symptomless apple fruit (that is, epiphytically), even when harvested from severely infected trees and orchards:

> Thomson (2000): Again, the most recent scientific review for a reference book on fire blight states: "Populations of *E. amylovora* are *rare on mature fruit* and when present are probably due to deposition from a nearby source of active inoculum. In every case where *E. amylovora* has been detected on fruit, it has been from orchards with high levels of fire blight infection."[75]
>
> Hale and Taylor (1999): No epiphytic fire blight bacteria were isolated from calyxes (the opposite end of the fruit from the stem) of 150 mature fruit harvested from an infected orchard.[76]
>
> Hale et al. (1996): No epiphytic fire blight bacteria were found on the calyxes and surfaces of 173 mature, symptomless apple fruit harvested from infected trees in New Zealand.[77]
>
> Clark et al. (1993): No epiphytic fire blight bacteria were detected on calyxes of 750 mature, symptomless apple fruit even from within 20 cm of inoculated blight sources (flowers) showing disease symptoms.[78]
>
> van der Zwet et al (1991): No epiphytic fire blight bacteria were detected on surfaces or calyxes of apple fruit from 6 susceptible cultivars from blighted orchards in West Virginia, U.S.A.[79]
>
> van der Zwet et al. (1990): No epiphytic bacteria were recovered from 80 mature, symptomless apple fruit from West Virginia, U.S.A., 40 possibly mature fruit from Washington, U.S.A., and 80 possibly mature fruit from Ontario, Canada; of 40 possibly mature fruit from Utah, U.S.A., harvested in a severely blighted orchard, only 1 contained

---

[75] 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).

[76] C.N. Hale and R.K. Taylor, *Effect of Cold Storage on Survival of* Erwinia amylovora *in Apple Calyxes*, Acta Horticulturae 489: 139-43 (1999) (infected orchard had less than 5 strikes per tree).

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

[78] R.G. Clark et al., *A DNA Approach to* Erwinia amylovora *Detection in Large Scale Apple Testing and in Epidemiological Studies*, Acta Horticulturae 338: 59-66 (1993).

[79] T. van der Zwet et al., *Evaluation of calyx tissues of several apple cultivars for the presence of* Erwinia amylovora, Phytopathology 81: 1194 (1991) (no indication of numbers of fruit tested).

epiphytic bacteria in the calyx. No epiphytic bacteria were detected after storage on any of 160 mature, symptomless fruit from Washington State, U.S.A. Epiphytic bacteria were recovered after storage from 5 of 175 mature, presumably symptomless fruit harvested within 10 meters of infection in severely blighted orchards in West Virginia, U.S.A.[80]

Roberts et al. (1989): No epiphytic fire blight bacteria were detected on the surfaces of 1,555 mature, symptomless apple fruit harvested from blighted (in some cases, severely blighted) trees of seven apple cultivars grown at five locations in Washington, U.S.A.[81]

Sholberg (1988): Epiphytic bacteria were detected on approximately 18-54 (the actual number was not given) of 54 mature, presumably symptomless apples harvested from a severely blighted orchard (including severely infected pear trees).[82]

---

[80] T. van der Zwet et al., *Population of* Erwinia amylovora *on External and Internal Apple Fruit Tissues*, Plant Disease 74: 711-16, at 714 (1990) (Exhibit USA-17). To understand the results of isolations of external bacteria reported in this paper, the results from *immature*, mature, and some possibly mature fruit must be distinguished. For example, from Washington State, 40 *immature* fruit and 40 possibly mature fruit were found to be free of epiphytic bacteria on surfaces, calyxes, and stems. From Ontario, Canada, 80 *immature* fruit and 80 possibly mature fruit were also found to be free of epiphytic bacteria on surfaces, calyxes, and stems. From West Virginia, U.S.A., epiphytic bacteria were found on 3 out of 80 *immature* fruit from "healthy" orchards and on 2-4 (the actual number is not presented) out of 80 *immature* fruit from severely blighted orchards, but epiphytic bacteria were not recovered from 80 mature fruit. T. van der Zwet Declaration, paras. 15-16 (July 16, 2002) (Exhibit USA- 18). From Utah, U.S.A., epiphytic bacteria were found on 10-13 (again, the actual number is not presented) out of 120 *immature* fruit, and in the calyx of 1 of 40 possibly mature fruit; all positive detections were made on fruit harvested from blighted trees in severely blighted orchards (50-200 or more strikes per tree). 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).

The United States also notes that the detection of epiphytic bacteria on immature fruit in West Virginia and on immature and one possibly mature fruit in Utah occurred when fruit was harvested within 10 meters of a source of fire blight inoculum. T. van der Zwet Declaration, paras. 8, 9, 13, 15 (July 16, 2002) (explaining that "the severe fire blight in the orchards of the Appalachian Fruit Research Station from 1984-1986 meant that [any] fruit were still subjected to nearby (within 10 meters) blighted trees" and "the pathogen pressure in the orchards was extremely high.") (Exhibit USA- 18); Letter from S.V. Thomson, Utah State University, to R.G. Roberts, U.S. Department of Agriculture, at 1 (August 23, 2002) (positive fruit harvested from blighted tree in severely blighted orchard) (Exhibit USA- 19).

[81] 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).

[82] P.L. Sholberg et al., *Occurrence of* Erwinia amylovora *of pome fruit in British Columbia in 1985 and its elimination from the apple surface*, Canadian Journal of Plant Pathology 10: 178-82, 180 tbl. 2 (1988) (epiphytic bacteria detected from fruit harvested from "severely damaged" orchard in which "[a]lmost every . . . apple tree was infected" after August hail storm). Although the precise number of positive fruit is not given, the United States has calculated (based on the experimental methods used) that 18-54 fruit could have been positive.

Hale et al. (1987): Epiphytic bacteria were detected in the calyxes of 3 out of 2100 mature, symptomless fruit harvested in New Zealand, and only from severely infected trees in a severely blighted orchard.[83]

Dueck (1974): No external bacteria were isolated from any of 60 mature, symptomless apple fruit harvested in Ontario, Canada, from severely infected trees. The report concluded: "Furthermore, apples from severely infected trees of a susceptible cultivar, having been exposed to high levels of inoculum during the growing season, were free of the bacterium at harvest time."[84]

36. As this review of the scientific literature suggests, the epiphytic (external) presence of fire blight bacteria on mature, symptomless apple fruit at harvest is extremely rare. In those few instances when external bacteria have been detected, the fruit were harvested from or within 10 meters of an infected tree in *severely* infected orchards.[85] Thus, in most cases, mature, symptomless apples, even when harvested from infected trees or orchards, will not be externally contaminated with fire blight bacteria.

37. The rarity of external contamination of mature, symptomless apple fruit is also linked to the biology of the fire blight bacteria and to the disease cycle.[86] Bacteria are most prevalent in infected hosts during the spring, when blossoms are present. The bacterial inoculum exuded in warm, wet conditions from infected shoots, cankers, and infected fruit and blossoms may infect new hosts via blossoms as well as other natural plant openings.[87] However, as conditions in the

---

[83] C.N. Hale et al., *Occurrence of* Erwinia amylovora *on apple fruit in New Zealand*, Acta Horticulturae 217: 33- 40, at 37 (1987) (fruit harvested from severely blighted, lightly infected, and fire blight-free orchards).

[84] J. Dueck, *Survival of* Erwinia amylovora *in association with mature apple fruit*, Can. J. Plant Sci. 54: 349-51, at 351 (1974) (emphasis added).

[85] T. van der Zwet et al., *Population of* Erwinia amylovora *on External and Internal Apple Fruit Tissues*, Plant Disease 74: 711-16, at 714 (1990) (epiphytic bacteria detected when fruit harvested within 10 meters of infected host in orchards with "severe" fire blight) (Exhibit USA-17); P.L. Sholberg et al., *Occurrence of* Erwinia amylovora *of pome fruit in British Columbia in 1985 and its elimination from the apple surface*, Canadian Journal of Plant Pathology 10: 178-82, 180 tbl. 2 (1988) (epiphytic bacteria detected from fruit harvested from "severely damaged" orchard in which "[a]lmost every . . . apple tree was infected" after August hail storm); C.N. Hale et al., *Occurrence of* Erwinia amylovora *on apple fruit in New Zealand*, Acta Horticulturae 217: 33- 40, at 33 (1987) (epiphytic bacteria detected when fruit harvested from "severely affected" trees, that is, with an average of 75 infections per tree).

[86] *See supra* § III.A (Factual Background – Fire Blight Disease and the Fire Blight Bacterium, *Erwinia amylovora*).

[87] European Plant Protection Organization, Data Sheet on Quarantine Pests: *Erwinia amylovora*, at 3 (1997) ("Hold-over cankers are the most important source of primary inoculum for blossom infection in the spring. Bacteria enter the plant through blossoms, natural openings (stomata, lenticels, hydathodes) or wounds, carried by insects or by wind-driven rain.") (Exhibit USA- 5).

orchard become less hospitable (that is, hotter and drier) and the opportunities for new infections (and, hence, the bacterium's reproductive chances through blossoms and other openings) diminish during the apple fruit growing season, the bacteria shows a marked decline in population counts,[88] becoming extremely rare on fruit by the time of harvest. The scientific evidence indicates that "bacteria on the surface of [apple] fruit dies within a short time."[89] Thus, in those rare instances in which external populations have been detected, this is "probably due to deposition from a nearby source of active fire blight."[90]

C. Bacteria Are Highly Unlikely to Survive Commercial Handling, Storage, and Transport of Fruit

38. The scientific evidence demonstrates that fire blight bacteria are not associated internally with mature, symptomless apple fruit. Such apples also are very rarely externally contaminated with bacteria, even when harvested from infected trees and orchards. However, even in a rare instance in which mature, symptomless fruit may be externally contaminated, such external populations would die off rapidly because the bacteria are vulnerable to environmental conditions[91] and not suited to external survival (other than on stigmas of developing flowers).[92] Thus, any bacteria that may be found externally on mature, symptomless apples are unlikely to survive normal commercial handling, storage, and transport procedures.[93]

---

[88] *See* R.G. Roberts et al., *The potential for spread of* Erwinia amylovora *and fire blight*, Crop Protection 17: 19-28, at 22 (1998) (reviewing literature relating to population decline during growing season) (Exhibit USA- 4).

[89] H.W. Anderson, *Maintaining virulent cultures of* Erwinia amylovora *and suggestions of overwinter survival in mummified fruit*, Plant Disease Reporter 36: 301-02 (1952), *cited in* 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.) (Exhibit USA- 2).

[90] 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.) (citations omitted) (Exhibit USA- 2).

[91] H.P. Maas Geesteranus & P.M. de Vries, *Survival of* Erwinia amylovora *bacteria on plant surfaces and their role in epidemiology*, Acta Horticulturae: 151: 55-61 (1984) (survival of bacteria reduced to hours by exposure to UV-light, elevated temperatures, or high humidity).

[92] M.N. Schroth et al., *Epidemiology and control of fire blight*, Annual Review of Plant Pathology 12: 389-412 (1974); *see also* S.V. Thomson, *Epidemiology of Fire Blight*, *in* Fire Blight: The Disease and Its Causative Agent, *Erwinia Amylovora*, at 17, 20-21 (2000) (J.L. Vanneste, ed.) (Exhibit USA-2).

[93] The United States also notes that, in the extremely unlikely event that there were external fire blight bacteria on any exported fruit, Japan has mandated a post-harvest chlorine treatment to disinfest the outside of apple fruit. As explained later in this submission, Japan has not taken into account quarantine or other treatment imposed by its own measures in its assessment of the risks posed by imported apples. *See infra* § IV.C (claim under Article 5.2 of the SPS Agreement).

39. After apples are harvested, they are normally kept in cool storage conditions at the packing site to maintain fruit quality and enhance storage life until ready for sorting, grading, packing, and export. Shipping to export markets also occurs at low temperatures in order to maintain product freshness.[94] In addition, apple fruit may be subject to quarantine measures that require cold treatment; for example, in the case of U.S. apples exported to Japan, Japan's measures for codling moth call for maintaining apples at a temperature of 2.2 degrees Celsius for 55 days.[95] Thus, exported apples will be subjected to cool storage conditions, and the scientific evidence indicates that fire blight bacteria are very unlikely to survive cool storage.

40. One large-scale study examined the survival of fire blight bacteria on fruit subject to normal commercial cooling and storing by surface-inoculating fruit with varying numbers of bacteria and measuring surviving bacteria after storage. Under both "commercial conditions" and "laboratory conditions," the study found that, 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.[96] Bacteria were *only* isolated from some of the fruit that had been inoculated with extremely large numbers of bacteria,[97] levels *far higher* than those that have been found on

---

[94] *See, e.g.*, J. Thompson, *Good Temperature Management Improves Fruit Quality*, Paper presented at 16th Annual Postharvest Conference, Yakima, WA (March 14-15, 2000) (available at http://www.postharvest.tfrec.wsu.edu/pgDisplay.php?article=PC2000O) (recommending cooling as soon as possible after harvest and again after packing and during transport).

[95] MAFF Notification No. 354, para. 4(1) (March 10, 1997) ("As a treatment for codling moth, they must be treated with pulp temperature at 2.2 degrees C for 55 days in a cold treatment facility, and then, fumigated with methyl bromide for 2 hours in a fumigation facility.") (Exhibit USA- 10).

[96] C.N. Hale & R.K. Taylor, *Effect of cool storage on survival of* Erwinia amylovora *in apple calyxes*, Acta Horticulturae 489: 139-43, at 141 (1999). Under "laboratory conditions," bacteria were isolated from fruit after 25 days cool storage but were not isolated from *any* of the fruit tested after cool storage plus 14 days room temperature storage. Under "commercial conditions," bacteria were isolated from 2 fruit after cool storage and 2 fruit after cool storage plus room temperature storage.

[97] C.N. Hale & R.K. Taylor, *Effect of cool storage on survival of* Erwinia amylovora *in apple calyxes*, Acta Horticulturae 489: 139-43, at 141 (1999) (under commercial conditions, bacteria were isolated from two of the fruit inoculated with 10^7 or 10^5 bacteria but not from *any* fruit with lower inoculation levels).

harvested mature, symptomless fruit.[98] This result is consistent with other work that has documented a marked decline in external bacterial populations on fruit due to cold storage.[99]

41. Harvested fruit are quickly put into cool storage in order to maintain product quality and enhance storage time and are stored, transported, and exported under low temperature conditions. Commercial handling procedures, such as immersion of fruit in a water tank (in order to move fruit without bruising to grading and packing line),[100] removal of trash, culling of injured or defective fruit, grading, cleaning, and drying would further negatively impact the expected survival of external bacteria. Thus, even if in very rare circumstances some mature, symptomless apple fruit harvested from or within 10 meters of blighted trees in severely blighted orchards were externally contaminated with bacteria, these bacteria would be highly unlikely to survive commercial handling, storage, and transport to Japan.

D. There Is No Vector to Transfer External Bacteria from an Imported Fruit to a Susceptible Host

42. The conclusion that mature, symptomless apple fruit are not a pathway for transmission of fire blight also stems from the fact that there is no documented vector or dispersal mechanism from an imported fruit to a susceptible host, despite billions of exported fruit to countries without fire blight. Thus, *even if* a mature, symptomless apple fruit were externally contaminated with fire blight bacteria, and *even if* the bacteria on such fruit survived normal commercial handling,

---

[98] For example, of the three studies that have found external bacteria on mature, symptomless fruit, one study isolated from 1-50 (that is, from 10^0 to 5×10^1) colonies of bacteria in the calyx of one fruit that "could have been nearly mature" harvested in Utah, U.S.A., and 10 colonies of bacteria from 5 fruit harvested in West Virginia, U.S.A. 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); T. van der Zwet et al., *Population of* Erwinia amylovora *on External and Internal Apple Fruit Tissues*, Plant Disease 74: 711-16, at 714 (1990) (Exhibit USA-17). A British Columbia study that harvested mature, presumably symptomless fruit from blighted apple trees interplanted with blighted pear trees in a "severely damaged" orchard after an August hail storm isolated 10^3 external bacterial cells. P.L. Sholberg et al., *Occurrence of* Erwinia amylovora *of pome fruit in British Columbia in 1985 and its elimination from the apple surface*, Canadian Journal of Plant Pathology 10: 178-82, 180 tbl. 2 (1988).

[99] *See, e.g.*, C.N. Hale & R.K. Taylor, *Effect of cool storage on survival of* Erwinia amylovora *in apple calyxes*, Acta Horticulturae 489: 139-43, at 141 (1999) (in another storage experiment, bacteria were not isolated after cool storage or cool storage plus room temperature storage from fruit that were naturally infested at harvest); P.L. Sholberg et al., *Occurrence of* Erwinia amylovora *of pome fruit in British Columbia in 1985 and its elimination from the apple surface*, Canadian Journal of Plant Pathology 10: 178-82, at 181 (1988) (bacteria could not be detected on externally contaminated fruit after storage at 2-4° C for 5 months); H.R. McLarty, *Longevity of fire blight bacteria in immature fruit*, Department of Agriculture Dominion Botanists Report 134-36 (1926) (bacteria not detected in calyx-inoculated fruit after cold storage); *see also* R.G. Roberts, et al. *The potential for spread of* Erwinia amylovora *and fire blight*, Crop Protection 17: 19-28, at 21-23 (1998) (reviewing literature) (Exhibit USA- 4).

[100] R.G. Roberts & S.T. Reymond, *Evaluation of post-harvest treatments for eradication of* Erwinia amylovora *from apple fruit*, Crop Protection 8: 283-88, at 286 (1989) (reporting negative impact of exposure to water on populations of bacteria).

storage, and transport, there is *no evidence* that bacteria on such a fruit would be transferred to a susceptible host resulting in infection.

43. The United States' review of the scientific literature has revealed no report of a vector or mechanism by which any fire blight bacteria on or in apple fruit has been transmitted to a susceptible host. As one comprehensive review states: "There 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."[101] The United States notes that the 1999 Japanese Pest Risk Analysis also does not identify any scientific evidence of a vector or dispersal mechanism to move bacteria from imported fruit to a host. Instead, the document merely asserts that infected or infested fruit *could* result in infection, without providing any scientific evidence of a vector.[102]

44. Two studies have specifically tried to examine whether bacteria can be vectored from contaminated fruit to a susceptible host. A 1996 experiment in New Zealand suspended heavily inoculated apple fruit 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. The study concluded: "This suggests that it is highly unlikely that infested fruit could be sources of infection either for pipfruit orchards or for alternative hosts."[103] A more recent and comprehensive experiment in New Zealand also found that there was no movement of fire blight bacteria from heavily inoculated fruit suspended in trees as close as possible to receptive sites (open blossoms) on apple trees.[104] Thus, both studies found *no evidence* that bacteria from externally contaminated fruit would be transferred to host tissues, confirming that there is no vector to move fire blight bacteria from discarded apple fruit to a receptive host.

---

[101] R.G. Roberts, et al. *The potential for spread of* Erwinia amylovora *and fire blight*, Crop Protection 17: 19-28, at 23 (1998) (emphasis added) (Exhibit USA- 4).

[102] 1999 Japanese Pest Risk Analysis, § 1-1, at 10 (claiming that "these fruit can become a source of infection after importation" but failing to identify or provide scientific evidence of a vector) (Exhibit USA-3); *id.* § 2-2-4-3, at 22 (claiming that "fresh fruits, if they are left outside near livestock animal farms as left over, trash, etc., they can be a source of fire blight occurrence" but failing to identify or provide scientific evidence of a vector); *id.* § 3-2-3, at 28 (claiming that "if shipments of apples with fire blight bacteria could not be recalled and are left in the environment where hosts of fire blight are present in Japan, then somehow it is possible that it could infect, establish, and spread on rose family fruit trees, such as apples and pears" but failing to identify or provide scientific evidence of a vector).

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

[104] Letter from R.K. Taylor & C.N. Hale, Hort Research, to R.G. Roberts, U.S. Department of Agriculture (August 26, 2002) (Exhibit USA- 20); R.K. Taylor et al., *The Viability and Persistence of* Erwinia amylovora *in Apples Discarded in an Orchard Environment*, Acta Horticulturae (forthcoming 2002) (Exhibit USA-20).

45. Significantly, by affixing contaminated fruit as close as possible to blossoms, both of these studies tested scenarios *far more likely to result in the transfer of bacteria* to host plants than simply discarding fruit would. Discarded fruit is most likely to be disposed of through normal waste removal procedures and thus would not be accessible for bacterial transfer. The small proportion of fruit discarded on the ground would be likely to be consumed by scavengers, also reducing the likelihood of bacterial transfer. In addition, as the remains of any discarded fruit quickly begin to decompose,[105] hypothetical fire blight bacteria would be subject to predation (that is, being consumed by other organisms),[106] microbial antibiosis (the production of antibiotics that inhibit reproduction or survival of the fire blight bacterium), and competition for survival.[107] Because the fire blight bacterium is a poor epiphyte and does not multiply outside of the plant other than on floral stigmas,[108] there is no evidence to suggest that externally contaminated fruit discarded into a soil environment would support the bacterial population growth necessary to provide inoculum for new infections. Thus, discarded fruit are not a viable means for spread of infection.

4. The Japanese Measures Impose Restrictions Unsupported by Any Scientific Evidence

46. The United States has demonstrated that the Japanese fire blight measures are inconsistent with Article 2.2 of the SPS Agreement because there is no evidence, let alone sufficient evidence, to support Japan's measures. The United States has also presented the scientific evidence that apple fruit have never transmitted and do not transmit the disease.[109] Because mature, symptomless apple fruit are not a pathway for the disease, each of the specific restrictions imposed by the Japanese measures – that is, the orchard freedom requirement, the

---

[105] S.V. Thomson, *Epidemiology of Fire Blight*, *in* Fire Blight: The Disease and Its Causative Agent, *Erwinia Amylovora*, at 16-17 (2000) (J.L. Vanneste, ed.) ("Most [apple] fruits decompose quite rapidly on the soil. . . .") (Exhibit USA- 2).

[106] *See* M. Hildebrand et al., *Survival studies with the fire blight pathogen* Erwinia amylovora *in soil and in a soil-inhabiting insect*, Journal of Phytopathology 49: 635-39 (2001).

[107] *See, e.g.*, 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) (biotic factors such as naturally occurring biological control and competition from other bacteria may explain declining or nonexistent levels of epiphytic fire blight bacteria on mature, symptomless apples at harvest); R.G. Clark et al., *A DNA approach to* Erwinia amylovora *detection in large scale apple testing and in epidemiological studies*, Acta Horticulturae 338: 59-66, at 63 (1993) (bacteria may not have spread from inoculation sites due to failure "to survive due to competition from other bacterial populations or due to antagonism by other organisms").

[108] S.V. Thomson, *Epidemiology of Fire Blight*, *in* Fire Blight: The Disease and Its Causative Agent, *Erwinia Amylovora*, at 20-21 (2000) (J.L. Vanneste, ed.) (Exhibit USA- 2).

[109] *See supra* § IV.A.2, 3.

buffer zone requirement, the three inspections requirement, the post-harvest chlorine treatment requirement, the Washington or Oregon requirement, and various post-harvest production requirements – has no basis in science. In this portion of its submission, the United States also notes any evidence upon which Japan justifies each restriction and explains the lack of any rational or objective relationship between such restriction and the scientific evidence.

A. Prohibition of Imported Apples from Orchards in Which Any Fire Blight Is Detected

47. The Japanese fire blight measures establish that any fruit from a "designated" export orchard in which fire blight is detected may not be exported to Japan. Japan explains that orchard freedom requirement is justified because "fire blight contamination of fresh apple fruit harvested from fire blight infected orchards or trees" has been reported. Japan also considers that "reports reveal a correlation between extent of fire blight occurrence in orchards and bacteria contamination rate of sampled fruit, and fire blight bacteria has not been detected from the fruits from infection free orchards."[110] However, the Japanese measures reflect a specific "correlation" between the extent of fire blight occurrence and the contamination of apple fruit not based on evidence: Japan deems *any* occurrence of fire blight, no matter how severe or light, in an orchard to pose an unacceptable risk of transmitting fire blight on *any* fruit from that orchard. Japan presents no scientific evidence to substantiate such a correspondence, and the scientific evidence does not support Japan's position.[111]

48. In practice, depending on the size of the orchard, Japan's orchard freedom requirement could prohibit fruit from being exported that was harvested tens, hundreds, or thousands of meters away from a single, lightly infected fire blight host (for example, an apple tree with a single, inactive canker) that may have exhibited symptoms many months before harvest (for example, one blighted blossom or shoot). Such an indeterminate restriction bears no rational or objective relationship to the scientific evidence.

B. Prohibition of Imported Apples from Any Orchard Should Fire Blight Be Detected Within a 500 Meter Buffer Zone Surrounding Such Orchard

49. The Japanese fire blight measures establish that a "designated" export orchard must be surrounded by a 500-meter buffer zone. If any fire blight is detected in the 500-meter buffer zone, no fruit from the designated export orchard may be exported to Japan. The 1999 Japanese

---

[110] 1999 Japanese Pest Risk Analysis, §3-2-2-1, at 25 (Exhibit USA-3); *see also* Letter from Ministry of Agriculture, Forestry and Fisheries to R. Spaide, U.S. Department of Agriculture, Enclosure § I.1 (December 6, 1996) (Exhibit USA-21).

[111] *See supra* § IV.A.3 (reviewing at least 11 experimental reports isolating either no internal or no external bacteria from fruit harvested from blighted trees and orchards).

Pest Risk Analysis states that the "[e]stablishment of buffer zones is necessary to secure export zones as disease free zones."[112]

50. Japan cites the following as evidence supporting its buffer zone requirement: the 500 meter regulation "in the fire blight eradication program in European countries"; the European and Mediterranean Plant Protection Organization requirements for a 50 square kilometer "protection zone," 250 meter zone for occurrence surveys, and 1 kilometer zone for spot surveys around "seedling orchards"; and the 400 meter zone the United States "is requesting on citrus fruit canker concerning Onshu tangerines exported from Japan."[113] Regardless of whether Japan has correctly described these requirements, none of the cited examples is pertinent.

(1) The first is a fire blight *eradication* program, not a program that speaks to the appropriate measures to address any risk of fire blight transmission on imported fruit.[114]

(2) The second involves measures for *seedling orchards*; however, because the risk of transmission of fire blight is much different for plants than for mature, symptomless fruit, trade in plants will require significantly different measures than trade in fruit.[115]

(3) The third involves requirements for *citrus canker on tangerines*, which is wholly irrelevant for fire blight transmission on mature, symptomless apple fruit.

51. Japan cites one non-buffer zone study that indicates that fire blight "bacteria dispersed as far as 250 meters in humid climate" from a fire blight source.[116] On its face, a report of *250*-meter dispersal does not support a *500*-meter buffer requirement. More importantly, this report

---

[112] 1999 Japanese Pest Risk Analysis, § 3-2-2-1, at 25 (Exhibit USA-3).

[113] 1999 Japanese Pest Risk Analysis, § 3-2-2-1, at 26 (Exhibit USA-3). In a December 1996 letter, Japan also cited the citrus canker eradication program in Florida and the 500 meter buffer zone required for New Zealand apple exports to Japan. Letter from Ministry of Agriculture, Forestry and Fisheries to R. Spaide, U.S. Department of Agriculture, Enclosure § 1.2 (December 6, 1996) (Exhibit USA- 21). These sources are also irrelevant: the former because it deals with citrus canker eradication, the latter because Japan's fire blight measures do not constitute scientific evidence to support its own measures.

[114] Japan's citation of this evidence does suggest, perhaps inadvertently, that the buffer zone requirement it imposes would only be appropriate if it were trying to *eradicate* fire blight within production areas of the United States, rather than ensuring that any imported U.S. apple fruit meet its appropriate level of protection.

[115] European and Mediterranean Plant Protection Organization (EPPO), *Data Sheet on Quarantine Pests:* Erwinia amylovora, Quarantine for Europe, at 5 (1997) (Phytosanitary Measures) (recommending "countries at high risk to prohibit importation of host plants for planting" but *not* recommending restrictions on importation of fruit) (Exhibit USA- 5).

[116] 1999 Japanese Pest Risk Analysis, § 3-2-2-1, at 26 (citing van Vaerenbergh et al (1987)) (Exhibit USA-3).

contains serious flaws, such as the use of a test that detects *dead* as well as live bacteria and the failure to confirm that the "dispersed" bacteria were of the same strain as the bacteria found on the source (and therefore not from some *other* fire blight host in the area). Finally, this report does not concern and would be of limited (if any) relevance to bacterial presence in or on mature, symptomless apple fruit.

52. In practice, mature, symptomless apple fruit in, for example, a fire blight-free orchard could be harvested anywhere from a few meters to thousands of meters away from an infected apple tree in the 500-meter buffer zone;[117] the apple tree in the buffer zone could be only lightly infected (for example, one blighted blossom, shoot, or canker); and the infection could only have been noted at blossom, with no symptoms exhibited thereafter. Nonetheless, *all* mature, symptomless fruit in the fire blight-free orchard would be prohibited from importation. Such a prohibition bears no rational or objective relationship to the scientific evidence.

C. Inspection of Export Orchards Three Times Yearly for the Presence of Fire Blight

53. In order to impose the requirements that an orchard and a 500-meter buffer zone surrounding such orchard be free of fire blight, Japan requires that the orchard and buffer zone be inspected three times yearly, at the blossom, fruitlet (that is, small fruit), and harvest seasons. As evidence, Japan cites one study in which fire blight bacteria were detected from fruit harvested from orchards where no fire blight had been detected during blossom and small fruit surveys; however, a "subsequent survey confirmed the existence of fire blight infected trees."[118] Japan concludes that this report "indicates [the] need[] for repetition of [the] occurrence survey," but the report supports the opposite conclusion. The blossom and fruitlet surveys will not reveal some instances of harvest season fire blight because fire blight bacteria may infect new hosts after the small fruit season or the disease may express itself in an already infected host. However, the scientific evidence indicates that fire blight bacteria have *only* been detected rarely on the outside of mature, symptomless apple fruit harvested from, or within 10 meters of, severely infected trees in severely blighted orchards.[119] Thus, the report cited by Japan actually supports the opposite conclusion from the one Japan draws: it is *only* a harvest season inspection that detects severely blighted orchards that *may* be relevant to the likelihood that there may be fire blight bacteria on the surface of mature, symptomless apple fruit. Even *that* inspection is

---

[117] If the infected tree were adjacent to the orchard and the fruit were harvested on the nearest edge of the orchard, the distance could be only a few meters. If the infected tree and the harvested fruit were each on the outer periphery of the buffer zone and orchard, respectively, the distance between them would be 500 meters. Of course, depending on the size of the orchard, the distance between the infected tree in the buffer zone and the harvested fruit could be many thousands of meters.

[118] 1999 Japanese Pest Risk Analysis, § 3-2-2-1, at 25 (citing Hale and Clark (1990)) (Exhibit USA-3).

[119] *See supra* § IV.A.3.B.

unnecessary because there is no scientific evidence that mature, symptomless apple fruit transmit the bacteria.

54. Japan also appears to cite evidence that apple trees are most receptive to fire blight bacteria during the blossom season and suggests (without citing evidence) that the small fruit season survey provides an opportunity to identify blighted stalks and leaves.[120] There is some evidence to support the view that inspections throughout the growing season may assist in detecting all instances of fire blight in an orchard.[121] However, detecting *all* instances of fire blight in an orchard is irrelevant to the question whether bacteria will be present on mature, symptomless apple fruit. As explained above, there is *no* scientific evidence that the presence of fire blight at the blossom or small fruit seasons affects the likelihood that fire blight bacteria will be found on mature, symptomless apple fruit. Thus, the three inspections requirement bears no rational or objective relation to the scientific evidence.

D. Prohibition of Imported Apples Unless Treated With Chlorine

55. Japan prohibits the importation of any apple fruit that has not been treated by immersing the fruit for one minute in a tank containing 100 parts per million free chlorine.[122] While there is scientific evidence relating to the effect of chlorine on populations of fire blight bacteria, there is not a rational or objective relationship between Japan's chlorine treatment requirement and the scientific evidence that mature, symptomless apple fruit are not a pathway for the fire blight disease.

56. There are at least two pieces of scientific evidence that document dramatic reductions in bacterial populations due to chlorine treatment. The first is the testing done by the United States at Japan's request of the efficacy of Japan's required chlorine treatment. The results of these confirmatory tests were *complete* eradication of fire blight bacteria from the surfaces of inoculated mature, symptomless apple fruit.[123] The second is an earlier published work that did

---

[120] 1999 Japanese Pest Risk Analysis, § 3-2-2-1, at 26 (Exhibit USA-3).

[121] For example, the European and Mediterranean Plant Protection Organization states: "To detect the disease, it is necessary to make inspections during the growing season, when the symptoms are visible. The time of inspection depends on the kind of host to be inspected and on the geographical location. It is preferable to inspect from after flowering until late summer, when the symptoms are more obvious." European and Mediterranean Plant Protection Organization (EPPO), *Data Sheet on Quarantine Pests:* Erwinia amylovora, Quarantine for Europe, at 3 (1997) (Detection and Identification–Detection and inspection methods) (Exhibit USA-5).

[122] Ministry of Agriculture, Forestry, and Fisheries Detailed Rules for U.S. Apples § 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.") (Exhibit USA-12).

[123] *See* Letter from B. Lee, U.S. Department of Agriculture, to M. Yoshimura, Ministry of Agriculture, Forestry, and Fisheries (December 2, 1993) (enclosing report entitled "Effectiveness of Chlorine to Eliminate *Erwinia amylovora* from the Surfaces of Contaminated Mature, Healthy-appearing Apple Fruit") (Exhibit USA-22).

not find complete elimination of bacteria from heavily surface-inoculated fruit but did find massive reductions in population counts; this published evidence suggests that the likelihood fire blight bacteria would survive a post-harvest chlorine treatment is 3.82×10^{-7} (or 0.00000038214).[124]

57. This scientific evidence of the efficacy of a chlorine treatment in reducing external bacterial populations, however, does not support any measures on harvested mature, symptomless apple fruit. Because there is no scientific evidence that mature, symptomless apple fruit transmit the fire blight disease, there is not sufficient scientific evidence for Japan to maintain the chlorine treatment restriction.

E. Prohibition of Imported Apples from U.S. States Other than Washington or Oregon

58. Japan prohibits the importation of U.S. fruit other than fruit produced in designated export orchards within Washington or Oregon, two U.S. States. The United States has in the past requested that Japan expand the list of States eligible to export apple fruit to Japan, to no avail.[125] While there is scientific evidence that fire blight bacteria are not associated internally or externally with mature, symptomless apple fruit from Washington,[126] there is not a rational or objective relationship between the scientific evidence and Japan's prohibition of apples other than those harvested in Washington or Oregon.

59. Japan presents *no* evidence to support its limitation of imported U.S. apples to Washington or Oregon fruit. The scientific evidence establishes that mature, symptomless apple fruit – regardless of origin – are not a pathway for the disease. As there is no scientific evidence that mature, symptomless apple fruit transmit the disease, the prohibition of U.S. apples from

---

[124] R.G. Roberts & S.T. Reymond, *Evaluation of post-harvest treatments for eradication of* Erwinia amylovora *from apple fruit*, Crop Protection 8: 283-88 (1989) (finding that chlorine treatment reduced bacterial cell counts on artificially inoculated fruit from hundreds of millions pre-treatment to the range of 13-38 post-treatment).

[125] In fact, after more than two years of correspondence and consultations on the U.S. request, the United States thought approval of California apples was imminent and submitted a revised U.S. Apple Export Work Plan for Japan's review. *See* Letter from A. Green, U.S. Department of Agriculture, to N. Saito, Ministry of Agriculture, Forestry, and Fisheries, at 1 & Enclosure (November 20, 2000).

[126] Almost half of all mature, symptomless apples discussed in the scientific literature that have been tested for internal and external bacteria have been harvested from Washington, and *no internal or external bacteria have been detected* from such fruit, even when harvested from infected trees. 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); T. van der Zwet et al., *Population of* Erwinia amylovora *on External and Internal Apple Fruit Tissues*, Plant Disease 74: 711-16, at 714 (1990) (Exhibit USA-17); R. 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).

States other than Washington or Oregon is not rationally or objectively related to the scientific evidence.

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

60. Japan prohibits the importation of U.S. apples unless other harvesting, production, and importation requirements are met: chlorine treatment of containers for harvesting, chlorine treatment of the packing site, and post-harvest separation of apples for export to Japan from those apples for other destinations. None of these requirements bear a rational or objective relation to the scientific evidence.

61. With respect to chlorine treatment of containers for harvesting, Japan claims that the requirement is necessary to avoid contamination of fruit by contaminated harvest containers.[127] Japan cites three papers in support (two of which merely cite to the first); however, the original report (Lelliott (1959)) presents circumstantial, not direct or scientific, evidence that contaminated fruit boxes could have been a source of inoculum and also states that the likelihood that fire blight was transmitted via infected fruit "is very slight and can probably be ignored."[128] Because this report does not present scientific evidence, it does not rationally support the requirement.

62. With respect to chlorine treatment of the packing site, which Japan asserts is a "safety measure[]" to prevent contamination of fruit by packing line equipment in the packing facility,[129] and the post-harvest separation of apples for export to Japan from those apples for other destinations, Japan simply does not present *any* evidence in support, and the United States is not aware of any supporting evidence. Thus, there can be no rational relationship between these requirements and evidence which does not exist.

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

1. Introduction: Japan's Fire Blight Measures Must Be Based on a Risk Assessment

---

[127] 1999 Japanese Pest Risk Analysis, § 3-2-2-2, at 26 (Exhibit USA-3).

[128] R.G. Roberts, et al. *The potential for spread of* Erwinia amylovora *and fire blight*, Crop Protection 17: 19-28, at 23 (1998) (discussing lack of evidence of transmission of bacteria through contaminated fruit boxes) (Exhibit USA-4).

[129] 1999 Japanese Pest Risk Analysis, § 3-2-2-2, at 27 (Exhibit USA-3).

63. In addition to not having sufficient scientific evidence to maintain its fire blight measures, Japan's fire blight measures are not based on a risk assessment and therefore are inconsistent with Article 5.1 of the SPS Agreement.

64. Article 5.1 states 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."[130] 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."[131]

65. 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; as the second deals with risks to human or animal health associated with food, beverages, or feedstuffs,[132] it is the first definition that is relevant in this case. The first definition 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 noted 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

---

[130] *EC–Hormones*, WT/DS26/AB/R, para. 180.

[131] *EC–Hormones*, WT/DS26/AB/R, para. 193.

[132] SPS Agreement, Annex A (Definitions), para. 4 ("*Risk Assessment*– . . . [T]he evaluation of adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.").

> (3) evaluate the likelihood of entry, establishment or spread of these diseases *according to the SPS measures which might be applied.*[133]

66. In this case, although the fire blight measures were introduced in 1994, Japan conducted an assessment in 1996 on the risks posed by various pests (including fire blight) in response to revisions to its Plant Protection Law and procedures intended to bring Japan into compliance with its obligations under the SPS Agreement. Japan conducted a second risk assessment in 1999 focused exclusively on fire blight.[134] While the United States recognizes that Japan's assessment of risks has fulfilled the first requirement under Article 5.1 – that is, it has *identified* fire blight as the disease whose entry, establishment, or spread Japan wants to prevent within its territory as well as potential associated biological and economic consequences – Japan has not fulfilled either of the two remaining requirements.

67. In examining whether Japan's risk assessment satisfies the second and third requirements under Article 5.1, it is worth recalling the Appellate Body's finding 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.*"[135]

68. Finally, the United States notes that Article 5.1 requires that SPS measures be based on a risk assessment "as appropriate to the circumstances . . . [and] taking into account risk assessment techniques developed by the relevant international organizations." As fire blight poses a risk to plant life or health, the risk assessment techniques developed by the International Plant Protection Convention are relevant here.[136] Indeed, Japan has indicated that its fire blight measures are based on the guidelines for pest risk analysis of the International Plant Protection

---

133 *Australia – Salmon* (AB), para. 121 (italics in original).

134 *See* U.S. Consultation Question 4 (Exhibit USA- 7). The United States notes that it requested, and Japan indicated it would provide, a copy of this 1996 document, but it has not been received.

135 *Australia – Salmon* (AB), para. 123 (italics in original).

136 *See* SPS Agreement, Article 3.4 (identifying "the international and regional organizations operating within the framework of the International Plant Protection Convention" as "relevant international organizations"); *id.*, Annex A, para. 3 (defining "international standards, guidelines, and recommendations" as, "for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention").

Convention.[137] The three stages for a pest risk analysis under the Convention's Standard for Pest Risk Analysis for Quarantine Pests correspond to the three-step process in the SPS Agreement;[138] thus, it will be useful to note, at appropriate points, how Japan has not taken into account the relevant international risk assessment techniques in its assessment of risks.

2. Japan Does Not Evaluate the Likelihood of Entry, Establishment, or Spread as well as Potential Associated Biological and Economic Consequences

69. The 1999 Japanese Pest Risk Assessment proceeds in three steps. First, it "describes details on fire blight in Chapter I." Second, it presents a "pest risk analysis for fire blight bacteria in Chapter II." Third, it presents a "pest risk analysis on the current plant quarantine measures for fire blight bacteria on fresh U.S. apple fruit in Chapter III."[139] While Japan purports to follow the "'International Standards for Pest Risk Analysis' (FAO guidelines),"[140] Japan fails to focus on the scientific evidence relating to the *importation of apples*, making only general statements of *possibility* rather than an assessment of *probability* of entry, establishment, or spread.

70. In Chapter II, entitled "Pest Risk Analysis on Fire Blight Bacteria," Japan identifies fire blight caused by *Erwinia amylovora* as "a potential quarantine pest." Japan evaluates the potentiality of establishment as "extremely high" (Japan labels this "a"), the potentiality of spread after establishment as "extremely high" ("a"), the potentiality of economic importance as "extremely high" ("a"), and the possibility of introduction as "extremely high" ("a").[141] Because the "potential economical importance is evaluated at 'a' and at least 2 or more items are evaluated at 'a'," Japan concludes according to its risk evaluation table that the relative evaluation of fire blight bacteria is "extremely high" ("A").[142] Finally, because "the difficulty in

---

[137] *See* U.S. Consultation Questions 5, 6, 7 (Exhibit USA- 7).

[138] International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests, at 8 (2001) (International Standards for Phytosanitary Measures Publication No. 11) (Outline of Requirements: Stage 1 – identifying the pests and pathways of quarantine concern; Stage 2 – evaluating the probability of entry, establishment, and spread and of potential economic consequences; Stage 3 – identifying management options for reducing risk, evaluating their efficacy, feasibility, and impact, and selecting appropriate measures) (Exhibit USA-15).

[139] 1999 Japanese Pest Risk Analysis, Introduction, at 4 (Exhibit USA-3).

[140] 1999 Japanese Pest Risk Analysis, Introduction, at 4 (Exhibit USA-3). This appears to be a reference to the International Plant Protection Convention's Standard for "Pest Risk Analysis for Quarantine Pests. *See* International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests, at 2 (2001) (International Standards for Phytosanitary Measures Publication No. 11) (Exhibit USA-15).

[141] 1999 Japanese Pest Risk Analysis, § 2-2-1 to 2-2-4, at 13-22 (Exhibit USA-3).

[142] 1999 Japanese Pest Risk Analysis, § 2-2-5, at 22 (Exhibit USA-3). It thus appears that in the Japanese risk assessment scheme, there are at least two levels: "a" (extremely high) and "A" (extremely high).

risk management is extremely high," Japan states that "in order to avoid introduction of fire blight bacteria, our conclusion is that it is necessary to designate fire blight bacteria subject to import prohibition."[143]

71. However, Japan's Pest Risk Analysis of fire blight merely determines that *Erwinia amylovora* is a pest of quarantine significance and presents some general (and largely irrelevant to the exported commodity) evidence relating to entry, establishment, or spread. It does *not* fulfill the second requirement of a risk assessment by evaluating the *likelihood* of entry, establishment, or spread through the importation of apples as there is no assessment of the 'probability' of entry, the 'probability' of establishment, or the 'probability' of spread of fire blight through apple imports.

A. Japan Did Not Evaluate the Likelihood of Entry and Ignored Key Evidence

72. For example, in its analysis of the "possibility of introduction," Japan states that "hosts of fire blight bacteria include . . . fruits, such as apples and pears. In those hosts, plants and plant parts which can possibly bring fire blight bacteria into Japan are (1) those plants which have records of infection or occurrence of fire blight bacteria under production or natural conditions, and (2) *those parts where fire blight bacteria can infect*, that is, live parts (excluding seeds, [but] *including fresh fruits*, flowers, and pollen)." Japan also states: "These hosts are imported into Japan as seeds and seedlings, horticultural plants, cut flowers, fruits, etc. (MAFF Plant Protection Station 1996). If imports of these plants into Japan are not restricted, it is highly possible that fire blight bacteria can be easily brought into Japan with the hosts."[144]

73. This passage is remarkable for the flaws in its analysis. First, the United States notes that it prematurely jumps from an assessment of the "possibility of introduction" to a conclusion that phytosanitary measures are required ("If imports of these plants into Japan are not restricted . . . "), revealing that Japan has prejudged the outcome of its risk assessment. Second, it concludes that imports of all plants and plant parts that are "hosts of fire blight bacteria" should be similarly restricted but does not provide any scientific evidence or analysis establishing that apple fruit presents a *similar probability* of introduction of fire blight bacteria as host plants (for example, apple trees) or other plant parts (for example, flowers and pollen). Third, and most fundamentally, it does not present *any* scientific evidence or analysis of the *probability* of entry of fire blight bacteria through apple fruit. Thus, on its face, the Japanese analysis of the "possibility of introduction" falls far short of an *evaluation* of the *likelihood* or *probability* of entry.

---

143 1999 Japanese Pest Risk Analysis, § 2-3-2, at 23 (Exhibit USA-3).

144 1999 Japanese Pest Risk Analysis, § 2-2-4-1, at 21 (emphasis added) (Exhibit USA-3).

74. The Japanese analysis is not saved by reference to Chapter I of the Pest Risk Analysis, which contains a paragraph entitled "Possibility of Transmission by Apple Fruit."[145] This paragraph, which is little more than a recitation of results from various studies on fire blight that does not distinguish evidence relevant to the exported commodity from other evidence,[146] also does not "evaluate the 'likelihood', i.e., the 'probability' of entry."[147]

75. That the Japanese Pest Risk Analysis does not evaluate the likelihood or probability of entry is evident in its fundamental failure to identify and discuss those scientific studies that are *relevant to the apples sought to be imported* (that is, mature, symptomless apples). A proper focus on studies relevant to mature, symptomless fruit would have allowed Japan to begin to assess the probability of imported U.S. apples being infected or infested with fire blight bacteria.[148] Instead, after presenting the results of studies on, *inter alia*, immature fruit, visibly infected or damaged fruit, artificially wounded and inoculated fruit in storage, visibly infected fruit left on trees, apple leaves, and pear fruit,[149] Japan concludes: "Therefore, the *possibility* of fire blight transmission by fresh apple fruit *cannot be denied*."[150]

76. There is no scientific basis to support Japan's conclusion that exported fruit pose a "possibility" of transmission from the evidence it presents on bacterial presence on immature fruit, visibly infected or damaged fruit, artificially wounded and inoculated fruit in storage,

---

[145] 1999 Japanese Pest Risk Analysis, § 1-1, at 9 (Exhibit USA-3).

[146] *See infra* § IV.B.4 (discussing necessary distinctions in scientific evidence to evaluate properly likelihood of entry of fire blight bacteria).

[147] *Australia–Salmon*, (AB), para. 123.

[148] For an evaluation of all of the evidence relevant to fire blight presence on or in mature, symptomless fruit, see *supra* § IV.A.3 (claim under Article 2.2 of the SPS Agreement). As the United States has demonstrated, the scientific evidence establishes that mature, symptomless apples have never transmitted and are not a pathway for the fire blight disease. *See supra* § IV.A.2.

[149] *See* 1999 Japanese Pest Risk Analysis, § 1-1, at 9 (citing van der Zwet & Beer (1992): visibly infected and mummified apple fruit; van der Zwet et al. (1990): immature apple fruit; Hale & Clark (1990): immature apple fruit; Clark et al. (1993): immature apple fruit; Anderson (1952): stab-inoculated pear fruit; Goodman (1954): visibly infected apple fruit left on branch over winter; Sholberg et al. (1988): apple leaves; McLarty (1922): stab-inoculated apple fruit in storage) (Exhibit USA-3).

[150] 1999 Japanese Pest Risk Analysis, § 1-1, at 10 (emphasis added) (Exhibit USA-3). Japan makes two similar claims in the following paragraph (the last in Section 1-1) that are mere statements of possibility, unsupported by scientific evidence. The first: "As it was explained above, mature apple fruit harvested from orchards or trees where fire blight occurs *can carry* fire blight bacteria" (emphasis added). However, Japan has not distinguished evidence on mature apple fruit from other evidence, and this statement is not an assessment of probability. The second: "Also, even if the mature fruit does not carry fire blight bacteria, *it is possible* that it contaminates by harvesting operation, etc., in the orchards where the source of infection is present" (emphasis added). Again, this statement is unsupported by any scientific evidence and is not an assessment of probability. *See id.*

visibly infected fruit left on trees, apple leaves, and pear fruit. Indeed, Japan makes the revealing statement that:

> [T]here are *some reports* that the possibility of fire blight transmission by fresh apple fruit can be denied or neglected. However, in these reports, they *only* stated that '*symptomless, mature fruit*' (McLarty 1922, Dueck 1974), 'healthy looking mature fruit' (Roberts et al. 1989), 'fruit harvested from symptomless orchards with[out] fire blight' (van der Zwet et al. 1990) *are safe*."[151]

There is no scientific basis to diminish this evidence by asserting that it "only" relates to mature, symptomless fruit when *this is the very fruit* that the United States seeks to export to Japan and for which Japan must assess risk. As the International Plant Protection Convention Standard on Pest Risk Analysis for Quarantine Pests indicates, the probability of entry of a pest is tied to the "probability of the pest being associated, spatially or temporally, with the pathway at origin," considering, for example, the "*occurrence of the pest in a life-stage that would be associated with commodities*," "seasonal timing," and "commercial procedures applied at the place of origin," such as "handling, culling, roguing, grading."[152] Thus, a proper evaluation of the likelihood of entry will take into account the scientific evidence relating to the exported commodity, perhaps especially evidence that contradicts the conclusion the risk assessment draws.[153] Japan's express refusal to consider the science relating to the presence of fire blight bacteria on or in mature, symptomless apple fruit renders its evaluation of the likelihood of entry inadequate and its assessment of the risks of entry, establishment, or spread of fire blight inconsistent with Article 5.1.

77. Finally, the United States notes the Appellate Body's statement 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 [it] conclude that there is a *possibility* of entry, establishment, or spread of diseases."[154] Thus, Japan's statement that a "possibility" of transmission "cannot be

---

[151] Japanese Pest Risk Analysis, § 1-1, at 10 (emphasis added) (Exhibit USA-3).

[152] 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).

[153] The United States notes that the Japanese Pest Risk Assessment did not present all of the scientific evidence available as of 1999 relating to the detection of *Erwinia amylovora* on mature, symptomless apples. *See* R.G. Roberts, et al. *The potential for spread of* Erwinia amylovora *and fire blight*, Crop Protection 17: 19-28, at 22, Table 1 (1998) (also citing Dueck and Morand, 1975; Hale et al., 1987; and Hale et al., 1996 as documenting "the absence of detectable populations of *E. amylovora* on mature, symptomless apple fruit at harvest") (Exhibit USA- 4).

[154] *Australia-Salmon* (AB), para. 123 (first set of italics added).

denied" without any assessment of the *likelihood* or *probability* of entry also renders its pest risk analysis deficient under Article 5.1 of the SPS Agreement.

B. By Ignoring Key Steps, Japan Failed to Evaluate the Likelihood of Entry

78. That Japan's Pest Risk Analysis did not evaluate the likelihood of entry can also be seen in its failure to describe fully the steps that must be completed for entry of the bacteria. The International Plant Protection Convention Standard on Pest Risk Analysis for Quarantine Pests lays out steps that comprise an evaluation of the probability of entry quite plainly:

(1) identification of relevant pathways;

(2) the probability of the pest being associated with the pathway at origin;

(3) the probability of survival of the pest during transport or storage;

(4) the probability of the pest surviving existing pest management procedures; and

(5) the probability of transfer of the pest to a suitable host.[155]

In the specific case of fire blight, to evaluate the likelihood of entry, Japan must analyze not only the likelihood that *Erwinia amylovora* may be isolated on or in mature, symptomless apple fruit (step 2), but also the likelihood that the bacteria would survive any normal commercial fruit handling (such as removal of trash, sorting, rinsing, grading, and packing) (steps 2 & 4), would survive any cold storage prior to, during, or after importation (step 3), would survive any exposure to the environment both before and after consumption (steps 2 & 5), and would be transferred from any imported apple tissue to the appropriate site on a host for fire blight at a time when the host is susceptible to infection (step 5).[156]

79. Simply put, Japan has not provided *any* evaluation of the likelihood that these multiple steps necessary for entry of the fire blight bacteria would be completed. The Japanese analysis is limited to the statement that "fresh fruits are used for consumption as fresh or for process[ing], through markets (Shogakkan, 'Food Material Dictionary' 1995). However, not all are marketed nor consumed completely for these purposes. During the marketing and process[ing], or at consumption stage, some are left in natural environment as left over, trash, etc." Furthermore, "in the case of cut flowers or fresh fruits, if they are left outside near livestock animal farms as

---

[155] International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests §§ 2.2.1.1-2.2.1.5, at 13 (2001) (International Standards for Phytosanitary Measures Publication No. 11) (Probability of entry of a pest) (Exhibit USA-15).

[156] *See* R.G. Roberts, et al. *The potential for spread of* Erwinia amylovora *and fire blight*, Crop Protection 17: 19-28, at 24-25 (1998) (Exhibit USA-4).

left over, trash, etc., they *can be* a source of fire blight occurrence."[157] This statement that discarded fruit "can be" the source of bacteria to transmit successfully the disease relates solely to step 5 listed above, but the claim is mere speculation as *no* scientific evidence is cited in support. Japan presents *no* evaluation of the likelihood or probability that the fire blight bacteria would survive each of the steps necessary for entry.[158] Thus, the Japanese Pest Risk Analysis is inconsistent with Article 5.1.

C. Japan Failed to Evaluate the Likelihood of Establishment and Spread

80. The United States similarly believes that the Japanese analysis of establishment and spread is not an evaluation of likelihood or probability. Again, the International Plant Protection Convention Standard on Pest Risk Analysis for Quarantine Pests lays out factors to consider in evaluating both the probability of establishment and the probability of spread. With respect to the probability of establishment, factors include the availability, quantity, and distribution of hosts in the pest risk analysis area, the environmental suitability of the pest risk analysis area, the reproductive strategy of the pest, its potential for adaptation, the method of pest survival, and cultural practices and control measures in the pest risk analysis area.[159] With respect to the probability of spread, factors include the suitability of the natural environment for natural spread of the pest, the presence of natural barriers, the potential for movement with commodities or conveyances, the intended use of the commodity, potential vectors of the pest in the pest risk analysis area, and potential natural enemies of the pest in the pest risk analysis area.[160]

81. Japan describes the presence of fire blight host plants in Japan,[161] the climatic conditions in Japan and fire blight distribution areas,[162] the historical record of expansion of distribution in other countries,[163] the possibility of distribution by wind/rain, insects, birds, and aerosol

[157] Japanese Pest Risk Analysis, § 2-2-4-3, at 22 (emphasis added) (Exhibit USA-3).

[158] *See supra* § IV.A.3 (presenting the scientific evidence underlying the fact that mature, symptomless apple fruit do not serve as a pathway for the disease).

[159] 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 establishment) (Exhibit USA-15).

[160] International Plant Protection Convention, Pest Risk Analysis for Quarantine Pests § 2.2.3, at 16 (2001) (International Standards for Phytosanitary Measures Publication No. 11) (Probability of spread after establishment) (Exhibit USA-15).

[161] 1999 Japanese Pest Risk Analysis, § 2-2-1-1, at 13 (Exhibit USA-3).

[162] 1999 Japanese Pest Risk Analysis, § 2-2-1-2, at 14 (Exhibit USA-3).

[163] 1999 Japanese Pest Risk Analysis, § 2-2-2-1, at 15 (Exhibit USA-3).

strands,[164] and the possibility of distribution throughout Japan in nurseries, through wind/rain in the monsoon season, and through the presence in cities of fire blight hosts.[165] However, these conclusory statements of possibilities again fall short of an evaluation of probabilities, particularly as Japan does not consider important contrary evidence. Japan does not identify the probable means by which the fire blight bacteria would enter and therefore the likely place of establishment (that is, the city, country, growing regions, or elsewhere). Japan apparently dismisses the possibility that the disease could be eradicated before spread,[166] despite evidence that both Australia[167] and Norway[168] successfully did so. Japan also does not evaluate whether the disease, once established, could be prevented from spreading, despite admitting the existence of evidence that Europe, with climatic conditions "similar to North America,"[169] has successfully maintained disease-free "specific areas of protection."[170] The failure to evaluate this evidence is all the more striking given that the European and Mediterranean Plant Protection Organization recommends European nations at high risk for fire blight introduction to restrict the importation of host plants for planting but *not* the importation of fruit of fire blight hosts.[171] Thus, while Japan presents some relevant scientific evidence, it does not take into account other relevant evidence nor does it present an evaluation of the likelihood of establishment and spread, further rendering its pest risk analysis inconsistent with Article 5.1.

D. *Conclusion*

82. As the Appellate Body in *Australia–Salmon* concluded (based on findings by the panel, which, in turn, cited expert evidence), the second requirement for a risk assessment under Article

---

[164] 1999 Japanese Pest Risk Analysis, § 2-2-2-2, at 15 (Exhibit USA-3).

[165] 1999 Japanese Pest Risk Analysis, § 2-2-2-3, at 15-16 (Exhibit USA-3).

[166] *See* 1999 Japanese Pest Risk Analysis, § 2-2-3-4, at 19-20 (Difficulty in control) ("Therefore, the source of infection cannot be completely eradicated, because it is actually impossible to thoroughly eliminate all hosts, not only infected trees in orchards but also garden trees, etc., in widely distributed areas.") (Exhibit USA-3).

[167] For example, Australia, a fire blight-free country, reported that fire blight was detected in the Royal Botanic Gardens in Melbourne and was successfully eradicated. Japan recognizes that "[t]here was a *temporary* occurrence in Australia in 1997," 1999 Japanese Pest Risk Analysis § 1-1, at 6 (Distribution) (emphasis added) (Exhibit USA-3), but does *not* take this fact into account in evaluating the likelihood of preventing establishment.

[168] Commonwealth Agriculture Bureau International (CABI), Crop Protection Compendium: Data Sheet on *Erwinia amylovora* (2002) (fire blight distribution country list) (Norway: fire blight reported eradicated in 1998) (Exhibit USA-6).

[169] 1999 Japanese Pest Risk Analysis, § 2-2-1-2, at 14 (Exhibit USA-3).

[170] 1999 Japanese Pest Risk Analysis, § 1-4, at 11 (Exhibit USA-3).

[171] European and Mediterranean Plant Protection Organization (EPPO), *Data Sheet on Quarantine Pests:* Erwinia amylovora, Quarantine for Europe, at 5 (1997) (Means of Movement and Dispersal) (Exhibit USA-5).

5.1 will not be met when the assessment makes "general and vague statements of mere possibility of adverse effects occurring; statements which constitute neither a quantitative nor a qualitative assessment of probability."[172] While Japan has cited to numerous pieces of scientific evidence, it has not utilized that evidence to make a qualitative or quantitative assessment of probability; rather, it has incorrectly characterized those reports as evidence of a possibility of infected or infested fruit being imported. Japan has also merely asserted, without citing any scientific evidence, a possibility of infected or infested fruit being discarded near a receptive host, a possibility that through some unknown means any surviving *Erwinia amylovora* could be transmitted to that host, and a possibility that such a transmission would result in infection, establishment, and spread:

> By any chance, if shipments of apples with fire blight bacteria could not be recalled and are left in the environment where hosts of fire blight are present in Japan, then *somehow it is possible* that it could infect, establish, and spread on rose family fruit trees, such as apples and pears, etc., and horticultural plants, etc. (hosts), which are grown widely from Hokkaido to Okinawa).[173]

In short, rather than "evaluate the likelihood" of entry, establishment, or spread, the 1999 Japanese Pest Risk Analysis does little more than conjecture about the possibility. This cannot satisfy the standard of Article 5.1 of the SPS Agreement, as elucidated by the Appellate Body.

3. Japan Did Not Evaluate the Likelihood of Entry, Establishment, or Spread According to the SPS Measures Which Might Be Applied

83. Under the third requirement of a risk assessment within the meaning of Article 5.1 and Annex A, Japan must evaluate the likelihood of entry, establishment or spread of fire blight disease according to the SPS measures which might be applied.[174] As the Appellate Body concluded in *Australia–Salmon*, "*some* evaluation of the likelihood is not enough."[175] Thus, even if the Japanese Pest Risk Analysis could be deemed to have identified some measures which might be applied and made some evaluation of their effect on the likelihood of entry, establishment, or spread, *that would not be enough*. A risk assessment that "identifies such measures but does not, in any substantial way, evaluate or assess their relative effectiveness in reducing the overall disease risk" does not "fulfil the third requirement" for a risk assessment, "i.e., it does not contain the required evaluation of the likelihood of entry, establishment, or

---

[172] *Australia–Salmon* (AB), paras. 129 (citing Panel Report, para. 124), 131.

[173] 1999 Japanese Pest Risk Analysis, § 3-2-3, at 28 (emphasis added) (Exhibit USA-3).

[174] *Australia–Salmon* (AB), para. 121.

[175] Id., paras. 124, 134 (italics in original).

spread of the diseases of concern according to the SPS measures which might be applied."[176] The Japanese analysis of the SPS measures which might be applied does not rise above the threshold of *some* evaluation of likelihood or probability.

84. Japan clearly identifies some SPS measures which might be applied to U.S. apples: the prohibition of imported apples from U.S. states other than Washington or Oregon; the prohibition of imported apples from orchards in which any fire blight is detected; the prohibition of imported apples from any orchard (whether or not it is free of fire blight) should fire blight be detected within a 500 meter buffer zone surrounding such orchard; the requirement that export orchards be inspected three times yearly (at blossom, fruitlet, and harvest stages) for the presence of fire blight for purposes of applying the above-mentioned prohibitions; chlorine treatment of containers for harvesting; a post-harvest surface treatment of exported apples with chlorine; and chlorine treatment of the packing line.[177]

85. However, even as to these measures, Japan "does not, in any substantial way, evaluate their relative effectiveness in reducing the overall disease risk":

> (1) With respect to the requirement that fruit be produced within Washington and Oregon, Japan provides *no* scientific evidence and *no* assessment of its relative effectiveness in reducing the overall disease risk.[178]
>
> (2) With respect to the fire blight-free orchard requirement (which also includes a requirement that apple orchards be free of alternative fire blight hosts), Japan apparently relies on the science presented "in [section] 1-1, Chapter I," to claim that "fire blight contamination of fresh apple fruit from fire blight infected orchards or trees" has been demonstrated and that "fire blight bacteria has not been detected from the fruits from infection free orchards."[179] As explained above, the Japanese analysis of the scientific evidence is deeply flawed,[180] and there is no rational relationship between the scientific evidence and this orchard-freedom requirement.[181] Japan also does not attempt to

---

[176] Id., paras. 133-34 (quoting Panel Report, para. 8.90).

[177] 1999 Japanese Pest Risk Analysis, § 3-2, at 24-28 (Exhibit USA-3).

[178] 1999 Japanese Pest Risk Analysis, § 3-2-2-1, at 25 (Exhibit USA-3).

[179] 1999 Japanese Pest Risk Analysis, § 3-2-2-1, at 25 (Exhibit USA-3).

[180] *See supra* §§ IV.A.2 (discussing scientific evidence that mature, symptomless fruit have never transmitted and are not a pathway for fire blight) & IV.B.2.A (Likelihood of Entry: Evidence not Evaluated).

[181] *See supra* § IV.A.4.A (discussing absence of scientific evidence supporting orchard-freedom requirement).