards established by the Ministry of Agriculture, Forestry and Fisheries.”<sup>19</sup> The relevant standards are currently set by MAFF Notification No. 354<sup>20</sup> and related “Detailed Rules.”<sup>21</sup>

19. MAFF Notification No. 354 and the Detailed Rules impose several restrictions on the importation of U.S. apple fruit in connection with fire blight or *Erwinia amylovora*:

First, fruit is prohibited unless produced in designated areas within the U.S. States of Washington or Oregon.<sup>22</sup>

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<sup>17</sup> Ministerial Ordinance No. 73: Plant Protection Law Enforcement Regulations, Art. 9 (Ordinance first enacted June 30, 1950) (Japan Plant Quarantine Association translation) (Exhibit USA- 9).

<sup>18</sup> Ministerial Ordinance No. 73: Plant Protection Law Enforcement Regulations, Annexed Table 2 (Exhibit USA-9).

<sup>19</sup> Ministerial Ordinance No. 73: Plant Protection Law Enforcement Regulations, Annexed List, para. 25 (Exhibit USA-9).

<sup>20</sup> MAFF Notification No. 354 (March 10, 1997) (U.S. translation) (Exhibit USA- 10). Notification No. 354 replaced an earlier Notification No. 1184, which first put into place the Japanese fire blight restrictions. See MAFF Notification No. 1184 (August 22, 1994) (U.S. translation) (Exhibit USA- 11).

<sup>21</sup> On April 1, 1997, the Ministry of Agriculture, Fisheries, and Forestry issued Detailed Rules to implement MAFF Notification No. 354, dated March 10, 1997. See MAFF Detailed Rules for U.S. Apples (April 1, 1997) (U.S. translation) (Exhibit USA- 12). Because the April 1, 1997 Detailed Rules amend but do not replace in full the August 22, 1994 Detailed Rules, which implemented MAFF Notification No. 1184, it is necessary to read the August 22, 1994 Detailed Rules in conjunction with the April 1, 1997 Detailed Rules in order to understand the full scope of the Japanese fire blight measures. See MAFF Detailed Rules for U.S. Apples (August 22, 1994) (U.S. translation) (Exhibit USA- 13).

<sup>22</sup> MAFF Notification No. 354, para. 1 (March 10, 1997) (“[F]resh apple fruits . . . must be produced in the areas designated by the U.S. plant protection authority as the areas . . . where the U.S. authorities inspect for fire blight at proper times in the States of Washington and Oregon, U.S.A.”) (Exhibit USA-10). Notification No. 354 and the Detailed Rules also contain requirements related to codling moth that are not at issue in this dispute and will not be reproduced here.

Second, these designated areas must be inspected three times yearly (at blossom, fruitlet, and harvest stages) for the presence of fire blight.<sup>23</sup>

Third, fruit is prohibited unless the export orchard is free of plants infected with fire blight and free of host plants of fire blight (other than apples), whether or not infected.<sup>24</sup>

Fourth, fruit is prohibited unless a 500-meter buffer zone surrounding the export orchard is free of plants infected with fire blight.<sup>25</sup>

Fifth, fruit is prohibited unless subjected to a post-harvest surface treatment with chlorine.<sup>26</sup>

Sixth, fruit is prohibited unless produced according to specified requirements, such as chlorine treatment of containers for harvesting<sup>27</sup> and chlorine treatment of the interior of the packing facility.<sup>28</sup>

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<sup>23</sup> MAFF Notification No. 354, para. 1 (March 10, 1997) (“[F]resh apple fruits . . . must be produced in the areas designated by the U.S. plant protection authority as the areas . . . where the U.S. authorities inspect for fire blight at proper times . . . .”) (Exhibit USA- 10); MAFF Detailed Rules, § 1(1) (April 1, 1997) (specifying, *inter alia*, that designated areas are “the areas where fire blight surveys are conducted at appropriate times”) (Exhibit USA- 12); MAFF Detailed Rules, § 1(2) (August 22, 1994) (“The American Authorities shall designate the orchards every year based on the result of the three times inspection of the orchards and buffer zones, in principle at the time of blooming and fruitlet and at the time just before the harvest. However, in case of strong storm like hurricane and/or hail storm, additional inspection by the American Authorities are required, except that heavy rain, wind and/or hail storm occur just before the inspection above.”) (Exhibit USA- 13).

<sup>24</sup> MAFF Detailed Rules, § 6(2)a (April 1, 1997) (“It must be confirmed that the fruit was produced in the disease-free area of the designated area.”) (Exhibit USA-13); *id.* § 1(1) (specifying, *inter alia*, that designated areas “consist of disease-free areas . . . which satisfy the following conditions”) (Exhibit USA-12); MAFF Detailed Rules, § 1(1)A (August 22, 1994) (export areas for fire blight are “[f]ree from any host plants . . . of fire blight . . . other than apple,” surrounded by a buffer zone, and “[f]ree from any plants infected with fire blight”) (Exhibit USA- 13).

<sup>25</sup> MAFF Detailed Rules for U.S. Apples, § 1(1)B (April 1, 1997) (buffer zone is a “[b]elt-shaped [area] . . . more than 500 meter[s] wide surrounding [the] export area” and is “[f]ree from any plants infected with fire blight”) (Exhibit USA- 12).

<sup>26</sup> MAFF Notification No. 354, para. 4(3) (March 10, 1997) (“As a treatment for fire blight, the fruit surface must be sterilized.”) (Exhibit USA- 10); MAFF Detailed Rules, § 6(1)c (April 1, 1997) (“(a) It must be confirmed that the fruit was soaked in the sodium hypochlorite solution (100 ppm or more chlorine concentration) for one minute or longer. (b) During the treatment, it must be confirmed that the chlorine concentration is maintained at 100 ppm or more.”) (Exhibit USA- 12).

<sup>27</sup> MAFF Detailed Rules § 2 (April 1, 1997) (Exhibit USA-12).

<sup>28</sup> MAFF Detailed Rules § 4(2)C (April 1, 1997) (Exhibit USA- 12).

Seventh, fruit is prohibited unless kept separated post-harvest from other fruit.<sup>29</sup>

Eighth, U.S. plant protection officials must certify or declare that fruit are free of quarantine pests, “are not infested/infected with . . . fire blight,” and were treated with chlorine.<sup>30</sup>

Ninth, Japanese officials must confirm that the U.S. official has made the necessary certification and that the chlorine treatment and orchard designations were properly made;<sup>31</sup> Japanese officials must also inspect both the disinfestation and packing facilities.<sup>32</sup>

#### IV. LEGAL ARGUMENTS

##### A. Japan’s Measures on U.S. Apples Are Inconsistent with Article 2.2 of the SPS Agreement Because They Are Maintained Without Sufficient Scientific Evidence

###### 1. Introduction: Japan Must Have Sufficient Scientific Evidence to Maintain its Measures

20. Japan prohibits the importation of U.S. apples unless they are harvested, treated, and imported in compliance with the Japanese fire blight restrictions. The Japanese fire blight measures are inconsistent with Article 2.2 of the SPS Agreement because they are maintained without sufficient scientific evidence.

21. 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.” In Article 2.2, WTO Members agreed to “ensure that any . . . 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.” It is the last obligation that is at issue here.<sup>33</sup>

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<sup>29</sup> MAFF Detailed Rules §§ 6, 7(1) (August 22, 1994) (Exhibit USA- 13).

<sup>30</sup> MAFF Notification No. 354, para. 3 (March 10, 1997) (Exhibit USA- 10).

<sup>31</sup> MAFF Notification No. 354, para. 5 (March 10, 1997) (Exhibit USA- 10); MAFF Detailed Rules §1(3)-(5) (August 22, 1994) (Exhibit USA-13).

<sup>32</sup> MAFF Detailed Rules § 5 (August 22, 1994) (Exhibit USA-13).

<sup>33</sup> The Appellate Body has found that, by failing to base a measure on a risk assessment in violation of Article 5.1, a Member is also, by implication, acting inconsistently with Article 2.2. *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R (adopted November 6, 1998), paras. 137-38 (“*Australia – Salmon*”). The

22. The obligation not to maintain an SPS measure “without sufficient scientific evidence” was at the center of the *Japan–Varietals* dispute.<sup>34</sup> 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 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).<sup>35</sup> 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.”<sup>36</sup> 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.”<sup>37</sup>

23. The Japanese fire blight measures prohibit the importation of apples *unless* they have been harvested, treated, and imported according to highly restrictive conditions. However, there is *no* evidence that the apple fruit sought to be exported from the United States<sup>38</sup> – that is,

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United States discusses the inconsistency of Japan’s fire blight measures with Article 5.1 in section IV.B of this submission.

<sup>34</sup> *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R; WT/DS76/R (adopted March 19, 1999) (“*Japan – Varietals*”).

<sup>35</sup> *Japan – Varietals*, WT/DS76/AB/R, paras. 73-80.

<sup>36</sup> *Japan – Varietals*, WT/DS76/AB/R, para. 84.

<sup>37</sup> *Id.*

<sup>38</sup> Under U.S. law, exported apple fruit must be of a Federal or State grade that meets a minimum quality established by regulation. U.S. Export Apple Act, 7 U.S.C. § 581. Exported U.S. apples must currently satisfy at least the requirements for the “U.S. No. 1” grade, 7 C.F.R. § 33.10 (minimum requirements for export apples), pursuant to which apples must be:

[M]ature but not overripe, carefully hand-picked, clean, fairly well-formed; free from decay, internal browning, internal breakdown, bitter pit, Jonathan spot, scald, freezing injury . . . and broken skin or bruises except those which are incident to proper handling and packing. The apples are also free from damage caused by . . . sunburn or sprayburn, limb rubs, hail, drought spots, scars, stem or calyx cracks, disease, insects, [or] damage by other means . . . .

United States Standards for Grades of Apples, 7 C.F.R. § 51.302 (requirements for U.S. No. 1 same as for “U.S. Fancy,” except for “color, russetting, and invisible water core”). Individual states may have standards that exceed the federal standards for grades. *See, e.g.*, Washington Administrative Code 16-403-140 (“Washington State standard

mature,<sup>39</sup> symptomless apples – would transmit the fire blight disease to Japan. To the contrary, all of the scientific evidence shows that mature, symptomless apple fruit have never transmitted and are not a pathway for the disease. Thus, there is no evidence, let alone sufficient evidence, for Japan to maintain its fire blight measures, and Japan has acted inconsistently with Article 2.2 of the SPS Agreement.

## 2. The Scientific Evidence Establishes That Mature, Symptomless Apple Fruit Have Never Transmitted Fire Blight and Do Not Transmit the Disease

24. The United States' review of the scientific literature reveals no evidence that mature, symptomless apple fruit transmit fire blight. Rather, the scientific evidence establishes that such fruit have never transmitted and do *not* play a role in the transmission of fire blight:

Thomson (2000): The most recent scientific review for a reference book on fire blight states: “[I]t has *never been demonstrated* that mature fruit are involved in dissemination of *Erwinia amylovora* and serve as a source of new infections in orchards. It would be extremely unlikely that contaminated fruit could be responsible for establishing new outbreaks of fire blight.”<sup>40</sup>

Roberts et al. (1998): This study, a critical review of all published data on the presence of fire blight bacteria on or in mature, symptomless apples and an estimation of the theoretical probability of transmission of the disease via those fruit, concludes: “Using 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. We have 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.*”<sup>41</sup>

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apple grades for extra fancy or fancy shall be equivalent to or better than the U.S. standards for grades of apples . . .”).

<sup>39</sup> United States Standards for Grades of Apples define “mature” apples as “apples [that] have reached the stage of development which will insure the proper completion of the ripening process. Before a mature apple becomes overripe it will show varying degrees of firmness, depending upon the stage of the ripening process.” 7 C.F.R. § 51.313. Certain grade requirements, such as color, will also necessitate that fruit be allowed to develop into maturity before being harvested.

<sup>40</sup> S.V. Thomson, *Epidemiology of Fire Blight*, in *Fire Blight: The Disease and Its Causative Agent, Erwinia Amylovora*, at 17 (2000) (J.L. Vanneste, ed.) (emphasis added) (citing additional sources concluding that fruit do not transmit the disease) (Exhibit USA- 2).

<sup>41</sup> 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 USA- 4); *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

European and Mediterranean Plant Protection Organization (1997): “[T]he risk of [fire blight] transmission on fruit is considered insignificant in current trade practice.”<sup>42</sup>

Thomson (1992): “The presence of *E. amylovora* on or in healthy fruit *has not been shown* to be a source of inoculum in fruit orchards. . . . It seems very remote that contaminated fruit could be responsible for establishing new outbreaks.”<sup>43</sup>

Roberts et al. (1989): “[H]ealthy, mature apple fruit, even when harvested from blighted trees, are unlikely to harbor *E. amylovora* populations and therefore are unlikely to pose a phytosanitary risk to areas free from fire blight.”<sup>44</sup>

Dueck (1974): “[T]he risk of disseminating fire blight bacteria on symptomless mature apples is considered negligible.”<sup>45</sup>

25. Thus, the scientific evidence indicates that mature, symptomless apple fruit have *never* transmitted the fire blight disease. In the absence of any affirmative evidence, the scientific literature describes the risk of transmitting the fire blight disease through mature, symptomless apple fruit as “negligible,” “unlikely,” “very remote,” “insignificant,” “extremely low,” or “extremely unlikely.” The United States notes that in describing the risk of transmission as “negligible” rather than “zero,” the scientific reports merely reflect “the uncertainty that theoretically always remains [that an event may occur] since science can never provide absolute certainty” that an event may *never* occur.<sup>46</sup>

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Thomson (1992)—that fruit are not involved in disease spread).

<sup>42</sup> European and Mediterranean Plant Protection Organization (EPPO), *Data Sheet on Quarantine Pests: Erwinia amylovora*, Quarantine for Europe, at 4 (1997) (Means of Movement and Dispersal) (Exhibit USA-5). The EPPO goes on to “recommend[] countries *at high risk* to prohibit importation of host *plants for planting*” but does *not* recommend any restrictions on importation of fruit. *Id.* at 5 (emphasis added).

<sup>43</sup> S.V. Thomson, *Fire blight of apple and pear*, in *Plant Diseases of International Importance*, vol. 3: *Diseases of Fruit Crops* 32-65 (J. Kumar et al., eds.) (1992).

<sup>44</sup> R.G. Roberts et al., *Evaluation of Mature Apple Fruit from Washington State for the Presence of Erwinia amylovora*, *Plant Disease* 73: 917-21, at 920 (1989).

<sup>45</sup> J. Dueck, *Survival of Erwinia amylovora in association with mature apple fruit*, *Can. J. Plant Sci.* 54: 349-51, at 351 (1974).

<sup>46</sup> See *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R (adopted February 13, 1998), para. 186 (“*EC – Hormones*”). As both the panel and the Appellate Body concluded in *EC – Hormones*, theoretical uncertainty is not the kind of risk which a risk assessment and, therefore, an SPS measure, is to address. See WT/DS26/AB/R, para. 186; WT/DS26/R, paras. 8.152-8.153. 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.

26. This scientific evidence is borne out by real world experience. Billions of fruit have been shipped worldwide *without a single documented instance of fire blight transmission via exported apple fruit*.<sup>47</sup> An infinitesimal portion of these exports were made under conditions as stringent as those set by the Japanese fire blight measures. In fact, of 66 fire blight-free countries, 58 impose *no restrictions on imported fruit for fire blight at all*.<sup>48</sup> Thus, although nearly all trade in apple fruit occurs without any restrictions for fire blight, there is no evidence that fire blight has ever spread through exported apples.

27. The export experience of the United States makes the point more tangible. Fire blight has been geographically dispersed in the United States since at least the 1920s.<sup>49</sup> U.S. export statistics indicate that the United States has exported 10,505,500 metric tons of apple fruit, or approximately 48.5 billion apples, over the last 35 years.<sup>50</sup> Nonetheless, there has not been a single instance of fire blight spread through exports of U.S. apple fruit in that time. Over these 35 years, the United States has exported 4,794,495 metric tons of apple fruit, or approximately 22.1 billion apples, to its top-ten fire blight-free export markets with no spread of fire blight through those exports:

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<sup>47</sup> R.G. Roberts, et al. *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17: 19-28, 25 (1998) (“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.”) (Exhibit USA- 4).

<sup>48</sup> See Exhibit USA-14 (table detailing any fire blight measures on imported fruit in fire blight-free areas). Notwithstanding the lack of any scientific evidence that mature, symptomless apple fruit transmit the disease, only Australia (which prohibits apple imports from countries with fire blight) maintains measures as restrictive or more restrictive than those of Japan. Five WTO Members (Argentina, Brazil, Chile, Uruguay, and Chinese Taipei) impose a mandatory or optional chlorine treatment, a common practice to maintain sanitary packing conditions.

<sup>49</sup> R.G. Roberts, et al. *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17: 19-28, 20 (1998) (Exhibit USA-4); EPPO, *Data Sheet on Quarantine Pests: Erwinia amylovora*, Quarantine for Europe, at 2 (1997) (Geographical Distribution) (Exhibit USA- 5).

<sup>50</sup> 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), 10,505,500 metric tons is equivalent to 48,524,905,500 apples.



<b>U.S. Apple Exports to Top-Ten Fire Blight-Free Markets</b>			
<b>Fire Blight-Free Area</b>	<b>Metric Tons</b>	<b>Number of Apples<sup>51</sup></b>	<b>Time Period</b>
Chinese Taipei	1,735,064	8,014,260,616	1970-2001
Hong Kong	932,656	4,307,938,064	1967-2001
Indonesia	366,739	1,693,967,441	1967-2001
Saudi Arabia	372,208	1,719,228,752	1969-2001
Thailand	280,550	1,295,860,450	1969-2001
United Arab Emirates	268,901	1,242,053,719	1978-2001
Malaysia	259,036	1,196,487,284	1967-2001
Venezuela	259,623	1,199,198,637	1967-2001
Philippines	181,400	837,886,600	1967-2001
Colombia	138,318	638,890,842	1967-2001

None of these areas has fire blight, none imposes measures similar to the Japanese fire blight measures,<sup>52</sup> and *none* of these areas has reported transmission of fire blight through imports of U.S. apple fruit.

28. There is no scientific evidence that mature, symptomless apple fruit have transmitted the fire blight disease. The scientific evidence as well as the real world trade statistics cited above demonstrate that billions of apple fruit imported without facing any restrictions for fire blight at all have not resulted in a single instance of transmission of the disease. Thus, there is no rational or objective relationship between the scientific evidence and the Japanese fire blight measures. By maintaining its fire blight measures without sufficient scientific evidence, Japan has acted inconsistently with Article 2.2 of the SPS Agreement.

### **3. The Scientific Evidence Underlying the Fact That Mature, Symptomless Apples Do Not Serve As a Pathway for the Disease**

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<sup>51</sup> Again, conversion of official U.S. export data by volume to an equivalent number of fruit has been made conservatively assuming that the average exported apple was an “88” in size (88 apples per 42 lb. box).

<sup>52</sup> All of these areas but Chinese Taipei impose no fire blight measures on apple fruit at all. Chinese Taipei requires a fruit freedom additional declaration or a chlorine dip, as well as a phytosanitary certificate. *See* Exhibit USA-14 (table detailing any fire blight measures on imported fruit in fire blight-free areas).

29. As the United States has demonstrated, there is no scientific evidence that mature, symptomless apple fruit have ever transmitted the fire blight disease, despite billions of fruit imported without facing any restrictions for fire blight at all. While this suffices to establish that Japan has acted inconsistently with Article 2.2 of the SPS Agreement, in this section the United States further explains the scientific evidence underlying the fact that mature, symptomless apples do not serve as a “pathway” for the fire blight disease.

30. The concept of a pathway for the disease is an important one. The International Plant Protection Convention<sup>53</sup> defines a pathway as “[a]ny means that allows the entry or spread of a pest.”<sup>54</sup> As a phytosanitary measure under the SPS Agreement is a measure applied “to protect . . . plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms,”<sup>55</sup> a phytosanitary measure must address a risk that arises due to an identifiable pathway, that is, a means that allows entry or spread of a pest.<sup>56</sup>

31. While the United States discusses Japan’s failure to base its measures on a risk assessment in more detail elsewhere,<sup>57</sup> it is useful to note here that the International Plant Protection Convention’s Standard for “Pest Risk Analysis for Quarantine Pests” makes the identification of a pathway a key component of any risk analysis and resulting phytosanitary measure. Thus, “[a]ssessing the probability of introduction requires an analysis of each of the *pathways with which a pest may be associated* from its origin to its establishment in the [pest

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<sup>53</sup> The International Plant Protection Convention (“IPPC”) provides the framework within which international standards, guidelines, and recommendations for plant health are developed. *See* SPS Agreement, Arts. 3.1, 3.2, 3.3, 3.4 & Annex A. Contracting parties to the IPPC adopt “international standards for phytosanitary measures” (“ISPMs”) through the “Interim Commission on Phytosanitary Measures. ISPMs are the standards, guidelines, and recommendations recognized as the basis for phytosanitary measures applied by Members of the World Trade Organization under the Agreement on the Application of Sanitary and Phytosanitary Measures.” International Plant Protection Convention, Glossary of Phytosanitary Terms, at 1 (2001) (International Standards for Phytosanitary Measures Publication No. 5) (Application).

<sup>54</sup> International Plant Protection Convention, Glossary of Phytosanitary Terms, at 12 (2001) (International Standards for Phytosanitary Measures Publication No. 5).

<sup>55</sup> SPS Agreement, Annex A, para. 1.

<sup>56</sup> Note that a “pest” under the International Plant Protection Convention is “[a]ny species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.” International Plant Protection Convention, Glossary of Phytosanitary Terms, at 12 (2001) (International Standards for Phytosanitary Measures Publication No. 5).

<sup>57</sup> *See infra* § IV.B (claim under Article 5.1 of the SPS Agreement).

risk analysis] area.”<sup>58</sup> The “*probability of the pest being associated, spatially or temporally, with the pathway at origin should be estimated,*” considering, for example, the “*occurrence of the pest in a life-stage that would be associated with commodities.*”<sup>59</sup> In addition, if a pest is associated with a pathway and may be imported, the risk of entry of the pest is nonetheless tied to “*dispersal mechanisms, including vectors to allow movement from the pathway to a suitable host.*”<sup>60</sup> If the pest risk assessment concludes that measures are necessary to manage the risk of introduction of a quarantine pest, a country must select appropriate risk management measures that “*are applied to pathways, usually consignments of a host, from a specific origin.*”<sup>61</sup>

32. Japan applies its fire blight measures to restrict imports of apple fruit. However, the scientific evidence indicates that:

- (1) fire blight bacteria *are not associated internally with the exported commodity* (mature, symptomless apple fruit);
- (2) fire blight bacteria *are rarely associated externally with the exported commodity*, even when harvested from blighted trees and orchards;
- (3) even if a mature, symptomless apple were externally contaminated with bacteria, 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 bacteria, there is *no dispersal mechanism or vector* to allow movement of such bacteria from the fruit to a suitable host.<sup>62</sup>

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<sup>58</sup> International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests § 2.2, at 12 (2001) (International Standards for Phytosanitary Measures Publication No. 11) (Assessment of the probability of introduction and spread) (emphasis added) (Exhibit USA-15).

<sup>59</sup> International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests § 2.2.1.2, at 13 (2001) (International Standards for Phytosanitary Measures Publication No. 11) (Probability of the pest being associated with the pathway at origin) (emphasis added) (Exhibit USA-15).

<sup>60</sup> International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests § 2.2.2, at 14 (2001) (International Standards for Phytosanitary Measures Publication No. 11) (Probability of transfer to a suitable host) (emphasis added) (Exhibit USA-15).

<sup>61</sup> International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests § 3.4, at 22 (2001) (International Standards for Phytosanitary Measures Publication No. 11) (Identification and selection of appropriate risk management options) (emphasis added) (Exhibit USA-15).

<sup>62</sup> There are additional conditions, such as discard near a fire blight host that is in a state receptive to infection, that also must be satisfied in order for exported fruit to transmit the disease to an importing country. See R.G. Roberts, et al., *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17: 19-28, 24

Because the chain of transmission – from association of bacteria with fruit (elements (1) or (2)) to bacterial survival of handling, storage, and transport (element (3)) to vectoring of bacteria to a suitable host (element (4)) – is never completed, imports of apple fruit are not a means of, and cannot result in, transmission of fire blight bacteria to Japan. Thus, because mature, symptomless apple fruit are not a pathway for the fire blight disease, there is no scientific basis to restrict imports of such fruit.<sup>63</sup>

A. *Mature, Symptomless Apples Do Not Harbor Fire Blight Bacteria Internally*

33. Numerous studies indicate that mature, symptomless apple fruit do not harbor endophytic (internal) populations of the bacteria.<sup>64</sup> Those studies include:

Roberts (2002): This report on the joint Japanese-U.S. research<sup>65</sup> is the largest investigation to date of whether mature, symptomless apple fruit harbor the bacterium internally. 30,900 fruit from 2 sites in Washington State, U.S.A., were harvested at 0, 10, 25, 50, 100, or 300 meters from a source of fire blight inoculum. Nine hundred fruit were analyzed at harvest for internal populations, and *no bacteria were detected, even from trees with or directly adjacent to fire blight*. Thirty thousand fruit were placed in commercial cold storage for 2-3 months (depending on date of harvest). *None of the 30,000 fruit developed external disease symptoms*. Of the 30,000 fruit, 1500 were sliced open, and *no internal disease symptoms were present*. Of the 1500 sliced fruit, the

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(1998) (presenting linear model with five parameters “to estimate the risk of fire blight bacteria being introduced and established via commercial shipments of mature apple fruits”) (Exhibit USA- 4). For purposes of this discussion, the United States focuses on the three most unlikely elements, bacterial presence on or in mature, symptomless apples, bacterial survival of normal commercial handling, storage, and transport of fruit, and existence of a vector to move bacteria from an imported fruit to a susceptible host.

<sup>63</sup> As the United States discusses later, Japan’s assessment of risks is fatally flawed because it does not distinguish evidence relevant to the exported commodity (mature, symptomless apple fruit) from other evidence (for example, immature, visibly infected, visibly damaged, or artificially inoculated fruit). *See infra* §§ IV.B.2.A, IV.B.4 (claim under Article 5.1 of the SPS Agreement).

<sup>64</sup> The United States notes that, in most studies presented that tested mature, symptomless fruit for internal and/or external bacterial populations, the experimental designs were purposely *biased in favor of positive detection* because fruit were not randomly selected but were harvested from blighted trees and orchards (in some cases, fruit were also harvested from blight-free orchards), and in many cases were harvested directly from blighted spurs or shoots. Nonetheless, these studies have not detected internal populations of bacteria in mature, symptomless apple fruit and have very rarely detected external populations of bacteria on such fruit.

<sup>65</sup> *See* Exhibit USA-1, para. 5-6 (chronology of U.S. efforts to resolve the dispute bilaterally).

internal surfaces of 500 were streaked and plated onto selective media, and *no fire blight bacteria were isolated from any fruit*.<sup>66</sup>

van der Zwet et al. (1990): This paper gives results from numerous experiments conducted in various locations.<sup>67</sup> The one relevant experiment harvested immature, mature, and some possibly mature fruit from 4 different geographic locations, and no internal bacteria were detected from any of the mature fruit (80 fruit from West Virginia, U.S.A.) or possibly mature fruit (40 fruit from Washington, U.S.A., 40 fruit from Utah, U.S.A., and 80 fruit from Ontario, Canada), *even when harvested from blighted trees*.<sup>68</sup>

Roberts et al. (1989): No internal fire blight bacteria were detected in 1,555 mature, symptomless apple fruit harvested over two years from blighted (in some cases, severely blighted) trees of seven apple cultivars grown at five locations in Washington, U.S.A.<sup>69</sup>

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<sup>66</sup> R.G. Roberts, *Evaluation of buffer zone size on the incidence of Erwinia amylovora in mature apple fruit and associated phytosanitary risk*, Acta Horticulturae (forthcoming 2002) (Proceedings of Ninth International Fire Blight Workshop) (Exhibit USA-16).

<sup>67</sup> Japan has, in the past, pointed to other experimental results in this paper, but the United States notes that they are not relevant. For example, in a storage experiment on mature fruit harvested from West Virginia, U.S.A., the paper reports development of internal disease symptoms on 4-15 percent of fruit. However, the paper itself underscores that the reported “[i]nternal fruit blight symptoms were difficult to distinguish from other fruit rots,” perhaps resulting in misidentification of the disease symptoms, and the experiment did not *test* whether fire blight bacteria were present (for example, by plating samples). Thus, there is no evidence that fire blight bacteria caused the reported symptoms. The same storage experiment was conducted on mature fruit harvested from Washington State, U.S.A., and no fruit developed internal disease symptoms. This experiment also did not test whether the bacteria were present. T. van der Zwet et al., *Population of Erwinia amylovora on External and Internal Apple Fruit Tissues*, Plant Disease 74: 711-16, at 713-14 (1990) (Exhibit USA-17). Also, another experiment that tested for internal and external bacterial presence at various distances from visible shoot blight symptoms only tested *immature* fruit. T. van der Zwet Declaration, para. 12 (July 16, 2002) (Exhibit USA- 18).

<sup>68</sup> T. van der Zwet et al., *Population of Erwinia amylovora on External and Internal Apple Fruit Tissues*, Plant Disease 74: 711-16, at 715, 714 tbl. 4 (1990) (Exhibit USA-17). This paper has been the source of some confusion as it reports on numerous different experiments conducted in different locations without distinguishing immature and mature fruit. However, the “Geographic Survey” experimental data, especially as clarified by two of the lead authors of the paper, support the position that mature, symptomless apples do *not* harbor internal populations of the bacterium. For example, from West Virginia, U.S.A., 80 *immature* fruit and 80 mature fruit were found to be free of internal fire blight bacteria. T. van der Zwet Declaration, para. 15 (July 16, 2002) (Exhibit USA-18). From Utah, U.S.A., 17 of 120 *immature* fruit were found to have internal populations, but none of 40 possibly mature fruit. Letter from S.V. Thomson, Utah State University, to R.G. Roberts, U.S. Department of Agriculture, at 1 (August 23, 2002) (Exhibit USA- 19). From Washington State, 80 fruit, 40 of which were *immature* and 40 of which were possibly mature (based on harvest dates), were found to be free of internal fire blight bacteria. From Ontario, Canada, 80 likely *immature* fruit and 80 possibly mature fruit (based on harvest dates) were found to be free of internal fire blight bacteria.

<sup>69</sup> R.G. Roberts et al., *Evaluation of mature apple fruit from Washington State for the presence of Erwinia amylovora*, Plant Disease 73: 917-21 (1989).

Dueck (1974): No internal bacteria were isolated from any of 60 mature, symptomless apple fruit harvested in Ontario, Canada, from severely infected trees. The report concluded: “*Mature apples are highly resistant to infection. Only when forcibly introduced into the cortex were fruit infected. . . . [U]nder orchard conditions apples, particularly from resistant cultivars, are not infected.*”<sup>70</sup>

Thus, of the 3,215 mature (or possibly mature), symptomless apple fruit that have been tested for internal fire blight bacteria, *none have been positive.*

34. These results are not surprising as they reflect the biology of the disease.<sup>71</sup> Blossoms that become infected tend to abort their fruit,<sup>72</sup> and any fruit that become infected (either through movement of the bacteria through internal tissues from a canker to the fruit or through external wounding of the fruit) do not develop normally. Instead, they “turn brown to black, shrivel and, like the blossoms, remain attached to the spur, taking on a mummified appearance.”<sup>73</sup> Thus, while *immature* apple fruit *may* contain detectable levels of internal fire blight bacteria without yet having developed disease symptoms,<sup>74</sup> by the time of harvest mature, symptomless apple fruit will *not* harbor internal populations of fire blight bacteria.

*B. External Bacteria on Mature, Symptomless Apple Fruit Are Found Very Rarely*

35. Because mature, symptomless apple fruit do not harbor internal fire blight bacteria, it is appropriate to examine the scientific evidence relating to external bacterial populations. The evidence indicates that fire blight bacteria are *very rarely detected on the outside of mature,*

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<sup>70</sup> J. Dueck, *Survival of Erwinia amylovora in association with mature apple fruit*, Can. J. Plant Sci. 54: 349-51, at 351 (1974) (emphasis added).

<sup>71</sup> See *supra* § III.A (Factual Background – Fire Blight Disease and the Fire Blight Bacterium, *Erwinia amylovora*).

<sup>72</sup> See, e.g., Hale et al., *Ecology and epidemiology of fire blight in New Zealand*, Acta Horticulturae 411: 79-85, at 82 (1996) (when blossoms were heavily inoculated with fire blight bacteria, “most of the flowers in the inoculated blossom clusters aborted and those fruitlets which did form did not survive until the first sampling”; moreover, “[i]nfected flowers, in clusters adjacent to the inoculated clusters, also tended to abort soon after symptoms were apparent”).

<sup>73</sup> European Plant Protection Organization, Data Sheet on Quarantine Pests: *Erwinia amylovora*, at 3 (1997) (Detection and Identification–Symptoms) (Exhibit USA-5).

<sup>74</sup> See, e.g., van der Zwet et al., *Population of Erwinia amylovora on External and Internal Apple Fruit Tissues*, Plant Disease 74: 711-16, at 714 tbl. 4 (1990) (17 of 120 immature, presumably symptomless fruit from Utah, U.S.A., were found to have internal populations of fire blight bacteria) (Exhibit USA-17). In the same study, 80 immature fruit from West Virginia, U.S.A., 40 immature fruit from Washington State, U.S.A., and 80 likely immature fruit from Ontario, Canada, that were presumably symptomless were found to be free of internal fire blight bacteria.