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ORGANIZATION**

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I. INTRODUCTION

1.1 On 10 December 2003, the Dispute Settlement

Panelists: Mr Christian Häberli
Ms Kathy-Ann Brown

1.7 The Panel met with the parties and third parties on 28 October 2004. The Panel consulted scientific and technical experts and met with them on 12 January 2005. The Panel held a second meeting with the parties on 13 January 2005.

1.8 The Panel issued its interim report on 10 March 2005. The Final Report was circulated to the parties on 21 April 2005. The report was circulated to Members in all three languages [15 June 2005].

II. FACTUAL ASPECTS⁵

A. THE DISEASE

1. Fire blight (*Erwinia amylovora*)

2.1 *Erwinia amylovora* (*E. amylovora*), the scientific name for the fire blight bacterium, was first reported in 1793. Symptoms of infection of host plants with fire blight depend on the parts infected. Infected flowers, 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.

Inoculum

2.14 Material consisting of or containing bacteria to be introduced into or transferred to a host or medium. Inoculation is the introduction of inoculum into a host or into a culture medium. Inoculum can also refer to potentially infective material available in soil, air or water and which by chance results in the natural inoculation of a host.

Pathogen

2.15 Micro-organism causing disease.

Pedicel

2.16 A short, thin stalk often associated with a stalk that supports a single flower.

Scion

2.17 A detached shoot or twig of a plant used for grafting.

Spur

2.18 A short branch of the tree that flowers and produces fruit.

Transpiration

2.19 The evaporation of water from plants.

Vector

2.20 An organism able to transport and transmit a pathogen.

B. JAPAN'S FIRE BLIGHT MEASURES

2.21 The following pieces of Japanese legislation are relevant to this dispute:

- Plant Protection Law No. 151 enacted on 4 May 1950 (and specifically Article 7 thereof);
- Plant Protection Law Enforcement Regulations enacted on 30 June 1950 (and specifically Article 9 and Annexed table 2 thereof);
- Ministry of Agriculture, Forestry and Fisheries (MAFF) Notification No. 354 dated 10 March 1997; and
- MAFF Administrative Directive, "Detailed Rules for Plant Quarantine Enforcement Regulation Concerning Fresh Fruit of Apple Produced in the United States of America " dated 30 June 2004 ("Detailed Rules"). This replaced the MAFF Directive "Detailed Rules for Plant Quarantine Enforcement Regulation Concerning Fresh Fruit of Apple Produced in the United States of America " dated 29 January 2002.⁶

2.22 Japan's conditions for the importation of apple fruit from the United States are as follows:

⁶Detailed Rules for Plant Quarantine Enforcement Regulation Concerning Fresh Fruit of Apple Produced in the United States of America (June 30, 2004) (Exhibit JPN-1).

- (a) Fruit must be produced in designated fire blight-free orchards. Designation of a fire blight free-area as an export orchard is made by the United States Department of Agriculture (USDA) upon application by the orchard owner. Currently, the designation is accepted only for orchards in the states of Washington and Oregon;
- (b) The export orchard must be free of plants with fire blight symptoms;
- (c) The fire blight-free orchard must be surrounded by a buffer zone (or border zone) of around ten-meters, free of fire blight symptoms;
- (d) The orchard and surrounding buffer zone must be inspected once per year at early fruitlet stage. Detection of a blighted tree in this area by inspection will disqualify the orchard;
- (e) Harvested apples must be treated with surface disinfection by soaking in sodium hypochlorite solution;
- (f) The interior of the packing facility must be disinfected by a chlorine treatment;
- (g) Fruit destined for Japan must be kept separate post-harvest from other fruit;
- (h) US plant protection officials must certify that fruits are free from fire blight and have been treated post-harvest with chlorine; and
- (i) Japanese officials must confirm the US officials' certifications and inspect packing facilities.

C. INTERNATIONAL STANDARDS,

- (a) would be infected by fire blight;
- (b) would harbour endophytic populations of the fire blight-causing bacteria, *E. amylovora*; or
- (c) would harbour epiphytic populations of bacteria capable of transmitting fire blight.

Second, the DSB concluded that the scientific evidence did not establish that apple fruit – whether mature or immature – would serve as a means or pathway of introduction of fire blight to a fire blight-free area.

3.2 The United States claims that Japan had not brought its phytosanitary measure into conformity with the DSB's recommendations and rulings by 30 June 2004 when the reasonable period of time for Japan to comply with its obligations had expired. To the contrary, Japan had issued a set of phytosanitary measures remarkably similar to the elements of its previous WTO-inconsistent apple import regime.

3.3 The United States claims that Japan's revised measures on the importation of apple fruit fail to comply with the DSB recommendations and rulings and with Japan's obligations under the *SPS Agreement* in that:

- Japan has failed to ensure that its fire blight measures are not maintained without sufficient scientific evidence and these measures are therefore inconsistent with Article 2.2 of the *SPS Agreement*;
- Japan has failed to ensure that its fire blight measures are based on an assessment of the risks to plant life or health and therefore these measures are inconsistent with Article 5.1 of the *SPS Agreement*; and
- Japan has failed to ensure that its fire blight measures are not more trade-restrictive than required to achieve its appropriate level of phytosanitary protection, taking into account technical and economic feasibility, and these measures are therefore inconsistent with Article 5.6 of the *SPS Agreement*.

3.4 The United States further claims that Japan has acted inconsistently with its obligations under Article XI of GATT 1994 and under Article 4.2 of the Agreement on Agriculture.

3.5 **Japan** argues that the United States has not established a *prima facie* case in respect of the claims it has made. Amendments to Japan's import regime for US apple fruit as compared to the measures in place at the time of the Original Panel had resulted in

- a reduction of inspection from three inspections to one inspection;
- a reduction of buffer zone (or border zone) from 500 to ten meters; and
- the elimination of the requirement that crates be disinfected.

3.6 Japan claims its measure is fully consistent with Articles 2.2, 5.1, and 5.6 of the *SPS Agreement*. In addition, Japan claims that given the consistency with the relevant articles of the *SPS Agreement*, its measure is also consistent with Article XI of GATT 1994 and Article 4.2 of the Agreement on Agriculture.

IV. ARGUMENTS OF THE PARTIES

A. THE SCOPE OF THE DISPUTE

1. Operational Criteria⁸

4.1 On 27 September 2004, the **United States** requested that the Panel make a preliminary ruling that Japan's Operational Criteria were not a measure taken to comply and were therefore not within the terms of reference of this Article 21.5 proceeding. In addition, the United States requested that the Panel not consider the Operational Criteria in determining whether Japan's measures taken to comply with the DSB's recommendations and rulings were consistent with Japan's WTO obligations. Neither a WTO panel, nor the Appellate Body had issued findings on a proposed measure. The DSU did not give authority to a panel to make "advisory rulings". The United States stressed that the purpose of

(d)

the Operational Criteria should be considered the embodiment and elaboration of the Detailed Rules, which had been notified to WTO Members on 29 June 2004. Moreover, there was no issue of transparency, because (i) the United States should have expected to see guidelines equivalent to the previous Work Plan, and (ii) a summary of the Operational Criteria had been introduced at two discussions held in March and May 2004 between Japan and the United States.

4.9 The **United States** recalled that bilateral discussions were undertaken on a confidential basis and should not be disclosed in the context of the Panel proceedings.

of the ten elements of the original measure in place. The United States also noted that Japan's

4.23 According to Japan the purpose of the Azegami

(1952)²⁰, and were no more supportive of Japan's revised measure than the already extensive scientific record examined by the Original Panel.

4.30 **Japan** maintained that Azegami *et al.* (2005) represented a clear departure from Anderson *et al.* (1952), which had recovered fire blight bacteria from *pear* fruit which were inoculated over a period of seven months. The Anderson study had confirmed only that (i) pear could be infected with a certain level of concentration of the bacteria and (ii) the bacteria could survive inside the host fruit over the winter season. In contrast, Azegami *et al.* (2005) demonstrated that (i) *mature apple fruit* – which were believed to be relatively resistant to the bacteria compared to pear fruit – could be easily infected (ii) through *pedicels* which hitherto had not been considered an effective conduit of bacteria into fruit.

4.31 The **United States** noted that the main conclusions claimed by the new studies were the existence of: (1) mature, symptomless apple fruit latently infected with *E. amylovora*, and (2) a pathway for introduction of fire blight into Japan from this latently-infected apple fruit. However, the United States argued, the new studies failed to contradict or amend the reams of peer-reviewed and time-tested science on apple fruit and fire blight. As a result, they also

- failed to establish that there was such a thing as a mature, symptomless yet latently infected apple fruit or that a pathway for the introduction of fire blight via apple fruit existed;
- failed to demonstrate that Japan's revised measures were not maintained without sufficient scientific evidence; and
- failed to alter in any way the scientific evidence and previous findings on that evidence.

4.32 **Japan** claimed that the new evidence not only reinforced Japan's position in this case, it also pointed to a way to reconcile all available evidence and strengthen the findings and conclusions of the Original Panel. The measure was designed to cope with the risk described by the experts advising the Original Panel and more clearly identified by Japanese scientists. The evidence could not be found insufficient unless the Panel required that a phytosanitary "risk" should be limited to those risks which have been demonstrated to have occurred, despite the absence of supporting precedents and despite the experts' caution against exportation from "(severely) blighted" orchards.

4.33 In addition, Japan contended that the United States had not made any attempt to establish how the apple fruit produced and processed through its current practice (i.e., the commodity it calls "mature, symptomless") would indeed meet the "mature, symptomless" apple fruit criteria of the Original Panel. As Japan had basically accepted

(a) Mature, symptomless apples

4.34 The **United States**

e.g., that "renewal of bacterial activity in the spring in the margins of indeterminate cankers (*i.e.*, cankers without pronounced margins) results in extension of the cankers".³⁰ Japan's inference that fire blight activity does not decline during the growing season is factually incorrect and unsupported by the results of Norelli *et al.* (2001). Furthermore, the Momol/Norelli paper provides no data to support an assertion that natural movement of *E. amylovora* into maturing apple fruit occurs in the later phases of the growing season.

4.37 In addition, Japan argued that the risk of latent infection of "mature, symptomless" apple fruit through pedicels was real, at least under experimental conditions. If the phytosanitary measure were to rely entirely on the inspection/sorting process of apple fruit, as the United States asserted, the risk of detection error would be more serious than the Appellate Body had thought.³¹ This finding of the

(b) Pathway for transmission of the disease

Tsukamoto *et al.*

4.54 Japan expressed confidence that additional experiments would show that flies would successfully feed on infected apple fruit and subsequently infect pear fruit. Japanese researchers had replicated the second phase of the experiment three times, and flies covered with bacterial suspension had fed on pear fruit and infected the host each time. Japan argued that in the absence of unknown intervening factors that would prevent flies from feeding on the pear fruit, the process of direct infection via flies from infected apple fruit to pear would be completed.

4.55 Japan acknowledged that the US comments on experimental conditions might raise a valid issue regarding the *level* of likelihood of occurrence of infection. However, the United States had failed to challenge experiment's conclusion that infection had occurred. Moreover, the possibility of fire blight transmission via flies in natural conditions had been suggested in numerous reports and handbooks.⁴⁰

4.56 The **United States** argued that the Tsukamoto experiment does not demonstrate that flies contaminated with fire blight bacteria as a result of contact with infected fruit will transmit the bacteria to host materials. An assumption and hope that the desired results will eventually be achieved through manipulation of methodologies and repeated attempts does not mean that, for purposes of the evaluation at hand, those results have ever or would ever occur. Japan's desire did not amount to scientific evidence, and did not add anything to the Panel's evaluation of Japan's measures (other than to reiterate the fact that despite its hopes to eventually achieve this result, Japan fails to do so). That Japan claims that the actual evidence (results) from the experiment (which were negative) supports (or faith that future studies will support) the conclusion that the pathway will be completed is completely outside the bounds of logic and the exercise of the scientific method.

Kimura *et al.* (2005)

4.57 The **United States** noted that the Kimura study characterized Azegami's work as demonstrating that mature apple fruit were easily infected through a "small bruise" or "minute scars" on the fruit as well as "the possibility of infection of fruit from pedicels through fruit bearing branches." In fact, Azegami's method had been to either cut off the abscission layer of the apple fruit pedicel or to make multiple wounds on the shoulder or calyx in the presence of high inoculum doses. Further, the Kimura paper concluded that "even at a stage where apple fruit get ripe, it is likely enough that *E. amylovora* in fruit bearing branches will infect the inside of apples." This conclusion clearly assumed that infection was occurring through the tissues of the pedicel. As noted above, the Azegami paper had not demonstrated that such infection (through the pedicel/abscission layer of a mature apple fruit) was possible. In fact, the Azegami study appeared to demonstrate just the opposite by noting that bioluminescence

4.59 The **United States** further recalled that Kimura *et al.* cited Tsukamoto *et al.* (2005b) for the proposition that *E. amylovora* had been recovered from the "flesh" of apple fruit and not from the core, alleging that previous studies only sampled core tissues and therefore failed to identify *E. amylovora* in the apple fruit. However the vascular bundles in which *E. amylovora* had been detected in the Tsukamoto *et al.* (2005b) study were contiguous with the vascular tissues of the apple fruit core. Furthermore, Kimura *et al.* mischaracterized the results of previous studies, as Roberts *et al.* (1989) had in fact reported that "[c]ore and cortex [i.e., flesh] tissues, including the stem, if present, and the entire calyx were removed by passing an ethanol-flamed cork borer through the vertical axis of each fruit." Therefore, the studies described in Roberts *et al.* (1989) had examined a portion of the apple fruit that included the "flesh" discussed in Azegami, Tsukamoto, and Kimura.

4.60 The United States claimed that results in Azegami *et al.*, which demonstrated that *E. amylovora*

4.65 According to the study, 10 per cent of the total household garbage in Japan that is thrown out of doors consists of apple cores. The United States noted that this seemed to be a very high estimate for a commodity that was not a staple of the Japanese diet, but was instead considered a specialty

measure to be unsatisfactory, the Panel make a specific ruling on what it finds unsatisfactory and how that could be brought to its satisfaction in respect of Article 2.2, in accordance with Article 19.1 of the DSU.

Pre-Harvest Requirements

- (a) Fruit must be produced in designated fire blight-free orchards. Designation of a fire blight-free area as an export orchard is made by the

and the question of whether or not bacteria could still infect the apple fruit through the pedicels or wounds late in the season depends

4.83 The **United States** countered that interception of codling moth in exported US apple fruit was simply not pertinent to an evaluation of whether US commercial quality controls for fire blight in apple fruit had ever failed, i.e., whether the US had ever shipped anything other than mature, symptomless apple fruit. Japan's evidence regarding a detection of codling moth in exports to Chinese Taipei did not provide any evidence concerning export or quality controls on apple fruit and fire blight. Japan had failed to present any evidence of the failure of US quality controls as they relate to fire blight and apple fruit in this compliance proceeding or that a failure of maturity or fire blight-related quality controls anywhere in the world had ever been responsible for the introduction of fire blight.⁵³

4.84 The United States commented that fire blight was a plant disease, and the scientific evidence demonstrated that mature apple fruit were not infected. Codling moth was a plant pest, known to employ mature fruit as a potential pathway. The presence of codling moth in a fruit was much more difficult to ascertain than fire blight because the exterior of a codling moth infested fruit, for example, might have only a pin-prick sized hole. In contrast, a hypothetically infected apple fruit would "fail to develop fully, turning brown to black, shrivel[], and becom[e] mummified."⁵⁴ Thus, the discovery of codling moth in apple fruit exported to Chinese Taipei was irrelevant to the question of US quality controls vis-a-vis fire blight.

4.85 The US Export Apple Act, in conjunction with overarching commercial considerations, ensured that only mature apple fruit were exported from the United States. Apple fruit that fail to meet the Act's requirements would not be issued an export certificate, and might not legally be exported. Exported fruit would have to meet the Act's criteria concerning, among other things, maturity, color and firmness. Further, the hypothetical shipment of immature apple fruit would be extremely damaging to US export interests and the reputations of individual growers and inspectors, as well as US apple fruit on the global marketplace.

4.86 **Japan** countered that possible liabilities arising from shipment of products other than "mature and healthy" apple fruit were attributable to the shippers/growers. It was always in the shippers' and/or growers' interest to disclaim any liability in their commercial contracts with importers. As a result, their "commercial considerations" and practices would be only as good an incentive (to ship healthy apple) as these potential (and limited) liabilities would require them to be. This incentive was absent because neither the Department of Agriculture nor a shipper/grower were held accountable for the consequences. The codling moth discovery testified to the lack of adequate precautions in shipping the apple fruit to foreign countries or territories from the United States.

4.87 The **United States** claimed in its first submission that Japan's measure limiting imported apple fruit to the US States of Washington and Or9 Tw8al ship i2f5.896TJ-21.4.8(nt0 TDriewfive blie)]21.4.pur

4.88 In its first written submission, **Japan** argued that its geographical restriction on US apple

Operational Criteria, when a blight strike was discovered in an orchard or block containing least-resistant varieties (thereby disqualifying the orchard), all adjoining orchards or blocks would similarly be disqualified unless the border/buffer zone met the higher standard (i.e., that the zone be entirely free of potential host materials). Conversely, should a blight strike be observed on a tree of a more-resistant variety, adjacent blocks or orchards would not be disqualified if the disqualified block was surrounded by a ten meter buffer zone free of fire blight.

4.99 **Japan** noted that Japan had never imposed requirements that the buffer zone be free of host plants. Any host plant could exist in the buffer zone under the previous measure, as well as under the new measure.

(d) The orchard and surrounding buffer zone must be inspected once per year at early fruitlet stage

4.100 The **United States** argued that the unjustified and unscientific nature of Japan's measures was further demonstrated by considering that the requirement of fire blight-freedom in orchards meant that a single fire blight strike on a single tree in a large export orchard would disqualify all apple fruit in the orchard, even those tens, hundreds, or thousands of meters away from the source of inoculum.

4.101 **Japan** countered that scientists recognized the risk of transmission of the disease from one tree to another adjacent tree. Japan argued that its definition was equivalent to the "(severely) blighted" condition referred to in the findings of the Original Panel. It was not the case that a single fire blight strike on a single tree in a large export orchard would disqualify all apple fruit in the orchard.

4.102 **Japan** explained that for practical reasons, Japan's policy was to conduct inspection by the officials in an inspection automobile (a "buggy"). Under the Operational Cr.0033 Tw[(nds o)3.8[17d9vf19 0 TD08c10

4.105 **Japan** noted that in the two cases in which fire blight had been discovered by Japanese officials at the harvest stage, the officials stated that they believed they would have discovered many other symptoms of fire blight in the orchard.⁶³ As the inspection was conducted in limited period of time, it only served to detect significant levels of fire blight, or a "(severely) infected" orchard. Japan noted that there was no precise definition of a "(severely) blighted" orchard, but the inspection that Japan was planning would not be substantially different from the level which would detect such an orchard.

4.106 Japan argued that Japan's criteria did not define a "(severely) infected" orchard directly, but rather defined the orchard indirectly by means of the stated methodology. Japan claimed that testimonies of Japanese experts indicated that the discovery of infection under the inspection methodology included in the Operational Criteria would occur only when there were widespread symptoms of fire blight in a given orchard. Thus, the Operational Criteria ensured that only a (severely) blighted orchard would be detected.

4.107 Japan commented that an alternative definition would be to define a "(severely) blighted" orchard directly according to Dr Hale's definition, in which 75 infected strikes per tree would be found. Implementing this standard would require a close inspection of the entire orchard, and additional time and resources. Japan argued that since the methodology of the Operational Criteria employed observation from a running vehicle, it would only detect an orchard in the condition Dr Hale would call severely blighted, and should be viewed as a functional equivalent of his standard. The Operational Criteria codified this inspection methodology which would be the minimum necessary and sufficient to identify a "(severely) blighted" orchard, and ensure that no further survey or no detailed inspection of the orchard (site) was required.

4.108 The **United States** noted that Dr Hale never spoke of inspections for severe blight on an *individual tree*, rather he spoke of inspections for 75-100 strikes *per tree* in "severely blighted orchards".⁶⁴

4.109 The United States recalled that under the fire blight-free regime in 1992, 1995, 2002, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, 2030, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2039, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2047, 2048, 2049, 2050, 2051, 2052, 2053, 2054, 2055, 2056, 2057, 2058, 2059, 2060, 2061, 2062, 2063, 2064, 2065, 2066, 2067, 2068, 2069, 2070, 2071, 2072, 2073, 2074, 2075, 2076, 2077, 2078, 2079, 2080, 2081, 2082, 2083, 2084, 2085, 2086, 2087, 2088, 2089, 2090, 2091, 2092, 2093, 2094, 2095, 2096, 2097, 2098, 2099, 2100, 2101, 2102, 2103, 2104, 2105, 2106, 2107, 2108, 2109, 2110, 2111, 2112, 2113, 2114, 2115, 2116, 2117, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2125, 2126, 2127, 2128, 2129, 2130, 2131, 2132, 2133, 2134, 2135, 2136, 2137, 2138, 2139, 2140, 2141, 2142, 2143, 2144, 2145, 2146, 2147, 2148, 2149, 2150, 2151, 2152, 2153, 2154, 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noted that "the probability of latent infection of mature apple fruit will depend on the *physiological conditions and activities of the bacteria from August to the end of the maturing process*."⁶⁸ If Japan was asserting that the proposed "risk" of apple fruit infection depended on the activity of bacteria until the end of the growing season when apple fruit were completely mature, there could be no rational relationship between that evidence and an "early fruitlet" inspection, which would provide no assurances regarding the "physiological conditions and activities of the bacteria" at the "end of the maturing process."

4.112 **Japan** countered that the fruitlet stage was the best observation point for the fire blight infection of an orchard, because at this stage the bacteria were most active and the symptoms were observable. If the orchard had already been (severely) blighted during the fruitlet stage, the orchard would likely produce a higher number of infected (immature) apples than otherwise. Similarly, the level of bacterial presence in a (severely) blighted orchard at the fruitlet stage would likely have been higher than other orchards, resulting in a higher probability of latent infection, if any, through pedicels.

4.113 The **United States** further claimed that Japan's revised measures created ambiguity regarding the number of inspections required. Whereas Japan's 1997 Detailed Rules clearly stated that the confirmatory inspection to be conducted by Japan was to be "carried out at the same time with the inspection of the American authorities for the designation of the orchards prior to harvest," Japan's revised 2004 Detailed Rules contained no such qualifying statement, stating simply that a "Japanese official shall confirm the designated orchards with the United States Authorities every year."⁶⁹ The United States noted in its first submission that this lack of specificity and qualification for Japan's revised confirmation inspection would necessitate an interpretation of Japan's 2004 Detailed Rules and might permit Japan to conduct its confirmatory inspection at a later date than the US inspection, effectively resulting in two inspections of the orchard.

4.114 **Japan** clarified that inspections occurred once at the fruitlet stage. The Original Panel had found that three inspections would not be necessary, as the inspection at the fruitlet stage would be most effective in detecting symptoms, and as the reliability of visual inspection of apple trees would not be likely to increase by repetition.

Post-Harvest requirements

4.115 The **United States** recalled that Japan had argued that various post-harvest measures, namely sterilization of packing facilities handling apples for export to Japan, and export and import inspection were consistent with Article 2.2 based on the fact that the Original Panel had not reached an analysis of these measures due to its exercise of judicial economy. The absence of a finding by the Panel on Japan's post-harvest measures did not, ipso facto, mean that the measures were maintained with sufficient scientific evidence within the meaning of Article 2.2, and only highlighted the need for findings on each of the specific elements of Japan's import regime for US apple fruit at issue in this proceeding.

4.116 The United States noted that fruit boxes could not be infected with anything as they were not living entities. Also, modern post-harvest handling procedures long ago abandoned wooden crates as had used in the mid-20th century for new (unused), disposable, assembled-as-needed boxes made of

4.117 **Japan** argued that Azegami *et al.* (2005) had corroborated the finding that mature, symptomless apple fruit could be infected through artificial wounds using bacterial suspension. Consequently, as long as apple fruit suffered from exterior damages and there was sufficient number of bacteria on the fruit boxes, there was a realistic likelihood that the fruit would be infected.

4.118 The **United States** noted that speculation and anecdotal postulations had been published about the source of inoculum for the first outbreak of fire blight in England in the 1950s. The experts confirmed the anecdotal and unsubstantiated nature of the conclusions in Lelliot, Billings and Barrie.⁷⁰ Infected fruit and contaminated honey bees had been dismissed by Lelliot as being highly improbable, while the re-use of contaminated boxes or infected budwood/nursery stock seemed more probable. There was no surviving evidence that would ever allow confirmation of the means by which fire blight was introduced into England, and there would never be such evidence despite the recent efforts of Billings and Barrie (2002) to discuss purely conjectural and circumstantial evidence that there was a "possibility that there was a greater risk than usual in 1955 of blighted pears (and hence, contaminated fruit boxes) being imported from the USA."⁷¹ Billings and Barrie presented no

did not own the area serving as the buffer zone) or other orchard inspection requirements that also lacked a basis in the scientific evidence.

4.122 **Japan** countered that the costs to US apple growers of complying with Japan's import regime had to be weighed against the possible costs of large-scale investigation and eradication costs, if fire blight was detected in Japan. These costs could be very high; for example, the *E. amylovora* incursion in the Royal Botanic Gardens, Melbourne in autumn 1997 had cost the Australian pome and nursery industries an estimated A\$20 million in lost revenue and an estimated 10.7 million plants had had to be surveyed between 1997 and 1999. Further, some apple orchards had been inspected in 2001 and were found qualified to export to Japan on the basis of three orchard inspections. For these orchards potential benefits of participating in the apple export programme outweighed the expected costs and risks. Japan was not aware of the reasons why apple fruit harvested from these orchards had never been exported to Japan.

- (e) Harvested apples must be treated with surface disinfection by soaking in sodium hypochlorite solution

4.123 The **United States** claimed that in the case of apple fruit and fire blight, the scientific evidence did not establish that mature apple fruit would harbour epiphytic populations of bacteria capable of initiating fire blight disease. Further, there was no scientific evidence that apple fruit intended for export had ever been or were likely to be epiphytically contaminated with fire blight or fire blight-causing bacteria in packing houses, much less that such contamination could then result in the introduction of fire blight into Japan. Therefore, a facility disinfection requirement, enforced under the auspices of preventing the hypothetical epiphytic contamination, was not justified.

4.126 **Japan** argued that this requirement was a normal requirement in any process in that it only required a level of sanitation typical in a commercial food production line and could easily be met by the use of normal detergents.

4.127 The **United States** noted that facility disinfestations were not standard in the US apple industry. It was not, as Japan contends, a "normal requirement" in the US apple industry, let alone "a normal requirement in any process." Facility disinfestations and chlorine dip were necessary in order to meet the requirements of Japan's Detailed Rules for apple exports. Moreover, even measures alleged to be normal or standard industry practice had to be maintained with sufficient scientific evidence within the meaning of Article 2.2.

(g) Fruit destined for Japan must be kept separate post-harvest from other fruit

D. ARTICLE 5.1

1. General

4.131 The **United States** claimed that Japan's September 2004 PRA⁷⁵ had failed to propose a valid scientific analysis of any "risk" of fire blight from the commodity exported by the United States - mature, symptomless apple fruit. Instead, it had relied on the proposition that mature, symptomless, yet latently infected fruit would somehow reach the Japanese market - a proposition unsupported by Japan's studies, as they had not demonstrated that such a commodity could exist in the real world.

4.132 **Japan** argued that new evidence showed that the risk of completion of the pathway by US (infected) apple fruit from a (severely) blighted orchard was real, and even higher than thought at the time of the Original Panel. Japan had undertaken revision of its 1999 PRA on possible introduction of fire blight disease into Japan specifically through apple fruit from the United States. The revised PRA was completed in June 2004 and further updated in September. The purpose of the revision was to comply with the findings and/or conclusions of the Original Panel and to revise the measure by the end of the reasonable period of time. The revised PRA considered and compared a variety of phytosanitary measures to cope with the risk which had been established through laboratory studies and the findings and conclusions of the Original Panel. The revised PRA first considered if visual export/import inspection would be sufficient to achieve the appropriate level of protection (ALOP) upon shipping and/or arrival at Japanese ports. The difficulty of detecting symptoms and errors was considered. Since latent infection by *E. amylovora* inside apple fruit could not be detected by visual export/import inspection alone, whether at the points of exportation or importation, it was judged insufficient to achieve the level of protection.⁷⁶

4.133 Japan maintained that the revision was done fully in accordance with the procedural requirements as set out in ISPM 11. The revised PRA proceeded in three stages, namely:

- Stage 1: Initiation of a PRA, which reviewed and discussed biological evidence and phytosanitary measures in foreign countries against the fire blight disease;
- Stage 2: Pest Risk Evaluation. In this stage, the risk of introduction of the disease and estimated damages were evaluated for US apple fruit; and
- Stage 3: Pest Risk Management, discussing possible counter measures to shut down pathways through (a) internally infected mature apple fruit, (b) infected immature apple fruit and (c) wounded/decayed apple fruit infected with the bacteria.

4.134 Japan explained that in May 2004, Japanese experts met to discuss the 2004 PRA and on 15 June 2004 the PRA had been completed.⁷⁷ On 30 June 2004 Japan had adopted the Revised Detailed Rules together with the Operational Criteria. On 8 September 2004 the final PRA had been issued. This revision reflected the publication status of new evidence, which had previously been referred to just as personal communications.

2. Evaluation of the likelihood of entry, establishment or spread

4.135 **Japan** claimed that the revised PRA considered all of the issues raised by Dr Hale at the Original Panel meeting with experts.⁷⁸ The revised PRA showed that there was a rational relationship

⁷⁵ Report on Pest Risk Analysis concerning Fire Blight Pathogen (*Erwinia amylovora*) (September 2004), Exhibit JPN-3; "the "revised PRA").

⁷⁶ Revised PRA, Stage 2.

⁷⁷ Report on Pest Risk Analysis concerning Fire Blight Pathogen (*Erwinia amylovora*) (June 2004) (Exhibit JPN-17).

⁷⁸ Panel Report on *Japan – Apples*, para. 8.279.

would be higher than previously believed potential error in fruit sorting and handling was relevant to evaluating the risks.

4.142 The **United States** noted Japan's revised PRA was ostensibly based on the four new studies put forward by Japan. The first step in Japan's revised pathway assumed the harvest of "[m]ature, apparently healthy apple fruit which have fire blight bacteria inside," and that the "latently infected" fruit were then sold on the Japanese market.⁸⁰ The United States claimed that the four studies, and most notably the study purporting to identify the existence of mature, symptomless, yet latently infected fruit, did not alter the Original Panel's clear findings and the scientific evidence on apple fruit and fire blight. The studies did not establish that such a thing as a latently-infected mature fruit existed in nature or that a vector existed to complete the pathway. In short, the studies and, as a result the 2004 PRA, did not establish that a pathway for introduction of fire blight from mature apple fruit exists.

Probability of survival during transport and storage

4.143 **Japan** claimed that Tsukamoto *et al.* (2005a) showed that when bacteria had been inoculated at a concentration of 10,000 cells or higher, they survived inside apple fruit for up to six months at 5 degrees Celsius. These results appeared not inconsistent with the results of a previous study that investigated the survivability of the bacteria inoculated at the calyx part of apple fruit.⁸¹ Japan argued that the bacteria could, once inside the fruit at certain concentration, survive the cold storage treatment and shipping and transportation.

4.144 The **United States** noted that the results of the experiments conducted in Tsukamoto *et al.* (2005a) could not be presumed to predict what would happen under commercial conditions because in the experiments fruit were subjected to high temperatures for long periods of time before being moved to cool storage (see paragraph 4.46).

Probability of fire blight surviving existing pest management procedures

4.145 **Japan** noted that the revised PRA reviewed the bacteria's ability to survive existing pest management measures. While the probability of the event might be "small," as the Original Panel had noted, the sorting process of apple fruit could inadvertently pass infected apple fruit. Moreover, the new pieces of evidence showed that even apparently healthy apple fruit could be latently infected by the bacteria, and these results were consistent with the findings of the Original Panel regarding the exports from a "(severely) blighted" orchard.

4.146 The **United States** noted that Japan's 2004 PRA attempted to address the shortcomings of the original PRA, particularly those concerning the pathway for introduction of fire blight into Japan via apple fruit, by relying on the four flawed scientific studies discussed in detail above. As a result, the

4.148 The **United States** argued that there was no evidence that the United States had ever exported anything other than mature, symptomless apple fruit. To the contrary, the United States had reviewed relevant databases and confirmed with relevant officials that no shipments of US apple fruit had been rejected by foreign importers due to either immaturity or symptoms of fire blight. Specifically, the United States had performed a search of the Foreign Notification of Non-compliance database, containing non-compliance statements collected by the United States Department of Agriculture from IPPC contact points, and checked with Federal, State and industry representatives responsible for overseeing apple export programmes.

4.149 The United States noted that Japan had failed to present any evidence that an "erroneous shipment" had or would occur. Japan apparently rested its argument on the Panel's statement that errors of handling or illegal actions are risks that "may be, in principle, legitimately considered by Japan," improperly inferring that this statement granted Japan the right to assume that US quality controls would fail. In noting that it was a risk that may be considered, however, neither the Original

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3. Evaluation of risk according to the measures which might be applied

4.153 **Japan** noted that the revised PRA had reviewed and assessed the necessity of individual elements of the Systemic Approach.⁸³ The revised PRA had considered the efficacy of each of the possible phytosanitary measures in thwarting the risk of the disease from a (severely) blighted orchard. Then the revised PRA discussed possible application of a combination of measures, when one measure was found inefficacious to prevent introduction and establishment of the fire blight through the pathways.

4.154 The revised PRA concluded that a zone that identified the orchard and provided security against encroachment of the disease from overlapping outside host plants was necessary. In addition, inspection needed to be held once a year at the fruitlet stage in order to maintain a level of phytosanitary security in the orchard. Japan emphasized that further inspection would be unnecessary.⁸⁴

4.155 Japan claimed that the available evidence indicated that it was necessary to restrict export of apples from orchards expressing severe symptoms. However, the evidence indicated that only the section (block) in the orchard where one (severely) infected tree had been found needed to be disqualified. Also the evidence supported the definition of a "(severely) blighted" orchard, as being an orchard where an inspector would readily find typical symptoms on the tree exterior (or on large branches) through visual inspection using an automobile (a "buggy"), subject to confirmation of the bacteria by an assay.

4.156 The **United States** argued that Japan's Pest Risk Analysis ignored US pre-harvest and post-harvest procedures for quality control. The PRA summarized the controls as follows: "as apples are generally judged 'mature' or 'symptomless' by visual sorting, there is always a risk that something other than mature, symptomless apple fruit may be . . . present in the shipment." By failing to address actual US practices and to dispute the effectiveness of those practices, Japan had failed to take into account ISPM 11.

4.157 The United States recalled that the scientific evidence indicated that no border zone was necessary because it "provides no additional phytosanitary protection". In addition, no fire blight had been isolated from mature apples even when harvested from severely blighted orchards.⁸⁵

4. Measures based on an assessment of risks

4.158 The **United States** argued that Japan could not claim its new measure in June 2004 was based on a risk assessment dated September 2004.

4.159 **Japan** responded that the PRA was available in mid 937", but the United States had never requested it. Japan recalled that the only difference between the June PRA and the September revision was the reference to the status of studies which were more formally finalized after June.

4.160 The **United States** claimed that Japan's revised measures could not be "based on" its September 2004 PRA within the meaning of Article 5.1. Measures premised on the existence of "mature, symptomless but latently infected apples" and a non-existent pathway for introduction, establishment and spread of fire blight did not rationally relate to a risk assessment that failed to

⁸³ Panel Report on *Japan – Apples*, para. 8.289.

⁸⁴ Revised PRA, Stage 3.

⁸⁵ The United States referred to R.G. Roberts, Evaluation of buffer zone size and inspection number reduction on phytosanitary risk associated with fire blight and export of mature apple fruit, *Acta Horticulturae* 590 (2002).

4.168 Japan highlighted that one branch science existed which dealt with how to address possible human errors. Furthermore, Dr Smith had acknowledged that the inspection by the authorities might not provide adequate information about the quality of shipments due to the sampling protocol.

4.169 The **United States** countered that the application of US Federal Grade standards was only one of the numerous layers of industry and regulatory practices and requirements which US growers applied when growing, harvesting, packing and exporting apple fruit. These practices and requirements had assured that exported fruit was mature. US quality control measures for apple fruit involved several pre-harvest and post-harvest steps that ensured that the final exported product is mature apple fruit. The measures included: pre-harvest testing of soluble solids, starch-iodine and/or firmness to ensure that apple fruit meet requirements for storage as well as consumer demands; consultation with industry horticulturalists in making harvesting decisions; storage on arrival at the packing facility in regular cold rooms or controlled atmosphere ("CA") cold rooms; packing according to one of two available protocols, "direct pack" or "pre-size"; and inspection by Federal and/or Federally-licensed State inspectors.⁹⁴ US apple producers would not ship immature apple fruit since this type of shipment would be rejected by the importer, result in economic loss for the exporter, adversely affect the reputation of US apple fruit in export markets, as well as potentially run afoul of the provisions of the US Export Apple Act. Indeed there was no evidence that the billions of apple fruit shipped internationally (a vast number of which were shipped without SPS measures for fire blight) have ever introduced fire blight into a fire blight-free area.⁹⁵

4.170 **Japan** noted that the alternative measure proposed by the United States was nothing other than the "current commercial practice" which the industry applied elsewhere. Not only was there no evidence or assurance that the products from this process would be "mature, symptomless" in terms of their quality, but there was no evidence that the process specifications would achieve Japan's ALOP.

4.171 Japan claimed that according to the United States the Authorized Certification Official (ACO) used a sampling programme to evaluate whether a shipment of apples could obtain export certificate. USDA had explicitly disclaimed any liability which might arise from the export certification. Japan argued that the incentive to comply with standards was absent if neither the ACO nor the shippers or growers were held liable for errors relating to apple shipments.

4.172 Japan argued that the United States sought to rely on the previous export experience with other countries to which the United States previously shipped apple fruit without any phytosanitary measure and which did not suffer from the spread of fire blight from the shipments. Japan emphasized that the natural environment of these areas (including Chinese Taipei) was significantly different from that of Japan and therefore was not immediately applicable. Japan requested that the United States disclose previous records of its export experience with these countries/areas and provide information regarding any shipment rejected by the plant quarantine authorities or by recipients of the shipments and the causes for the rejection.

4.173 The **United States** stressed that the scientific evidence established that billions of apple fruit had never transmitted fire blight and mature, symptomless apple fruit were not a pathway for the disease. There was no record of a US apple producer having shipped immature apple fruit.

⁹⁴ "Pre-Harvest and Post-Harvest Storage, Grading, and Handling Practices of Apples" (Exhibit USA-1).

⁹⁵ Panel Report on *Japan – Apples*, para. 8.149. The United States has shipped approximately 53.5 billion apples world-wide over the last 37 years (this statistic combines the last two years' apple exports from the US (572,258MT (2002), 528,309MT (2003)) with the 48.5 billion apple fruit figure presented by the United States in 2001). See First Written Submission of the United States, September 4, 2002, para. 27.

(b) Appropriate level of sanitary and phytosanitary protection

4.174 The **United States** commented that a measure restricting imports to mature apple fruit achieved Japan's appropriate level of phytosanitary protection – a level of protection that would allow Japan to prevent the introduction of fire blight into Japan and maintain its fire blight-free status. This level of protection might be achieved

mature, symptomless apple fruit.⁹⁹ If the finding would be interpreted as endorsement of exportation of any apple fruit, whether mature or immature, or healthy or infected, then there would not be any justification for taking any measure, including the export/import inspection, or the proposed restriction to mature, symptomless apples. The United States could not rely solely on the finding of the Original Panel on completion of the pathway, in its attempt to establish a *prima facie* Article 5.6 case.

4.180 The **United States** emphasized that there was no evidence that the United States had ever exported anything other than mature, symptomless apple fruit, and there were numerous requirements and practices in place which assured this. The US statements referred to by Japan were only for the purpose of making the point that, even if immature fruit were somehow, hypothetically exported, the scientific evidence did not establish that the pathway would be completed.

4.181 **Japan** noted that the US claim that there was "no evidence that the United States has ever exported anything other than mature, symptomless apple fruit." was an attempt to narrowly define the relevant history. A shipment of pear fruit from continental United States had been discovered to be heavily blighted at a port of Hawaii.¹⁰⁰ Whether it had been pear fruit or apple fruit was not material in this context; the producer/shipper obviously had failed to control the quality of the fruit commodity at the shipping/release stage.

4.182 The **United States** stressed that commercial controls on pear fruit, as well as apple fruit, had evolved significantly since 1943 when the anecdotal shipment of pear fruit allegedly arrived in Hawaii (see paragraph 4.79)

(c) Significantly less restrictive to trade

4.183 The **United States** argued that a restriction of imports to mature US apple fruit would be significantly less trade-restrictive than the nine-measure import regime currently maintained by Japan. The extremely low level of US apple fruit imports to Japan and the corresponding high-levels of economic risk to which US apple growers were exposed indicated the trade restrictive effect of Japan's measures. The various elements of Japan's import regime, such as fire blight-free orchards, inspections, fire blight-free buffer zones, and chlorine treatment restricted trade by eliminating mature and therefore symptomless apple fruit from export to Japan. The United States concluded that under Japan's system, a US apple grower placed himself at risk when he decided to plant an orchard for export to Japan.

4.184 The United States further argued that under Japan's current regime, there were numerous scenarios in which mature apple fruit – which would not present a risk of introduction of fire blight into Japan – were nonetheless disqualified for export to Japan. For example, if a single fire blight strike was detected in a grower's orchard, or in the buffer zone surrounding the orchard, the grower's investment was lost as his apple fruit were no longer exportable to Japan. As a result of this risk, Japan's trade-restrictive apple fruit import regime had, over time, eliminated the incentive for US growers to attempt to export to Japan, and thus protected Japanese growers from competition.

4.185 The United States noted that the proposed alternative measure of restricting imports to mature apple fruit was significantly less trade-restrictive. Under the proposed alternative, entire orchards would no longer be disqualified for discovery of a single fire blight strike on a tree or in a buffer zone, and all mature apple fruit would be eligible for export to Japan. If imports were restricted to mature apple fruit, American apple growers would financially be able to compete to fill orders for export to Japan.

⁹⁹ Panel Report on *Japan – Apples*, para. 8.171.

¹⁰⁰ University of California (1965).

alternative was not. There was an evident difference in the level of protection offered by Japan's measure and the alternative proposed by the United States.

F. ARTICLE XI OF GATT

4.191 The **United States** claimed that Japan's measures were not legitimate SPS measures. Instead, they were non-tariff trade barriers in breach of Article XI of the General Agreement on Tariffs and Trade 1994 ("GATT 1994"). The United States noted that Article XI of the GATT 1994 stated that "[n]o prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licenses or other measures, shall be instituted or maintained by any Member on the importation of any product of the territory of any other Member." There was no dispute that Japan's measures restricted imports of apples through means other than duties, taxes or other charges.

4.192 **Japan** commented that since the new measure was consistent with the relevant Articles of the SPS Agreement, it was presumed to be covered by Article XX(b) of GATT 1994, under Article 2.4 of the SPS Agreement.

G. ARTICLE 4.2 OF THE AGREEMENT ON AGRICULTURE

4.193 The **United States** claimed that Japan's measures were also non-tariff barriers in breach of Article 4.2 of the Agreement on Agriculture which provided that "Members shall not maintain, resort to, or revert to any measures of the kind which have been required to be converted into ordinary customs duties, except as otherwise provided for in Article 5 and Annex 5." According to the footnote to Article 4, measures required to be converted into ordinary customs duties "included quantitative import restrictions, variable import levies, minimum import prices, discretionary import licensing, non-tariff measures maintained through state-trading enterprises, voluntary export restraints, and similar border measures other than ordinary customs duties." Again, there was no dispute that Japan's measures were restrictions on imports of apples and that these restrictions had not been tariffed.

4.194 **Japan** noted that the new measure was consistent with Article 4.2 of the Agreement on Agriculture, as it was a SPS measure fully consistent with the SPS Agreement and thus was maintained under "other general, non-agriculture-specific provisions of GATT 1994 or of the other Multilateral Trade Agreements in Annex 1A of the WTO Agreement," as defined in footnote 1 to that Article.

V. SUMMARY OF THIRD PARTY SUBMISSIONS

A. AUSTRALIA

5.1 Australia expressed a strong interest in the following areas:

- the nature of an Article 21.5 proceeding and the Panel's jurisdiction to examine certain measures and claims;
- the relationship between Articles 2.2 and 5.1 of the SPS Agreement; and
-

that all third parties be given an opportunity to respond in writing to all relevant written questions presented to the parties in the proceedings, in line with Articles 10 and 13 of the DSU.

B. BRAZIL

1. Article 5.1

5.3 Brazil considered that, in order to determine whether the measure adopted by Japan was in fact a "measure taken to comply", the Panel should first determine whether the "new" evidence brought by that country proves that a "mature, symptomless apple fruit" was indeed a vector of fire blight to a host plant and constitutes, therefore, an adequate risk assessment for the purposes of Article 5.1. If the revised SPS measure taken was not supported by a PRA appropriate to the circumstances, in accordance with the provisions of Article 5.1, it should not therefore be considered as a "measure taken to comply". Brazil noted that even if the 2004 PRA was based on "new" evidence, it could still not be deemed to be a valid "risk assessment", because Japan failed to demonstrate that "mature, symptomless apple fruit" could be "latently infected" and that it could serve as a "potential pathway" for the transmission of fire blight to host plants in Japan.

2. Article 2.2

5.4 Brazil observed that Japan's "new" scientific evidence did not seem to prove that "mature, symptomless apple fruit": (i) would be infected by fire blight; (ii) would harbour endophytic populations of the fire blight-causing bacteria or epiphytic populations of bacteria capable of transmitting fire blight; or (iii) would serve as a means or pathway of introduction of fire blight to a fire blight-free area. As the United States and New Zealand had noted the "new" evidence "failed to contradict or amend the reams of peer-reviewed and time-tested science on apple fruit and fire blight". The experimental processes used to reach these conclusions, moreover, could hardly be expected to occur under natural conditions.

5.5 Brazil questioned whether the new evidence had really informed or influenced the revised measures by Japan, since the new evidence (which had not yet been published) had only been

of quality controls on apple fruit that ensured their maturity in order to meet the requirements of these laws and regulations. The alternative measure introduced by the United States was also significantly less restrictive to trade by eliminating Japan's requirement during the production and shipping process.

5.8 China commented that since a Member had the right to determine its appropriate level of protection, this dispute should examine whether the US proposed alternative measure could meet Japan's level of protection. China argued that if

even if the two issues were "intertwined".¹⁰⁷ A central jurisdictional issue in such cases was therefore what was the "measure taken to comply".

5.13 The European Communities claimed that if a Panel chose to exercise judicial economy in respect to a claim regarding a measure, or if a Panel made a ruling on what is the measure at issue, in principle, if a Member did not agree, it should appeal. The scope of any subsequent implementation proceedings could be affected if there were no appeal. In particular if the complaining Member wished to raise a matter again, it might have to do so in a fresh panel, rather than in the context of Article 21.5 DSU proceedings.

1. United States request for preliminary ruling

5.14 The European Communities agreed with the United States in its request for a preliminary ruling that draft or proposed measures were not "measures taken to comply" within the meaning of Article 21.5 DSU. However panels should take into account facts or measures that arose after their establishment, when this was necessary to "secure a positive solution to the dispute" and if they might inform the Panel's assessment of other matters. If the Operational Criteria had been adopted by the end of these proceedings, and this Panel had found that those Operational Criteria brought the measure into conformity with the covered agreements, then this Panel might find that Japan had complied with the recommendations of the DSB and that no further recommendation was necessary.¹⁰⁸

5.15 The European Communities did not consider that such measures, even if un-adopted, should necessarily be removed from the record, or ignored by the Panel. Such documents might also shed light on the good faith of the Parties in the context of implementation, which might also be relevant this Panel's deliberations.

5.16 The sense in which the Operational Criteria were "irrevocable" was unclear, if the possibility for modifying them remained, as long as they had not been "accepted" by the United States. However, statements by a Member as to how certain measures would be interpreted or applied in the future might be sufficient for the purposes of dispute settlement. The European Communities argued that the United States was misguided in seeking a preliminary ruling that would eliminate at this stage of the proceedings the Operational Criteria from any further consideration by this Panel, given that the Operational Criteria could be relevant for certain substantive issues.

2. Article 21.5 of DSU proceedings

(a) Submissions of the parties

5.17 The European Communities noted that the parties' submissions were unclear on the question of the scope of these Article 21.5 DSU proceedings. The United States particularly referred, as "central to the DSB's findings", to conclusions in certain paragraphs¹⁰⁹ in sections D.4 and D.5 of the Original Panel Report, namely: there was not sufficient scientific evidence that mature, symptomless apples were likely to harbour bacteria capable of transmitting fire blight; and it had not been established with sufficient scientific evidence that the last stage of the pathway would likely be completed; or that apple fruit were likely to serve as a pathway for the entry, establishment or spread of fire blight in Japan.

¹⁰⁷ Appellate Body Report on *EC-Bed Linen (Article 21.5 – India)*, para. 78.

¹⁰⁸ Appellate Body Report on *Chile – Price Band System*, paras. 126 to 144. See also Panel Report on *India-Autos*, paras. 8.4-8.28.

¹⁰⁹ Panel Report on *Japan – Apples*, paras. 8.136, 8.168, 8.171 and 8.176.

5.18 Japan referred to conclusions in section D.6 of the Panel Report: regarding the 500 meter buffer zone and three times yearly inspection; and the absence or inadequacy of Japan's risk assessment. Japan had asserted that this Panel should "most appropriately and effectively" proceed "by looking into the measure's compliance with these recommendations and rulings". It noted that the Panel had not made findings or conclusions in relation to the other provisions referred to by the United States. However, conclusions sought by Japan in these proceedings, and the arguments submitted in support of those conclusions, extended to all the matters raised in the United States submission.¹¹⁰

5.19 Article 21.5 DSU provided that "Where there was disagreement as to the existence or consistency with a covered agreement of measures taken to comply with the recommendations and rulings such dispute shall be decided through recourse to these dispute settlement procedures, including wherever possible resort to the Original Panel". Thus, in

5.23 The original Appellate Body Report recommended that "the Dispute Settlement Body request Japan to bring its measure, found in this Report, and in the Panel Report as upheld by this Report, to be inconsistent with its obligations under th

purposes of commencing dispute settlement proceedings

such assessment, this Panel must take into account the new scientific evidence presented by Japan, and weigh it together with old and new evidence.

5.33 The European Communities noted that Japan did not appear to have adopted provisional measures within the meaning of Article 5.7. There might be circumstances in which the scientific evidence was sufficient for a risk assessment, and any risk was below a Member's appropriate level of protection. New scientific evidence then emerged suggesting that the risk was in fact higher than previously thought. Typically, in these circumstances a Member might first adopt provisional measures, pursuant to Article 5.7. The Member would then keep the situation under review and eventually, as the science developed further, either convert the provisional measure into a definitive measure, or remove it, reverting to the original situation. The European Communities contended that in the case of revolutionary science new scientific evidence could justify a swing from the perspective that certain SPS measures were not justified to the perspective that a definitive measure was justified, without passing through this intermediary stage of a provisional measure.

4. Article 5.1

5.34 If the Panel found the 2004 PRA to meet the requirements of a risk assessment within the meaning of Article 5.1, the Panel would need to further consider whether or not the "measures taken to comply" are "based on" a risk assessment. In this respect, the European Communities observed that the words "appropriate to the circumstances" made it clear that Members had a certain degree of flexibility in meeting the requirements of Article 5.1. The term "risk assessment" in the SPS Agreement had to be understood in the broad sense of "risk analysis" as defined by the Codex and meaning of Arsuaense of Ann.15Awthany42 Tw[(conve2 of Arsuaense of TD3TJ21.con3(u)-7.3(,20. fis shituati.1(m)a.

6. Scientific experts

5.38 The European Communities considered that this Panel should have recourse to scientific and technical advice from experts. This Panel should consider whether new facts might take a matter in whole or in part outside the scope of Article 21.5 DSU proceedings when deciding whether or not to consult experts.

E. NEW ZEALAND

1. Japan's original and revised measure

5.39 New Zealand noted that a number of factual findings made by the Original Panel underpinned the DSB's ruling that Japan's original fire blight measure was WTO inconsistent. The Original Panel concluded that there was a negligible risk of possible transmission of fire blight through apple fruit and that there was not sufficient scientific evidence that apple fruit were likely to serve as a pathway

fire blight. The conclusions, derived from highly artificial experiments, did not alter the record of scientific evidence or to challenge the key findings of the Panel relating to the likelihood of transmission of fire blight through trade in apples.

5.44 At most, the new studies could be said to demonstrate that

5.45 in a highly artificial laboratory environment it was possible to infect mature apples with fire blight bacteria by doing things to them that would never occur in the natural environment and would immediately render them commercially useless;¹²⁸

5.46 it was possible, by confining surfaced sterilised flies against the cut surface of fruit artificially inoculated with high concentrations of fire blight bacteria for a period of six hours, to extract a low concentration of bacteria from the body of the flies;¹²⁹ and

5.47 it was possible to transmit fire blight bacteria to fruit and plant parts by dunking surface sterilised flies in a high concentration of fire blight bacteria, and then leaving them in close contact with a range of damaged immature apple and pear fruit and plant parts for an unspecified period of time.¹³⁰

5.48 New Zealand submitted that the record did not indicate that the new evidence informed the development of the revised measure or that the revised measure was based on it. The measure in question was developed following the recommendations and rulings of the DSB in December 2003 and was notified to the DSB by the required timeframe of 30 June 2004. There was no mention of new scientific evidence at the time of notification to the DSB. Although the measure was implemented in June 2004, none of these studies were shared with the United States until the filing of Japan's submission of 13 September 2004.¹³¹ Even Japan acknowledged that the studies had not been completed until September, which was after the measure had been implemented and before they had to be formally published. All these factors raised serious concerns over the link between the new evidence and the revised measure, and indicated that the revised measure was not capable of being based on scientific evidence as required by Article 2.2.

3. Article 2.2

5.49 Japan's new studies did not change the scientific evidence regarding fire blight and apples. As the United States had pointed out, in putting forward these new studies Japan appeared to be trying to establish two concepts: that mature, symptomless apples could be latently infected with fire blight bacteria and that a potential pathway existed for the introduction of fire blight into Japan from this latently infected fruit.¹³² New Zealand agreed with the United States that the new studies failed to contradict or amend the established science on apple fruit and fire blight and thus the central findings of the Panel outlined above had not been displaced by the new studies put forward by Japan.

(a) Azegami *et al.* (2005), "Invasion and colonization of mature apple fruit by *Erwinia amylovora* tagged with bioluminescence genes" (Exhibit JPN-6).

5.50 Azegami *et al.* (2005) attempted to cast doubt on previous research by demonstrating that the flesh of mature apples was capable of becoming infected with populations of *E. amylovora* after the apple has become mature. They described a series of artificial laboratory interventions that resulted in

¹²⁸ Exhibit JPN-6.

¹²⁹ Exhibit JPN-9.

¹³⁰ Exhibit JPN-9.

¹³¹ Second Written Submission of the United States, page 16, footnote 21.

¹³² Second Written Submission of the United States, para. 14 and Second Written Submission of Japan, para. 52.

the detection of viable cultures of *E. amylovora* in the flesh of mature apples. The methods used to achieve the infection were highly artificial and not reflective of natural conditions and the context for the experiment was inconsistent with natural conditions in orchards.

5.51 Azegami *et al.* (2005) did not discuss normal movement of *E. amylovora* within plant tissue. Rather they describe four methods of artificial inoculation of mature apple fruit with high concentrations of bacteria (10^7 , 10^8 CFUs/ml) that do not occur naturally in late summer when apples are maturing:

- Through a cut pedicel (stalk);
- Direct inoculation to the depth of half a centimetre by a bundle of ten needles;
- Into surgical cuts in twigs near mature fruit; or
- Directly onto the cut surface of sliced mature fruit.

5.52 Experiments a), b), and d) which resulted in inoculation of mature apple fruit under laboratory conditions did not take into account the effect of the environment and the host on the ability of *E. amylovora* to invade such tissue. All scientific descriptions of the progress of fire blight disease under natural conditions described it as emanating at spring time from infected blossoms or from pre-existing, overwintering, cankers. Leaves, flowers and actively growing shoot tips were the tissues

late summer) would have had to cross the abscission layer (which had never been demonstrated to

moved from an infected twig through the abscission layer into the flesh of mature fruit. Whether or not high concentrations of *E. amylovora* could survive in the flesh of artificially inoculated mature fruit held at laboratory temperatures to promote infection and then held at 5 degrees Celsius was only theoretically interesting, and irrelevant to fruit produced under normal circumstances for commercial trade.

- (c) Tsukamoto *et al.* (2005b). "Transmission of *Erwinia amylovora* from blighted mature apple fruit to host plants via flies" (Exhibit JPN-9).

5.62 Tsukamoto *et al.* (2005b) tried to further extend the negligible probabilities proposed by Azegami *et al.* (2005) and Tsukamoto *et al.* (2005a) by suggesting that endophytic populations of *E. amylovora* in mature apples (that had never been demonstrated to occur), had been able to move in commercial trade then transferred to a susceptible host via the feet and mouth parts of common flies. This contrasted with the results of Taylor *et al.* (2003)¹³⁹ who demonstrated under natural orchard conditions that transmission of *E. amylovora* from discarded infested fruit to a susceptible host had not occurred.

5.63 Once again scientists used a series of unnatural procedures to demonstrate that a highly improbable event was possible under exceptional circumstances. The procedures involved:

- Inoculating mature fruit with high concentrations (10^8 CFUs/ml) of *E. amylovora* using a hypodermic syringe.

- Typically species of flies that visit rotting fruit were not naturally attracted to flowers and twigs, they might visit these occasionally to rest, but they did not remain for more than a few seconds.
- Fly species that visit rotting fruit did so for the nutrients released by the rotting process whereas species of flies that visit flowers did so for the pollen and nectar. The mouthparts of the different fly species were not the same. Mouthparts required to access one food source were incapable of accessing the other.

5.67 The conditions described by Tsukamoto *et al.* (2005b) did not reflect the conditions encountered in orchard environments. Levels of *E. amylovora* obtained from the flies confined with cut inoculated fruit were too low to infect mature apples. Also the results from Tsukamoto *et al.* (2005b) did not demonstrate transfer of *E. amylovora* from rotting fruit to a susceptible host since the flies used had been first dipped in a concentrated broth of *E. amylovora*. Instead, by having to employ these contrived mechanisms, the studies proved the improbability of the scenario they had set out to prove.

5.68 In relation to whether apple fruit were a pathway for transmission of fire blight, Tsukamoto *et al.* (2005b) did not in any way challenge the Original Panel findings that: with respect to mature, symptomless apple fruits, the risk that the transmission pathway be completed was "negligible"; and it had not been established with sufficient scientific evidence that the last stage of the pathway (i.e. transmission of fire blight to a host plant) would likely be completed (for either mature or immature fruit).

(d) Kimura *et al.* (2005). "The probability of long-distance dissemination of bacterial diseases via fruit" (Exhibit JPN-10)

5.69 Kimura *et al.* (2005) attempted to use the unsubstantiated and questionable findings of the three papers presented by Azegami *et al.* (2005), Tsukamoto *et al.* (2005a) and Tsukamoto *et al.* (2005b) and to validate them by quantifying them with probabilities. The paper first focussed on substantiated research regarding the epidemiology of bacterial diseases, discussing well-documented pathways for their entry and establishment in new areas. Kimura *et al.* (2005) then proceeded to try to use the dubious results described by Azegami *et al.* (2005), Tsukamoto *et al.* (2005a) and Tsukamoto *et al.* (2005b) to suggest that the amr T2 1 Tf2.5956

However New Zealand emphasized that any requirement, onerous or not, must be based on the scientific evidence.

(c)

(2005a), Tsukamoto *et al.* (2005b) and Kimura *et al.* (2005) as the sole source of new information. As set out above, New Zealand considered this research to be flawed. It failed to establish the results which Japan set out to establish. Therefore, the PRA did not adequately evaluate the likelihood of entry, establishment or spread of these diseases, as well as the associated potential biological and economic consequences, as required by the SPS Agreement.

5.83 Second, New Zealand agreed with the United States that the revised Pest Risk Analysis suffered from the same deficiencies as the original Pest Risk Analysis. It was not sufficiently specific to the matter at issue because it failed to address the commodity which was actually being exported by the United States – mature, symptomless fruit - and instead concentrated on a commodity that did not exist in nature – mature, symptomless, yet latently infected fruit.

5.84 The only justifiable conclusion of an objective risk assessment for fire blight was that the risk of introduction of fire blight (i.e. entry and establishment) on apple fruit remained negligible. The findings of the Panel remained unchanged and no phytosanitary measures were justified.

VI. PANEL'S CONSULTATION WITH SCIENTIFIC EXPERTS

A. PANEL'S PROCEDURES

6.1 The Panel recalled that paragraph 2 of Article 11 of the SPS Agreement provided that:

"In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative."

6.2 Noting that this dispute involved scientific or technical issues, the Panel consulted with the parties regarding the need for expert advice. Neither party objected to the Panel's intention to seek advice from the experts who provided advice in the first *Japan – Apples* case. The Original Panel had decided to appoint the following individuals as experts, pursuant to Article 13 of the DSU and Article 11.2 of the SPS Agreement:

Dr Klaus Geider, Professor of Molecular Genetics and Phytopathology, Federal Biological Research Organization, University of Heidelberg, Ladenburg, Germany;

Dr Chris Hale, Consultant specializing in plant protection, Waitakere City, New Zealand;

Dr Chris Hayward, Consultant on Bacterial Plant Diseases, Indooroopilly, Queensland, Australia; and,

Dr Ian Smith, Director-General, European and Mediterranean Plant Protection Organization, Paris, France.

6.3 After consultation with the parties, the Panel communicated the following working procedures for consultations with scientific and technical experts on 18 October 2002 to the scientific experts:

The parties are asked not to engage in any direct contact with the individuals selected.

The experts shall be requested to act in their individual capacities and not as representatives of any entity. They shall be subject to the DSB's Rules of Conduct for the Understanding on Rules and Procedures Governing the Settlement of Disputes (WT/DSB/RC1).

The Panel will prepare specific questions for the experts. The parties will have an opportunity to comment on the proposed questions, or suggest additional ones, before the questions are sent to the experts.

The experts will be provided with all relevant parts of the parties' submissions on a confidential basis.

The experts will be requested to provide responses in writing; copies of these responses will be provided to the parties. The parties will have an opportunity to comment on the responses from the experts.

A meeting with the experts will be held during which the experts will be invited to present their replies to questions, complement these as necessary, and respond to additional questions from the Panel and the parties. The parties will be invited to the meeting with the experts, and provided the opportunity to comment immediately on the statements of the experts. Prior to said meeting, the Panel will ensure that: (i) the parties' comments on the experts' written responses are provided to the experts; and (ii) each expert is provided with the written responses of the other experts to the Panel's questions. Parties are free to include scientific experts in their delegations.

6.4 The United States informed the Panel that it considered its submissions to the Panel to be public documents. The experts were invited to meet with the Panel and the parties to discuss their written responses to the questions and to provide further information on 12 January 2005.

6.5 As with the Original Panel, the Secretariat prepared a summary of experts' written replies to the Panel's questions, as well as a transcript of the meeting with the experts, for inclusion in the Panel's report. The experts were given an opportunity to comment on the drafts of these texts before they were finalized. A summary of the information provided by the experts in writing is presented below. A transcript of the meeting with the experts is included in Annex 3.

B. SUMMARY OF THE WRITTEN RESPONSES BY THE EXPERTS TO THE PANEL'S QUESTIONS

General questions on new scientific studies presented by Japan

6.6 As general introductory comments, **Dr Geider** declared that some points and questions raised by the panel touch experimental limits and face problems to transpose results from the laboratory to orchards and that after the hearing January 2003, it was difficult to dig still deeper into special points and to expect now the clear answer lacking before. He pointed out in 2002/2003 that the presence of a pathogen could be experimentally detected, but it was impossible to prove its absence. Steps of a possible pathogen spread could be shown in the lab, but they might never occur naturally.

6.7 Dr Geider commented that the vast collection of data about strain patterns in Europe allowed the conclusion of very rare dissemination of fire blight and the assumption that the disease was only introduced once or at very few occasions (see Conclusions). A considerable risk should be seen in private activities of handling plants and plant tissue, which could not be completely eliminated for the global activities in trade and tourism. Within Europe and the Mediterranean region these activities did not result in a detectable translocation of pattern types.

Question 1: Do you consider that any or all of the new studies provided by Japan meet the criteria usually applicable in the field (in terms of peer-review, publication, in depth-research etc.) to be relevant scientific evidence? (See Japan's reply to Question 16 of the Panel.)

6.8 **Dr Geider** stated that since the last hearing 2002/03, he was not aware of peer-reviewed new studies about spread of fire blight affecting the trade issue and that his paper: S. Jock and K. Geider: "Molecular distinction of American *Erwinia amylovora* strains and of two Asian pear pathogens by analysis of PFGE patterns and *hrpN* genes. Environmental Microbiology 6 (2004) 480-490" could be considered to contribute to that topic. The main message was the endemic persistence of fire blight in North America for a long time, expressed in divergent PFGE patterns of American/Canadian strains and conclusions about rare primary introduction events of fire blight into Europe and the Mediterranean region. His recent paper by S. Jock, C. Langlotz, and K. Geider: <Survival and possible spread of *Erwinia amylovora* and related plant-pathogenic bacteria exposed to environmental stress conditions. Journal of Phytopathology (2005), in press> (Abstract attached at the end of these comments) might touch in part similar approaches as the preprints of Tsukamoto *et al.* and Azegami *et al.*

6.9 Dr Geider added that the content of the manuscript also referred to survival of *E. amylovora* in HR lesions of non-host plants, a topic, which might not apply for trade of apples. The two unpublished Japanese studies relied on bioluminescence from the *lux*-operon, which depended on an active cell metabolism to recycle the substrates for light production. The signals did therefore not reflect cell density. According to his lab data, surface spread of *lux*-labeled *E. amylovora* cells, but not of *E. coli* cells, could also be shown on freshly cut potato slices. *E. amylovora* might be able to colonize several types of plant tissue. The pathogen could also grow in some non-host plants such as apricots, but was unable to persist in the tissue tTJ--34.a to Tf22.918 0 TD8.007 Tc0.0328 Tw[(co19ron,)5.T2 1 Tf1.8

6.13 **Dr Hayward** mentioned that there were five studies to consider:

- (a) Exhibit JPN-6 Azegami *et al.* (2004) "Invasion and colonization of mature apple fruit by *Erwinia amylovora* tagged with bioluminescence genes. Journal of General Plant Pathology 70 (6) December 2004. (Azegami I)
- (b) Exhibit JPN-8 Tsukamoto *et al.* (2005) "Infection frequency of mature apple fruit with *Erwinia amylovora* deposited on pedicel and its survival in the fruit stored at low temperature. Journal of General Plant Pathology (submitted). Undergoing peer review. (Tsukamoto I).
- (c) Exhibit JPN-9 Tsukamoto *et al.* (2005) "Transmission of *Erwinia amylovora* from blighted mature apple fruit to host plants via flies." Research Bulletin Plant Protection Service Japan." Accepted for publication. (Tsukamoto II).
- (d)

(c) P3kamopi Er206

6.18 **Dr Smith** explained that the studies had been commissioned in relation to the Dispute (which was surely quite legitimate), and their progress through the process of submission, refereeing and publication was necessarily constrained by the timetable

- (b) Are you aware of any scientific evidence or studies demonstrating that the abscission layer of apple would be damaged or cut under natural conditions?
- (c) Does the scientific evidence demonstrate the existence of latent infection occurring in mature apple fruit under natural conditions?
- (d) Does the scientific evidence demonstrate that bacteria which exist in a fruit bearing twig could infect apple fruit in the United States during the period from August until just prior to harvest?

In your reply, please address paras 17-21 of US oral statement, paras. 19-21 of US second submission (including US Exhibit 21), US and Japan's replies to Question 8 of the Panel (including Japan Exhibit 16), US reply to Question 3 of Japan and US Comments on Japan's Answer to Question 8 of the Panel. Please also address New Zealand's comments on post-maturity infection (para. 47 of New Zealand third party submission and replies to Questions 1 and 2 from Japan).

6.23 For questions a and b, **Dr Geider** stated that he was not aware of scientific data addressing the abscission layer of apples as a barrier for *E. amylovora*. As pointed out by others, it might develop late in fruit ripening. Nevertheless, the abscission layer could then reduce or even abolish any transition of bacteria from the twig to the apple tissue. Damage of the layer was possible in heavy wind when apples on trees were shaken.

6.24 For question c, Dr Geider noted that experimenTdfpossTc718 Tw3aeese i to damesign th.4(t 1addwe)-rhe5 . estion co Aature apple frwith balow ameE. a

fruit. However, fruit were inoculated on 22 and 27 September, and 5 October, and harvested at maturity on 22 October. Consequently, at inoculation time they might not have been mature, in which case the abscission layer was likely to have been incomplete. There was no photographic evidence of maturity provided in this Azegami *et al.* study. The evidence presented by Azegami *et al.* (2005) did, in fact, suggest that the intact abscission layer effectively prevented spread of bacteria from inoculated twigs via the pedicel into fruit at maturity. The recent study of Azegami *et al.* (Exhibit JPN-16) was, once again, unpublished information on a study carried out under artificial conditions.

6.28 Dr Hale noted for question b that it was possible that the abscission layer could have been damaged under natural conditions. However, if this did occur then the fruit would likely fall from the tree. It was also unlikely that there would be large populations of *E. amylovora* present in orchards that could inoculate the pedicel side of the damaged abscission layer with concentrations of *E. amylovora* great enough to cause infections. He was unaware of any scientific evidence that suggested that this occurs under natural conditions.

6.29 Dr Hale noted for question c that there was no published scientific evidence to suggest the existence of latent infection with *E. amylovora* in mature, symptomless apple fruit under natural conditions. Much had been made of the fact that van der Zwet *et al.* (1990) referred to *E. amylovora* being found in mature, symptomless fruit. However, as pointed out and discussed at length at the Original Panel proceeding, both Dr van der Zwet and Professor Thomson clarified in written statements that the positive detections had been in immature fruit, with one possible exception. In this single case, epiphytic bacteria had been detected in the calyx, not the flesh, of an apple from a blighted tree in a severely blighted orchard (Exhibit JPN-13).

6.30 Dr Hale noted that for question d there did not appear to be any published scientific information demonstrating that *E. amylovora* present in fruit bearing twigs could infect fruit during the period from August until just prior to harvest. Roberts (2002) harvested apples from trees with multiple fire blight strikes per tree and large oozing cankers on trunks suggesting that inoculum sources in fruit bearing twigs might well be present. However, *E. amylovora* had not been isolated from inside the fruit tissues tested. As apples would be immature in the United States in August, any infection from fruit bearing twigs before the abscission layer was completely formed would not be likely to result in mature, symptomless fruit. Any fruit infected through this route would be unlikely to mature.

6.31 **Dr Hayward** replied that he was not aware of any evidence that bacteria which existed in a fruit bearing twig could infect apple fruit in the United States during the period from August until just prior to harvest. The experiments described in Azegami II attempted to address this question. Four-year-old Jonagold apple trees in a quarantine glasshouse were inoculated into fruit-bearing twigs 30, 25 and 17 days prior to harvesting of mature fruit. *Erwinia amylovora* was isolated from the interior of about 10 per cent of outwardly healthy fruit. The results could not be interpreted to mean that the pathogen penetrated through an intact abscission layer, because penetration prior to formation of the abscission layer could not be excluded.

6.32 **Dr Smith** noted initially that the Azegami study, by using a bioluminescent strain, was making a distinct advance in the study of the movement of fire blight bacteria within host tissues. This technique seemed promising for the examination of a number of hypotheses about latent infection of apple fruits.

- (a) No. It pointed to this question as a matter which might now be investigated, in further research. It was a plausible presumption, but had not been proved.
- (b) No. (but this was a specialist matter beyond his normal knowledge).

- (c) No. It demonstrated the existence of latent infection in mature apples under unnatural conditions. The observations on how the bacteria spread within the flesh of the apple

isolated *E. amylovora* from within the fruit cortex and stem tissues as well as from the core tissues of apples from severely infected orchards. That *E. amylovora* was not isolated in these studies suggested that the pathogen had not been present in the fruit tissues. However, the published scientific data provided evidence of mature fruit being epiphytically infested when *E. amylovora* was found in the calyx (Hale *et al.* 1987; Thomson (Exhibit JPN13)) as a result of flower infestation in the spring.

6.43 **Dr Hayward** replied that he agreed with the US statement. The work of Azegami I and II did not prove the existence of mature, symptomless, latently infected apple fruit.

6.44 **Dr Smith** commented that it seemed unlikely that such bacteria would have been missed.

Question 6: Is there a clear physiological distin

apple cores (but, by the method used, it seemed likely that some cortex tissue would also have been present in the samples). There seemed to be some verbal confusion concerning the use of the words "cortex" and "flesh". "Cortex" tissue was "flesh" tissue.

Question 7: The US makes reference to "mature, therefore symptomless, apples" (see, e.g. footnote 2 of US first submission). Do you concur that mature apples are necessarily symptomless (with respect to fire blight)? Please explain.

6.50 **Dr Geider** stated that mature apples might have symptoms of soft-rot. These might be initiated by *E. amylovora* and then colonized by rotting microorganisms. Again, mature fruits did not develop typical disease symptoms of fire blight. There might be few data applying modern analyses such as PCR showing that "healthy" apples from orchards could carry *E. amylovora* in the core part. According to reports from New Zealand *E. amylovora* had been occasionally detected in the calyx.

6.51 **Dr Hale** noted that apples infected with *E. amylovora* during the immature stage of growth did not develop to maturity. Despite the unpublished evidence of Azegami *et al.* (2005) that mature fruit could be infected under artificial experimental conditions of inoculation of cut pedicels, there was no evidence of infection of mature fruit occurring naturally in orchards at harvest time. Consequently, it was most likely that mature fruit would be symptomless as far as fire blight was concerned. Immature fruit certainly became infected, probably from infected flower parts early in the season, and from external sources during the season. Although infection of mature fruit in orchards had not been documented, whenever this had been suggested, in depth analyses had confirmed that fruit had been, in fact, immature.

6.52 Dr Hale commented that it was probably more correct to refer to "mature, symptomless fruit" rather than to "mature, and therefore symptomless fruit" as far as fire blight was concerned, although equivalence was implied.

6.53 **Dr Hayward** replied that he accepted that the US exported mature apple fruit free of fire blight symptoms. The weight of evidence was that if there was infection at the blossom stage the immature fruit or fruitlet would not develop; and mature, symptomless fruit on the evidence available were devoid of populations of *E. amylovora*. Apple fruit maturity was a relatively well defined concept.

6.54 **Dr Smith** commented that this matter had been established in the Original Panel Proceedings. Mature apples with external fire blight symptoms had never been seen. The word "necessarily" was not appropriate, in that it implied there should be an essential reason why mature apples were not affected by fire blight. There was no very clear scientific explanation why this should be so; it just was. Another possibility to be considered was that mature apples could show internal symptoms, not visible externally. But there was no information in the literature to suggest that this ever happened, ~~and~~ it seemed in principle unlikely since in several studies bacteria had not been found to be able to penetrate the apple cortex.

6.56 **Dr Hale** noted that the results of Azegami *et al.* (2005), although suggesting that mature fruit could be invaded by *al.*

possible spread of *E. amylovora* to mature fruit. Rather, as the Norelli *et al.* (2001) study suggested, the movement of bacteria was from the scion to the rootstock i.e. downwards. There was no suggestion in either of the detailed studies of movement of *E. amylovora* in apple trees by Norelli *et al.* (2001) (also as Momol *et al.* 1998) or Gowda & Goodman (1970) that there was any movement of *E. amylovora* into mature apple fruit at the end of the season.

6.64 **Dr Hayward** replied that the work of Norelli *et al.* (2001) was primarily concerned with the movement of the fire blight pathogen downwards from the shoots of the artificially inoculated scion into the rootstock. Their paper did not provide data indicating that natural movement of the pathogen into maturing apple fruit occurred in the later phases of the growing season. There was ample evidence in the literature that a slowing down of fire blight activity occurred as the summer progresses. Norelli and co-workers had inoculated the shoots of scions in May, June and July, and had found evidence of a relatively low incidence and rate of spread downwards of internal populations of the pathogen when scions were inoculated in May or June and a relatively higher incidence and rate of spread when inoculations were made in July. The work of Gowda and Goodman (1970) showed that the movement and persistence of *Erwinia amylovora* within artificially inoculated plants was discontinuous rather than continuous with a sharp decline in population of the pathogen at distance from the point of inoculation. The pathogen had not persisted in non-succulent stem tissue. This

6.68 Dr Hale noted that buffer zones might be recommended for eradication purposes, particularly around nurseries, rather than as a requirement around a production site. There was very little literature on the effects of buffer zones on the fire blight status of orchards. Clark *et al.* (1993) reported that *E. amylovora* had not been detected in the calyxes of some 60000 fruit tested from inspected orchards with 500 metre buffer zones. However, more recently Roberts (2002) had shown conclusively that no buffer zone of any size was justified by existing scientific data to provide phytosanitary protection, as mature, symptomless fruit, harvested from either blighted trees or adjacent to blighted trees, did not harbour *E. amylovora*. In this study 30,900 mature, symptomless fruit had been harvested from 0 –300 metres from fire blight inoculum sources. None of the fruit that had been subsequently cool-stored had developed fire blight symptoms and *E. amylovora* had not been detected in any of the fruit, even when harvested from blighted trees or in close proximity to fire blight sources.

6.69 Dr Hale commented that as there was no published scientific evidence that mature, symptomless fruit from resistant or least resistant apple varieties contained internal populations of *E. amylovora*, even when harvested from blighted trees or from adjacent to inoculum sources, then there would appear to be no justification for border zones at all. Consequently, there was no need to distinguish between resistant and least resistant varieties in terms of their susceptibility to fire blight.

6.70 **Dr Hayward** replied that he was unable to comment on the question "How is an orchard defined for export purposes" and that he did not know whether this was based on international agreement(s) or common practice. There would be differences between different fruits and countries.

6.71 Dr Hayward commented that the field experiments of Roberts (2002), planned jointly between Japan MAFF and the USDA-ARS, were most relevant to border zones and their effect on the fire blight status of an orchard (or sub-orchard). At the first of the two sites chosen 'Gala' trees had been used as the source of inoculum, at the second site susceptible infected pear trees had been interplanted with apple trees including 'Fuji' and 'Gala'. 'Fuji' and 'Gala' were considered to be among the least resistant of apple cultivars to fire blight disease. The results which Roberts had obtained showed that a buffer zone of any size provided no phytosanitary security. Apples examined immediately after harvest or those cold stored for three months had been equally free of fire blight. There had been no difference between fruit harvested from trees 0, 10, 25, 50, 100 or 300 meters from the source of the fire blight inoculum.

6.72 **Dr Smith** highlighted that ISPM no. 5 Glossary of Phytosanitary Terms defined a "place of production" as: "Any premises or collection of fields operated as a single production or farming unit. This may include production sites which are separately managed for phytosanitary purposes", and a pest-free place of production as a "Place of production in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period." It defined a "pest-free production site" as: "A defined portion of a place of production in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained for a defined period and that is managed as a separate unit in the same way as a pest free place of production". An export orchard might, accordingly, be a "place of production" or a "production site", and phytosanitary measures might as appropriate apply to either. This terminology was internationally agreed (though this did not necessarily mean that all exporting contracting parties explicitly used these concepts). It was common practice. The definitions did not limit in any way the terms' application to any kind of crop in any country. However, whether the requirement for a pest-free place of production, or a pest-free production site, was an effective phytosanitary measure was a technical question depending primarily on the biology of the pest and also on the management of the crop. To make these measures effective, it might be necessary to require freedom also for the immediate vicinity (a concept used by the European Union), or to a defined buffer zone (a term in ISPM no 5). Or this type of measure might simply not be effective at all (e.g. for an insect pest that readily flies hundreds of metres). Because

fire blight only spread to the surface of fruits over very short distances, it would have been perfectly reasonable to propose that production sites within a place of production could be "managed as a separate unit in the same way as a pest-free place of production" by being surrounded by a fairly narrow border zone. The degree of susceptibility of the apple variety was not a point of major importance (assuming that the width of the border zone must in any case be set in relation to a susceptible variety).

Question 11: Is there a commonly accepted procedure for the inspection of apple orchards for fire blight symptoms? Please describe how such inspections are undertaken. How do they compare with Japan's inspection methods? (See paras. 56-58 of Japan's first submission, the Operational Criteria-Exhibit JPN-2, and US and Japan's replies to Question 7 of the Panel.)

6.73 **Dr Geider** stated that to his knowledge, there were differing demands for inspection. Fire blight was best noticed in Spring/early Summer, times not close to fruit ripening. It was a rare event and also difficult to detect new fire blight incidences at the harvesting period.

6.74 **Dr Hale** noted there did not appear to be a commonly accepted procedure for inspection of apple orchards for the presence of fire blight symptoms. If an inspection was deemed to be required as part of any operational procedures, then any methodology needed to be agreed by the parties concerned. The use of four-wheel motorcycles had been discussed at the time but had never been employed when inspections had been done in New Zealand.

6.75 **Dr Hayward** replied that for first and second questions he had no comment. Concerning the third question, he commented that the Operational

Question 14: In the light of recent scientific developments and/or the new scientific evidence presented by Japan, would you wish to modify your response to Question 24 from the Original Panel proceedings regarding buffer zones?

6.86 **Dr Geider** stated that he would not really modify his answer. Buffer zones sounded secure. There were many examples that fire blight could quickly move into "clean" orchards, often after persistence with unattended host plants such as hawthorn hedges in the neighborhood.

6.87 **Dr Hale** noted that the unpublished evidence presented by Japan did not alter the earlier response to Question 24 from the Original Panel proceedings regarding buffer zones. There was no scientific evidence that mature, symptomless apple fruit under natural conditions harboured populations of

6.91 **Dr Hale** noted that it was a fact that Japan required fruit to be stored at 2.2 degrees Celsius for 55 days as a treatment for codling moth.

6.92 Dr Hale noted that there was probably not likely to be much difference in survival of *E. amylovora* between 2.2 degrees Celsius (Japan's requirement for codling moth treatment) and the 5 degrees Celsius used in the *E. amylovora* survival experiment (Tsukamoto *et al.* 2005a). However, the important issues were those of experimental infection of mature fruit by artificial inoculation of cut pedicels, and the incubation of the artificially inoculated fruit at 25 degrees Celsius for 9 days before cool storing.

6.93 Dr Hale commented that there was no published scientific evidence to suggest that mature, symptomless fruit were infected via the pedicels under natural conditions. The incubation of inoculated fruit at 25 degrees Celsius for 9 days prior to cool storage at 5 degrees Celsius was certainly not a situation that would apply under normal commercial condition of harvest, cool storage, and export of apples. Consequently, the Tsukamoto *et al.* (2005a) study relating to the survival of *E. amylovora* in inoculated and incubated fruit did not present any useful information. The ability to isolate *E. amylovora* from artificially inoculated fruit after several months was, in fact, not new information as pointed out in the US response to Question 7 from Japan.

6.94 **Dr Hayward** replied that the apples used in the Tsukamoto I study had been artificially inoculated through the pedicel. They had been incubated for 9 days at 25 degrees Celsius, a temperature within the optimum range for growth (25-27 degrees Celsius; J-P Paulin, 2000) for *E. amylovora* in culture in the laboratory, then stored at 5 degrees Celsius for up to 6 months. The minimum temperature for growth of *E. amylovora* was given as within the range of 3-5 degrees Celsius (J-P Paulin, 2000) in culture, but was dependent on the substratum. For example, Taylor and Hale (2003) had obtained *growth* in a 20 day period at a temperature of 2.2 degrees Celsius in a nutrient medium but a *decline* at this storage temperature in populations of the pathogen in the apple calyx after inoculation at high, medium and low inoculum levels of inoculum. The minimum temperature for growth was likely to vary to a small degree with the nature of the substratum, particularly solid versus liquid nutrient medium. Populations of *Erwinia amylovora* declined on apple stems and calyxes to an undetectable level when stored for six month at a temperature of 2-4 degrees Celsius (Sholberg *et al.* 1988).

6.95 Dr Hayward noted that the treatment to which the artificially inoculated apples had been subjected in the Tsukamoto I study had been unlike that used in commercial conditions. For example, New Zealand held mature apples in cold store at temperatures ranging from 0.5 to 2.0 degrees Celsius with a variation of +/- 0.5 degrees Celsius. Japan's Detailed Rules on post-harvest treatment required that harvested apples are kept at a pulp temperature of 2.2 degrees Celsius (+/- 0.6 degrees Celsius) for 55 days as a measure against the codling moth (Exhibit JPN-1).

6.96 Dr Hayward noted that the apples subjected to the treatment in the Tsukamoto I study had deteriorated and had developed fire blight symptoms during storage. The experiment did not relate to normal commercial conditions. The experiment appeared to relate to the assumption that there were mature, symptomless, latently infected fruit resulting from the hypothetical late infection event in which bacteria pass through the fruit pedicel just prior to the formation of the abscission layer. There was no evidence for this late infection event.

6.97 **Dr Smith** commented that the New Zealand remarks were pertinent. Tsukamoto (I) was the weakest part of the "new studies". It would not have been difficult to conduct the study at more than a single temperature. If it had been shown that latent infections of the kind artificially created in the Azegami study did occur naturally, then it would have been essential to broaden the Tsukamoto study to include a variety of storage conditions, to determine how long these latent infections could really persist.

Question 16: In the 2004 PRA (p. 19), Japan makes reference to potential contamination via fruit boxes. Is there any scientific evidence demonstrating that contaminated fruit boxes would infect/infest apple fruit that is shipped in these boxes? Please comment in light of your response to Question 31 from the Original Panel proceeding. (See also US and Japan's replies to Question 10 of the Panel.)

6.98 **Dr Geider** stated that it had been a guess of Eve Billing and co-worker that fire blight might have been introduced to England via contaminated fruit boxes. It was not possible to trace this event back to the 50's except by speculation and circumstantial evidence. *E. amylovora* could survive indeed for a long time in wood. They had found bacteria with infested apple stems after seven years of storage in a cold room. Modern fruit packing often used paper boxes and circumvented thus the use of wooden caskets.

6.99 **Dr Hale** noted that as pointed out by the United States in response to Question 10 from the Panel, disposable cardboard boxes, rather than wooden or plastic crates, were now used in commercial apple export systems. Mature, symptomless apple fruit would not pose any risk when shipped in this type of container as there was no likelihood that the containers could become contaminated and

6.100

England for many years before that, without fire blight having been introduced. The authors considered this "surprising", but Dr Smith suggested that this only showed their preconceptions. On the contrary, it was further evidence that fruits were not a pathway.

Question 17: Do you concur with Japan's assertion that the requirement of disinfestation of packing facilities "is a normal requirement in any process"? (para. 25 of Japan's oral statement) Is there any scientific evidence that *E. amylovora* has spread through packing/sorting lines to non-contaminated fruit? Please comment in light of your responses to Questions 26 and 27 from the Original Panel proceeding. (See also US and Japan's replies to Question 11 of the Panel.)

6.103 **Dr Geider** stated that there was no evidence that *E. amylovora* had spread by fruit packing. If there were contaminated fruits, healthy fruits would not become infected unless by wounding. Again, there was little propagation of *E. amylovora* in mature apples and to his experience no ooze formation had been caused by the fire blight pathogen. Disinfection of containers might have only been needed in case of reuse, fruit treatment still seemed to be unnecessary in respect to distribution of fire blight and might cause a health risk for consumers.

6.104 **Dr Hale**

Question 18: In the light of recent scientific developments and/or the new scientific evidence presented by Japan, would you wish to modify your response to Question 30 from the Original Panel proceedings, regarding the likelihood of bacteria on apple fruit surviving normal commercial, shipping and export procedures?

6.109 **Dr Geider** stated *E. amylovora* cells on the fruit surface had a low chance to survive, when brought into the fruit, they would most likely stay alive during normal commercial processing (see also attached abstract).

6.110 **Dr Hale** noted that the only new evidence presented was the unpublished study of Tsukamoto *et al.* (2005a) that suggests that *E. amylovora* could survive for up to six months in stored fruit after artificial inoculation at cut pedicels. Inoculated fruit had been incubated for 9 days at 25 degrees Celsius before being stored at 5 degrees Celsius until the *E. amylovora* isolations were carried out. This situation did not simulate, in any way, the commercial conditions in which mature, symptomless fruit, with no evidence of harbouring endophytes, are typically handled.

6.114 **Dr Geider** stated that the proposed pathway needed a good inoculum source like oozing apples exposed to flies, which then have to visit flowers or young shoots of fire blight host plants. It was almost impossible that inspected fruits would develop these heavy symptoms from fire blight and flies would then spread the disease. The events might not practically occur and were scientifically unlikely.

6.115 **Dr Hale** noted that it was difficult to concur with Japan's argument that from the results of the experimental Pathway Study (Tsukamoto *et al.* 2005b) the "logical" conclusion was that the combination of artificially infected apple fruit, flies, and suitable host plants poses a risk of completion of the disease pathway.

6.116 Dr Hale noted that the experimental conditions imposed bore little resemblance to the real world conditions likely to be found. The flies had been provided with no choice but to visit the heavily infected apple fruit and it was quite understandable that, under the experimental conditions to which they had been exposed, they could have become contaminated with *E. amylovora* from the oozing apple. However, in a separate experiment, heavily contaminated flies had been then, again, given no choice but to visit wounded susceptible pear and apple fruitlets and wounded shoots of pear and apple. Again, under the no choice experimental conditions imposed, it was understandable that the flies had visited the wounded tissue in search of nutrients and moisture. It was important to note that neither the apple fruitlets nor the apple shoots had become infected after visits from the heavily infected flies. It was possible that the flies had not been attracted to the apple shoots and fruitlets.

6.117 Dr Hale noted that from the results of the Pathway Study (Tsukamoto *et al.* 2005b) it could not be concluded that flies contaminated with *E. amylovora* from inoculated apples did, in fact, cause infection in susceptible host tissues. This pathway had not been completed in the experiments. As Japan admitted in its response to Question 19 from the Panel, "the issue of the probability of completion of the pathway through infected apple fruit has not been resolved by the experiment". Consequently, there was no evidence of completion of a pathway of the disease even in the artificial experimental conditions imposed in the study. Conclusions about how these conditions related to the natural environmental situation, could only be conjecture.

6.118 Dr Hale highlighted that Miller & Schroth (1972) had shown that insects collected from a

the natural environment. In view of the artificiality of the experiment he could not accept the

6.127 **Dr Geider** stated that it seemed reasonable to distinguish the visiting behavior of fly species (garbage/flowers). It was possible to establish an *E. amylovora* population with 10 CFU in a flower. The bacteria could grow to a density exceeding 10 million CFU per flower provided favourable climatic conditions and the absence of other bacteria to compete as antagonists in multiplication of *E. amylovora*. Dense populations of *E. amylovora* would result in necrotic flowers.

6.128 **Dr Hale** noted that the Pathway Study (Tsukamoto *et al.* 2005b) did not provide convincing scientific evidence that the flies used in the experiments were vectors for the spread of fire blight. The experimental conditions to which the flies were subjected were far removed from natural conditions. The situation relating to the possible transmission of *E. amylovora* from discarded, infested, mature apple fruit to susceptible tissues, i.e. flowers and new shoots of host plants, had been documented by Taylor *et al.* (2003). A number of insects, including flies, had been trapped in the vicinity of susceptible host tissues. However, none of these had been contaminated with *E. amylovora* from the infested, discarded, mature apples when highly sensitive molecular techniques for detection in insect washings, including those from flies, had been used.

6.129 **Dr Hayward** agreed with the statements by New Zealand and the United States regarding flies as possible vectors for the spread of fire blight.

6.130 Dr Hayward noted that the paper by Taylor *et al.* (2003) reported evidence of the viability, persistence and possible spread of *Erwinia amylovora* in apples discarded in an orchard over a 20 day period at flowering. They had used a strain of the pathogen selected for resistance to two antibiotics, rifampicin and nalidixic acid; in this respect their methodology was similar to that used successfully in many studies in soil microbiology and plant pathology. The criticism could be made that the doubly resistant mutants might be less fit for survival in the environment because of the physiological "burden" of antibiotic resistance. He had not been able to find any evidence in support of this concept. He was not sure that there was an alternative method.

6.131 Dr Hayward further commented that Taylor *et al.* (2003) had showed that populations of the mutant declined in the calyx of inoculated apple fruit discarded in the orchard and they had been unable to recover the mutant from insects trapped in the orchard, or find any evidence of transmission from the calyx-infested apples to susceptible hosts. This was a good study which might serve as a model for similar investigation in other countries where fire blight was endemic; one study was probably not sufficient to give a definitive answer.

6.132 **Dr Smith** stated that as both the US and the New Zealand comments made clear, it was not enough to work with any sort of "flies". The Japanese submission treated its Calliphorid experimental flies on the same basis as Pegomya or Syrphids, which were quite different insects (though also "flies", in that they are Diptera) with quite different feeding habits. Calliphorids have been reported to feed on decaying vegetable matter, as well on the animal carcasses on which they lay their eggs. It was not at all clear that they would settle on, or feed on, relatively fresh fruits, on the ground or on the tree, or whether *E. amylovora* would survive in fruits sufficiently decayed to attract Calliphorids. Other lines of study could be envisaged, determining which insects were in the field attracted to rotting apples, or were found around pear or apple fruits (cf. the results of Taylor *et al.*, who caught bees, muscid flies, ants, moths, aphids, mosquitoes, bumble bees and various beetles). Use of such insects would much better satisfy the criteria of "plausible ecological conditions", provided that the experimental conditions allowed them some freedom to behave naturally. Relative to the present study, the most significant result of Taylor *et al.* was that they were not able to recover the bacterium at all, from any insect tested.

Question 22: Please comment on the probability estimates for long-distance dissemination of *E. amylovora* presented in Kimura (2005) (Exhibit JPN-10). In your reply, please also comment

obtained were evidently of a different order from those for the likelihood of establishment from a single infected fruit entering Japan. Since, as argued elsewhere, the results of the other New Studies were only of a preliminary nature, every probability estimate based on them was debatable. The text made no allowance for the greater or lesser uncertainty of these different estimates. It was indeed desirable in PRA that an attempt should be made to estimate probabilities quantitatively. But the uncertainty of these estimates was so high that it was misleading to combine them into an overall probability estimate. In particular, the Pathway study provided no real basis for any quantitative estimate of probability. It could only claim that the pathway was a possible one, whereas Taylor *et al.* (2003), with completely negative results, lead to a best estimate that the probability was zero. So the argument returned to a yes/no qualitative basis.

Question 23: Is there any scientific evidence demonstrating that crows or jungle crows serve as vectors for the transmission of *E. amylovora* ? (See page 25 of Japan's September 2004 PRA and para. 27 of US oral statement.)

6.138 **Dr Geider** commented that birds had been discussed as vectors to spread fire blight. In particular, introduction of the disease to remote oases in Israel could have involved birds. There was a report about survival of *E. amylovora* on the feet of birds. Long distance spread of fire blight by birds seemed unlikely, because this flying vector would have distributed the disease quickly all over a country starting at narrow spots with fire blight. By experience, the disease had spread sequentially from blighted orchards to other areas mainly by insects visiting flowers.

6.139 **Dr Hale** noted that there did not appear to be any scientific evidence that crows served as vectors for the transmission of *E. amylovora*. There had been unsubstantiated reports that birds might have been implicated in long-distance spread of fire blight in Europe (Meijneke 1974; Siedel *et al.* 1994 – cited in Thomson 2000). However, this evidence could only be considered to be circumstantial.

6.140 **Dr Hayward** stated that he had been unable to find any evidence showing that crows or jungle crows served as vectors for the transmission of

6.143 **Dr Hale** noted that there was no published scientific

the research on fire blight internationally over many years, if rots in mature fruit had been of any significance then it was certain that it would have been documented. There were many other causes of rots in mature apples and *E. amylovora* did not survive well in the presence of other microorganisms.

6.149 Dr Hale noted that the probability of establishment of *E. amylovora* in Japan and the probability of spread of fire blight after establishment were discussed in detail, as required for the PRA. However, the relevance of these details was questionable as there was no convincing scientific evidence that latently-infected, mature, symptomless apples existed, would be exported, or that the pathway for spread would be completed. Consequently, although Japan had followed the IPPC guidelines for preparing the PRA, it unjustifiably assumed both the existence of mature, symptomless, latently-infected apples as the commodity at issue, and the presence of an unsubstantiated pathway for introduction, establishment, and spread of the disease.

6.150 **Dr Hayward** commented that the IPPC document he had was ISPM No. 11, Pest Risk Analysis for Quarantine Pests, Including Analysis of Environmental Risks and Living Modified Organisms, dated April 2004. He further noted that Japan's September 2004 PRA (66 pages, 130 references cited) was a very thorough and valuable compilation of information from Japanese and international sources, generally complete and up to date. The relevant paper by Taylor and Hale ("Cold storage affects survival and growth of *Erwinia amylovora* in the calyx of apple" Letters in Applied Microbiology 37: 340-343, 2003) was not there. The paper by Taylor, Hale, Gunson and Marshall (2003) published in Crop Protection was very similar work to that of Taylor, Hale and Marshall in Acta Horticulturae 590: 153-156, 2003. Both papers were cited in the revised PRA. The centre paragraph on p.29 of the revised PRA was a fair comment on these two studies and in accord with his response to Question 21 (last sentence). The format of the revised PRA followed that of ISPM 11 closely.

6.151 **Dr Smith** stated that the September 2004 PRA followed ISPM no 11 much more closely than the earlier PRAs. In particular, pathways were evaluated separately and in detail, and so were measures in the pest risk management. The possibilities for use of the measures individually or in combination were considered. The evaluation of pathways did not, however, sufficiently consider how large an inoculum of *E. amylovora* was carried by the apple. Even if a pathway could be completed, it would not function if the inoculum was too small (this point related particularly to the possibility that fruits becoming contaminated by transfer from crates, facilities, etc). In a few minor ways, the PRA did not quite correspond to the Standard. In particular, the rather full account of the disease which appeared under Initiation was not strictly needed at that point. Such an account belonged either in an introduction, or else relevant elements from it should be cited in the risk assessment. The PRA did not consider all possible pathways. Strictly speaking, if another pathway (such as plants for planting) was left open, the validity of the measures and the consistency of protection could be called into question (cf. Salmon case). Certainly, this pathway was not open in the present case, but it was necessary to make this clear: see Section 2.2 of the ISPM, end of first paragraph: "The probabilities for pest entry associated with other pathways need to be investigated as well.". Also, the stage of risk assessment called "Pest categorization" (section 2.1) was not explicitly addressed (but could be considered superfluous). In general, it seemed desirable that PRAs should follow fairly closely the structure of ISPM no 11, making it much simpler to justify that the Standard had been followed.

Question 26: In light of the conclusions of the new scientific studies presented by Japan, does Japan's September 2004 PRA identify various options for reducing risks? Does it evaluate the efficacy and impact of these options in reducing risk to an acceptable level? In your reply, please also comment on Tables 7, 8 and 9 on pages 54 and 57 of the September 2004 PRA.

6.152 **Dr Geider** stated that some of the proposed precautions seemed to be reasonable, others might put a heavy impact on fruit trade. As said above, global activities in trade and tourism might surpass the risk of very low probability to introduce fire blight with fruits.

6.153 **Dr Hale** noted that the September 2004 PRA identified a number of measures for the reduction of risks identified as a result of the conclusions reached by the authors from the studies presented by Japan. These included options to prevent entry of *E. amylovora* via internally infected mature fruit from severely infected orchards, infected immature fruit, and infected wounded/decayed fruit. The efficacy and impact of each of these options for reducing risks to an acceptable level were evaluated and discussed in detail and the effectiveness of the suggested options for phytosanitary measures against the identified pathways were presented in Tables 7 and 9 of the PRA, and the difficulties associated with the implementation of the options analysed in Table 8. However, the options and measures suggested did not take into account the overwhelming published scientific evidence that there was no proven pathway for the long distance transmission of *E. amylovora*, and hence the spread of fire blight, by mature, symptomless apple fruit, that was the commodity at issue in this dispute. Infected, immature apple fruit would not be exported as the fruit was likely to be shrivelled and unmarketable and, if harvested, would be eliminated before packing as a result of the rigorous sorting procedures employed commercially. Mature fruit that had decayed as a result of infection with *E. amylovora* had not been reported – fruit rots were far more likely to be caused by numerous other pathogens including fungi, other bacteria, etc.

6.154 **Dr Hayward** replied that he had difficulty in accepting section 3-2 of the PRA "Options for phytosanitary measures against *Erwinia amylovora* related to US apple" pp. 47-59. The conclusions depended upon the studies of Azegami I and II, and Tsukamoto I and II, purporting to demonstrate the existence of "mature, symptomless, latently infected" fruit; for reasons given earlier the existence of such entities was unproven. Submissions from the United States attested to the thoroughness of the screening of harvested apples and the improbability that an immature apple would pass screening. There was a theoretical possibility of a late stage infection event (cf. responses to questions 3d, 4 and 15, last para), the probability of this occurring might be somewhere between negligible and zero. Even if mature, symptomless, latently infected fruit exist (which was unproven), and if there were immature fruit passing screening, which was highly unlikely, these hypothetical entities had to be subjected to cold storage which was inimical to the pest (*Erwinia amylovora*).

6.155 **Dr Hayward** did not accept that the work of Tsukamoto II demonstrated completion of the pathway, transmission from discarded fruit by insects (or by birds or through the agency of wind and rain) to a healthy host plant because of the artificiality of the *in vitro* studies.

6.156 **Dr Hayward** noted that it was extremely difficult to find evidence in the literature of completion of the pathway imported infected/infested fruit to a healthy host, even in the case of another bacterial disease, citrus canker, where infection of the fruit surface was well known and commonplace. This was not to suggest that citrus canker and fire blight were closely similar in epidemiology; they were not. Nevertheless outbreaks of citrus canker had been associated with budwood not with movement of fruit even though large quantities of infected fruit had been moved around the world for decades.

6.157 **Dr Hayward** commented that Tables 7, 8 and 9 represented a reasonable and logical approach, including examination of the economic feasibility of the different risk management options, as required by ISPM 11, but the conclusions could not be accepted because of the underlying assumptions based on Azegami I and II and Tsukamoto I and II.

6.158 **Dr Smith** noted that broadly, the evaluation was done correctly. Problems arose, nevertheless. First, the justification of the measures lays in the real probability that the pathways carried the bacterium as suggested. The focus of the measures was now on "internally infected

mature fruit", although the existence of this category was still scientifically disputed. It was also on "Infected immature fruit" and "Infected wounded or decayed fruit". Assuring that the orchard was not infected was certainly one way of reducing these last two risks, but there were surely other measures which could be used, and which would have to be considered if the "internally infected mature fruit" category was dismissed. Secondly, all the arguments in the PRA tended to show that bacteria on the surface of the fruit were not important (in contrast to the discussion during the Original Panel proceedings). Yet, the disinfection measures were maintained (they were considered "not effective" or "not applicable" in Tables 7-9).

Question 27: If less than 5 per cent of a shipment of apple fruit is damaged, and such a shipment may contain infected/infested apples, is there any scientific evidence that this would result in apple fruit from that shipment providing a pathway for the introduction, establishment and spread of fire blight in Japan (pages 22-23 of September 2004 PRA).

6.159 **Dr Geider** stated that the events, which had established fire blight in Europe or in New Zealand, were hidden. The dominant or only source for spread of fire blight seemed to be introduction by trade with infested host plants. It was unrealistic to assume a shipment of apples, where 5 per cent of fruits were heavily contaminated with *E. amylovora*. European pears (*Pyrus communis*) had a tendency to rot quickly, in contrast to Asian (Nashi) pears (*P. pyrifolia*). Rot in apple tissue was often localized. Still, *E. amylovora* had to be proven as the agent causing the rot by a careful analysis of the bacterial and even fungal populations of fruits with symptoms. Most important, *E. amylovora* had a low capacity to survive in a "hostile" environment. In necrotic tissue, it would be soon replaced by other bacteria, such as soft-rot Erwinias and *Erwinia herbicola* (syn. *Pantoea agglomerans*). He did not know about publications describing the bacterial populations in rotten apple tissue. From leaf spots caused by *P. syringae*, a continued change of bacterial species in the necrotic leaf area had been described. A general statement about "blighted fruits" as a major source for *E. amylovora* seemed to be risky from a judgment of damaged pears or apples. Papers, which deduced an infection by fire blight from the appearance of fruits, could deal with false interpretations. Rottenness and even ooze could be produced by many microorganisms. In agreement with Dueck (1974), *E. amylovora* could not be readily detected in symptomless fruit, even when harvested from naturally infected trees.

6.160 **Dr Hale** noted that as discussed in the September 2004 PRA, no inspection process was likely to detect *E. amylovora* associated with fruit. However, it was to be assumed that inspection procedures for other diseases were considered to be adequate by importing countries, providing a 95 per cent confidence level that almost all fruit are free from damage. To his knowledge there was no scientific evidence to suggest that mature, symptomless apples from a shipment with any damaged fruit would contain apples infected with *E. amylovora* that would provide a pathway for, or have ever been involved in the introduction, establishment, and spread of fire blight. In fact, there were no specific pathways recorded that document movement of *E. amylovora* from fruit, either imported or domestic in origin, to susceptible host tissues (Roberts

Conclusion

6.163 **Dr Geider** concluded that the primary events establishing fire blight in New Zealand, in Europe and the Mediterranean region could not be recreated. By the analysis of PFGE pattern of the isolated strains, it could be concluded that fire blight originated from one or very few introductions of the disease. In contrast to the North American divergent PFGE pattern types European and Mediterranean *E. amylovora* strains were quite related in the restriction fragments obtained in an *Xba*I digest. A change of one or two DNA fragments indicate allowed diversity of the highly related *E. amylovora* genomes from isolates in these countries. The divergence could have been derived from evolution of a single *E. amylovora* strain. In New Zealand, only pattern type Pt1 was found. From Egypt fire blight had moved by sequential spread to the neighbouring countries of north-east, to Turkey, the Balkans and Iran. All strains from these countries carried pattern type Pt2 except a few strains from Israel and Bulgaria with the unusual pattern type Pt5. From England, spread to Central Europe (pattern type Pt1) and Western Fran.0006 Tc5.65t.9((1adit9)7.6(eric)-3.9)JTJe/p0.175s ylheA uuof epan.0

in paragraph 8.25, which the United States considers reflects more accurately the nature of the Operational Criteria. The United States considers that the Operational Criteria implement rather than interpret Japan's legislation.

7.7 The Panel agrees that, *stricto sensu*, the Operational Criteria may not be "interpretations", even though they clarify how the authorities of Japan actually intend to implement the Detailed Rules. However, in the absence of evidence to the contrary, they are an official document issued by the Government of Japan. As a result, the Panel only deems it necessary to replace the term "interpretation" with the more general term "statement", since what ultimately matters is that the United States and the Panel can "rely" upon the Operational Criteria as an official statement by Japan of the way the Detailed Rules are applied.

7.8 The Panel further considers it appropriate to modify paragraph 8.25 so that it better corresponds to the terms used in the second sentence of paragraph 8.19.

7.9 Having regard also to paragraphs 8.76 and 8.119, the United States requests the Panel to clarify in paragraph 8.89 that, in light of its analysis, Japan's requirement of orchard designation, including its limitation of eligible orchards to those in the states of Washington and Oregon, and Japan's requirement that export orchards be free of plants infected with fire blight, are also not supported by sufficient scientific evidence.

7.10 Japan objects to this suggestion *inter alia* because there is no "measure" limiting production sites to those located in the states of Oregon and Washington. The restriction is related to the fact that the United States has not provided documentation regarding quarantine pests and diseases other than fire blight in other states. Japan refers to the findings of the Original Panel in this respect, claiming that the situation has not changed.¹⁴⁶

7.11 The comments of the United States in relation to paragraph 8.89 actually raise two issues. The first one relates to the question whether a finding is necessary regarding the fact that currently only orchards in the states of Oregon and Washington are eligible for designation as fire blight-free for purposes of exports to Japan. It is correct that our findings in the interim report did not expressly address that question. This is because we did not deem it necessary for two reasons.

- (a) First, we recall that Japan stated that the exclusion of states other than Washington and Oregon was because the United States has not provided documentation regarding quarantine pests and diseases other than fire blight in relation to other states. We agree with Japan that if apples from states other than Oregon and Washington cannot be exported because the United States failed to comply with phytosanitary requirements relating to diseases other than fire blight, the fact that those apples may be free of fire blight will not make them exportable to Japan. Neither before this Panel nor before the Original Panel, did the United States demonstrate that Japan imposes measures relating to fire blight in relation to other quarantine pests or diseases. Since the restriction primarily relates to other pests or diseases, we see no reason to make a finding on it. However, for the sake of transparency, we clarify this aspect in a footnote to paragraph 8.89.
- (b) Second, even if we were to assume that the restriction relates to fire blight, our finding in paragraph 8.89 is that the requirement that each orchard be designated as fire blight-free is not supported by sufficient scientific evidence within the meaning of Article 2.2 of the SPS Agreement. Our understanding of the relevant facts is that the exclusion of states other than Oregon and Washington is not a specific

¹⁴⁶ Panel Report on *Japan – Apples*, para. 7.25.

requirement but a factual consequence of the designation process. Indeed, Japan has repeatedly stated that it could designate orchards in other states provided the necessary information is given by the US authorities.

7.12 Finally, even if the exclusion of other states constituted a measure, since designation as such is not scientifically justified, exclusions resulting from the existence of a designation process are also not justified. No finding would be required in that case either.

7.13 The second issue raised by the United States in relation to paragraph 8.89 is that the US comments reveal that our conclusions were probably not spelled out clearly enough. This is why we modified the last sentence of paragraph 8.89.

C. ORIGINAL COMMENTS BY JAPAN AND COMMENTS OF THE UNITED STATES ON THE ORIGINAL COMMENTS BY JAPAN

7.14 Japan has requested that we delete paragraph 8.90, raising an argument regarding other plant diseases, including citrus cankers.

7.15 Paragraph 8.90 was designed to clarify that orchard inspection may be justified in other circumstances than those relating to fire blight. Since it does not refer to any specific disease, we see no reason to delete that paragraph.

7.16 Japan also suggests that we delete our reference to human health in paragraph 8.96 because this case is not about human health. We agree that fire blight does not threaten human health. However, we simply referred to a statement by one of the experts.

7.17 Japan has also requested that we modify paragraph 8.187. Japan considers that the measure at issue is not the main reason why US apple growers have ceased to export apples since 2002. Japan argues that the insignificant demand for US apples results from the appearance, taste and quality of the exported apples.

7.18 The United States argues that this is a totally new argument on which it was not given an opportunity to comment and which, in any event, is not factually supported.

7.19 We note that, on the one hand, it is generally admitted that consumer demand in the context of a market access restriction cannot be a reliable factor to assess actual demand, to the extent that it is influenced by the availability (or lack thereof) of the restricted product on the market.¹⁴⁷ On the other hand, the United States has argued that the main reason why exports did not take place were the costs

7.21 We recall that, pursuant to Article 15.2 of the DSU, a party may request the Panel "to review precise aspects of the interim report". We recall that a previous panel confronted with interim review comments questioning large sections of the interim report refused to address comments which did not relate to precise aspects of the interim report.¹⁵⁰ We note that Japan's comments regarding our finding under Article 2.2 of the SPS Agreement do not identify specific paragraphs that should be modified.

7.22 On the contrary, Japan argues first that the Panel's findings can only be valid if exported apples are indeed mature and symptomless. In this regard, Japan requests the Panel to examine whether the United States may actually export only mature, symptomless apples pursuant to its own legislation. We note that the question whether the United States exports mature, symptomless apples pursuant to its own legislation is discussed in our findings under Article 5.6 of the SPS Agreement. Japan does not request us to review precise aspects of the section of our interim report relating to Article 5.6 of the SPS Agreement. In particular, we note that neither during the proceeding, nor at the interim review stage, did Japan provide evidence that the United States ever exported to Japan apples that were contaminated with *E. amylovora*. Nor did Japan submit convincing evidence that the US quality control process contains flaws susceptible to lead to the exportation of apples contaminated with *E. amylovora* in the future. We also note that the Original Panel already discussed the possibility of human errors.¹⁵¹

7.23 Second, Japan seems to suggest that we address at this stage the process of verification that exported apples are mature and symptomless. We largely agree with the United States that Japan's

"[The aim of the dispute settlement system] is to resolve the matter at issue and 'to secure a positive solution to a dispute'. To provide only a partial resolution of the matter at issue would be false judicial economy. A panel has to address those claims on which a finding is necessary in order to enable the DSB to make sufficiently precise recommendations and rulings so as to allow for prompt compliance by a Member with those recommendations and rulings 'in order to ensure effective resolution of disputes to the benefit of all Members.'"¹⁵⁵

8.6 We do not believe that the Original Panel only provided a "partial resolution of the matter". We recall, however, that the United States requests that we treat the phytosanitary requirements at issue as several measures and make findings on the legality of each of them. Japan, while holding to the view that each requirement is part of a "system", also requests us to make specific findings on each element of its revised measure. Under these circumstances, we agree with the parties and decide, as we are entitled to, not to exercise judicial economy¹⁵⁶ whenever we believe that making a specific finding would facilitate prompt and full compliance by Japan at this stage.

8.7 In addition, the United States argues that the "Operational Criteria", i.e. administrative instructions which Japan claims to apply as part of the actions it took to comply, are not within the terms of reference of the Panel. The United States made a request for a preliminary ruling of the Panel on this issue. We address this matter as part of our discussion of the scope of the measure taken to comply.

8.8 Other issues of a procedural nature are addressed where necessary, as part of the discussion on substantive provisions.

B. THE "MEASURE(S) TAKEN TO COMPLY"

1. **Japan's legislation**

(a) The legislation

8.9 The phytosanitary requirements subject to this recourse by the United States to Article 21.5 of the DSU are based on the following legislation:

- (a) Plant Protection Law No. 151 enacted on 4 May 1950 (and specifically Article 7 thereof);
- (b) Plant Protection Law Enforcement Regulations enacted on 30 June 1950 (and specifically Article 9 and Annexed table 2 thereof);
- (c) Ministry of Agriculture, Forestry and Fisheries (MAFF) Notification No. 354 dated 10 March 1997; and
- (d) MAFF Administrative Directive, "Detailed Rules for Plant Quarantine Enforcement Regulation Concerning Fresh Fruit of Apple Produced in the United States of America " dated 30 June 2004 ("Detailed Rules"), amending the MAFF "Detailed Rules for Plant Quarantine Enforcement Regulation Concerning Fresh Fruit of Apple Produced in the United States of America" dated 29 January 2002.

¹⁵⁵ Appellate Body Report on *Australia – Salmon*, para. 223 (footnotes omitted).

¹⁵⁶ See Appellate Body Report on *US – Lead and Bismuth II*, paras. 71 and 73.

(e) In addition, Japan claims to implement the Detailed Rules through administrative instructions called "Operational Criteria". As mentioned above, the United States claims that the Operational Criteria are not part of our mandate. We address this claim hereafter.

(b) Treatment of the "Operational Criteria" by the Panel

(i) *Introduction*

8.10 On 27 September 2004, the United States requested that the Panel issue a preliminary ruling to the effect that Japan's Operational Criteria were not a measure taken to comply within the meaning of Article 21.5 of the DSU and were therefore not within the terms of reference of this proceeding. In addition, the United States requested that the Panel not consider the Operational Criteria in determining whether Japan's measures taken to comply with the DSB's recommendations and rulings were consistent with Japan's WTO obligations.

8.11 On 7 October 2004, we invited Japan to comment on the US request in its written rebuttals, which Japan did. On 22 October, we informed the parties of the following:

"Having considered the views expressed by both parties, and without prejudice to those views, the Panel concludes that it would be more appropriate to address the issues raised by the United States in the context of its overall review of Japan's compliance or otherwise with the covered agreements referred to in the Panel's terms of reference. As a result, parties should feel free to further express views on the Operational Criteria in the course of the coming substantive hearing, if they so wish."

8.12 Parties subsequently argued the matter during the substantive meeting with the Panel.

(ii) *Summary of the arguments of the parties*¹⁵⁷

8.13 According to the United States, the DSU does not give authority to a panel to make "advisory rulings" on a proposed or potential future measure. The Operational Criteria had not been "taken to comply with the recommendations and rulings of the DSB" by the time of the establishment of the Panel and so could not be within the Panel's terms of reference. Japan had not notified them to the WTO, nor had Japan referred to them in its 29 July request for arbitration under Article 22.6 of the DSU or its 30 July statement to the DSB. Although Japan indicated that it had intended to discuss and agree on the Operational Criteria with the United States, the United States had first learned of the Operational Criteria when it received Japan's first submission.

8.14 Japan argues that the Operational Criteria have all the characteristics of a "measure" under the SPS Agreement. These Criteria are a "supplementary guideline" setting forth methods to implement the Detailed Rules although they do not take the form of an enforceable regulation. They are administrative criteria of the Japanese Government. The Operational Criteria are a specific irrevocable offer which Japan would be obliged to implement if the United States agreed to them.

8.15 Japan argues that if the Panel did not consider the Operational Criteria it would be forced to either accept, or reject, the Detailed Rules without information relevant to their interpretation. The Detailed Rules were formulated according to Japanese administrative law practice. Japanese laws and regulations stipulate a general regulative mechanism, and government authorities stipulate rules, guidelines and directives within their mandate. Although the precise wording, documentation and

¹⁵⁷ A more detailed account of the arguments of the parties can be found in paras. 4.1-4.9 of this Report.

Japan filed its first written submission.¹⁵⁹ Japan alleges that the United States was aware of the substance of the Operational Criteria before that date.¹⁶⁰ However, we see no reason not to believe that the United States was made aware of the decision of Japan to apply the above-mentioned requirements through "Operational Criteria" only when Japan filed its written submission before the Panel. Therefore, we consider the explanation given by the United States to be a showing of good cause, within the meaning of paragraph 13 of our working procedures. As a result, we did not, and do not now, find that the US request is inadmissible on ground of lateness.

8.18 The Panel recalls that a review under Article 21.5 of the DSU applies to "measures taken to comply with the recommendations and rulings" of the DSB. It notes the argument of the United States that the Operational Criteria are not "measures" and were apparently not even adopted at the time the matter was referred to the Panel.

8.19 The Panel is not of the view that the binding or non-binding nature of the Operational Criteria should play a role in determining whether they should be reviewed in this proceeding. As soon as the Operational Criteria were brought to the attention of the United States and the Panel, they became an official statement of how Japan intended to implement its legislation on fire blight on which the United States and the Panel could rely.¹⁶¹ As such, the Operational Criteria are a fact.¹⁶² The duty of the Panel to make an objective assessment of the facts pursuant to Article 11 of the DSU implies that the Operational Criteria, as a fact, be taken into account by the Panel if they are properly before it.

8.20 The second and more important issue before us is whether a text dated 13 September 2004, i.e. more than one month after the establishment of the Panel and more than two months after the end of the reasonable period of time (30 June 2004), may be reviewed by the Panel.

8.21 Panels have dealt with events that occurred in the course of the proceedings and that had affected the existence or persistence of a violation.¹⁶³ Previous Article 21.5 panels have been confronted with measures adopted after the end of the reasonable period of time but before their establishment, or measures adopted soon after the establishment of the panel. In *Australia – Salmon (Article 21.5 – Canada)*, the complaining party requested that a measure not identified in the request for establishment be nonetheless reviewed by the compliance panel. In its report, the panel said:

"We do not consider that measures taken subsequently to the establishment of an Article 21.5 compliance panel should *per force* be excluded from its mandate. [...] In compliance panels we are of the view that there may be different and, arguably, even more compelling reasons [than before an original panel] to examine measures introduced during the proceedings. As noted earlier, compliance is often an ongoing or continuous process and once it has been identified as such in the panel request, as it was in this case, any 'measure taken to comply' can be presumed to fall within the panel's mandate, unless a genuine lack of notice can be pointed to."¹⁶⁴

8.22 We consider that the approach of the *Australia – Salmon (Article 21.5 – Canada)* panel could equally apply in this case.

8.23 We also note that in *Japan – Agricultural Products II*, the Panel found that Japan should have notified a non-binding administrative practice pursuant to Article 7 and Annex B of the SPS

¹⁵⁹ See para. 4.7, above.

¹⁶⁰ See para. 4.2, above.

¹⁶¹ See Panel Report on *US – Section 301 Trade Act*

8.30 As a result, the Panel decides to treat all the requirements imposed by Japan as elements of one measure. However, we may make specific findings on the different elements of this measure if we believe this will assist in the prompt resolution of the dispute.

(b) Identification of the measure taken to comply

8.31 We recall that, in *Canada – Aircraft (Article 21.5 – Brazil)*, the Appellate Body specified that Article 21.5 proceedings are limited to those measures taken to comply with the recommendations and rulings of the DSB. In the opinion of the Appellate Body:

"[...] the phrase 'measure taken to comply' refers to measures which have been, or which should be, adopted by a Member to bring about compliance with the recommendations and rulings of the DSB. In principle, a measure which has been

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of the compliance measure and we take as our starting point the conclusions reached by the Original Panel with respect to that scientific evidence.

2. Existence of sufficient scientific evidence that apples can serve as a pathway for the entry, establishment and spread of fire blight in Japan

(a) Introduction

8.39 The Original Panel concluded the following with respect to the scientific evidence regarding entry, establishment and spread of fire blight in Japan through apple fruit:

"(a) If infection or infestation of immature apple fruit is not contested, infection of mature, symptomless apples has not been established;

(b) the possible presence of endophytic bacteria in mature, symptomless apples is not generally established;

(c) the presence of epiphytic bacteria in mature, symptomless apples is considered to be extremely rare;

(d) assuming that either of the situations of infection or infestation listed above would arise, the entry, establishment or spread of the disease as a result of the presence of these bacteria in or on apple fruit would require the completion of an

- (b) Tsukamoto *et al.* (2005a)¹⁷³ which purports to demonstrate that mature apples can be infected through cut pedicels and that the bacteria can survive for several months in the apple at low temperatures.
- (c) Tsukamoto *et al.*

not as such a reason for us to deny any relevance to these studies.¹⁷⁸ Each of the studies relied upon by Japan should be assessed on its own merits.

(b) Does the scientific evidence, and in particular

(ii) *Tsukamoto et al. (2005a)*¹⁸⁵

8.53 In essence, Japan claims that the *Tsukamoto et al. (2005a)* study shows that *E. amylovora* has the ability to survive for a period of a few months under cold conditions, which corresponds to the period and temperature conditions applicable to US apple fruits during handling, cold storage and shipment to Japan.

8.54 The United States replies that the artificially inoculated fruit were maintained in conditions which favoured the development of the bacteria and were completely different from those applicable to apples exported to Japan. The phenomenon of infection through the pedicel described in *Azegami et al. (2005)* and *Tsukamoto et al. (2005a)* is an artefact of laboratory experimentation.

8.55 Having considered the arguments of the parties and third parties on this study, we considered that, for the purposes of the Panel's assessment, the main issue arising from it related to the storage conditions applied to the apple fruit after their inoculation, in particular the fact that they seemed to differ substantially from the usual commercial storage conditions applied in the United States. We therefore consulted the experts on the storage conditions applied to inoculated apples in *Tsukamoto et al. (2005a)*.

8.56 Dr Hale recalled that there is no published scientific evidence to suggest that mature, symptomless fruit were infected via the pedicels under natural conditions. The incubation of inoculated fruit at 25 degrees Celsius for nine days prior to cool storage at 5 degrees Celsius was certainly not a situation that would apply under normal conditions of harvest, cool storage and export of apples. Consequently, Dr Hale considered that the *Tsukamoto et al. (2005a)* study relating to the survival of *E. amylovora* in inoculated and incubated fruit did not present any useful information.¹⁸⁶ Dr Hayward also considered that the treatment applied to apples in *Tsukamoto et al. (2005a)* was unlike that used in commercial conditions. Dr Hayward added that the inoculated apples had been incubated for nine days at 25 degrees Celsius, a temperature within the optimum range for growth in culture in the laboratory.¹⁸⁷ Dr Smith commented that *Tsukamoto et al. (2005a)* was the "weakest part" of the new studies.¹⁸⁸

8.57 We conclude from the above that the *Tsukamoto et al. (2005a)* study does not support the view of Japan that *E. amylovora* inoculated in a mature apple would survive cold storage treatment in real commercial conditions.

(c) Does the scientific evidence support the assertion that the pathway could be completed between a discarded infested/infected apple and a host plant in Japan, so as to lead to the establishment and spread of fire blight in Japan?

(i) *Tsukamoto et al. (2005b)*¹⁸⁹

8.58 Japan essentially claims that *Tsukamoto et al. (2005b)* demonstrates that the completion of the pathway is more likely than thought at the time of the Original Panel. Three elements of the *Tsukamoto et al. (2005b)* experiment methodology captured natural ecological conditions. Flies endemic to Japan were known vectors of fire blight disease. Japanese pear fruit, which were highly susceptible to *E. amylovora*, were realistically representative of Japanese host plants. Moreover, the timing of apple importation/ 0 2

contamination of flies in the second phase of the experiment was approximately equal to the level observed in insects found in blighted orchards in natural conditions. According to Japan, it was logical to conclude that the combination of infected apple fruit, flies and suitable host plants posed a risk of completion of a pathway of the disease into Japan.

8.59 The United States argues that the methods employed in the study were so far removed from what might actually take place under orchard production conditions that the resulting data is not useful in assessing the risk of transmission of fire blight or determining a probabilistic estimate of a real world event. In particular, according to the United States, Tsukamoto *et al.* (2005b) did not demonstrate that greenbottle flies acquired cells of *E. amylovora* from infected fruits of their own volition (i.e. when not artificially forced to associate with infected apple fruit). Tsukamoto *et al.* (2005b) does not demonstrate that the flies had directly or indirectly carried *E. amylovora* from the infected fruit to the susceptible host material.

8.62 The Panel further inquired whether, in the opinion of the experts, the conditions the flies were subjected to related to "plausible ecological conditions", as stated by Japan.

8.63 Dr Hale confirmed that the experimental conditions the flies had been subjected to did not bear any relationship with "plausible ecological conditions".¹⁹⁷ Drs Hayward and Smith expressly concurred.¹⁹⁸ Dr Smith in particular insisted that the insects had been placed in a no-choice situation.¹⁹⁹ while Dr Geider stressed that this was a theoretical situation.²⁰⁰

8.64 On the third question, Dr Geider stated that it seemed reasonable to distinguish the visiting behaviour of fly species (garbage/flowers).²⁰¹ Dr Hale considered that the Tsukamoto *et al.* (2005b)

previous studies described in Roberts *et al.* (1989) had examined a portion of the apple fruit that included the flesh discussed in Azegami *et al.*

by the Panel also concur on the view that the transmission of fire blight to a host in Japan by an infected apple is unlikely. As mentioned by Dr Smith before the Original Panel, "from a scientific position, the logical conclusion of saying that there is an absolutely negligible risk of movement of fire blight with fruits is in fact a completely unrestricted trade."²⁰⁸

8.74 However, we recall that, neither before the Original Panel nor before this Panel, did the United States request to be entitled to export apples under whatever conditions it wants. Rather, the United States has suggested that it should be entitled to export mature, symptomless apples. The Original Panel concluded that the concepts of "mature" and "symptomless" were relevant in terms of contamination of the fruit and scientifically pertinent.²⁰⁹ This conclusion is not affected by the

8.78 According to Japan, the experts before the Original Panel expressed caution against exporting apples from (severely) blighted orchards. In addition, Japan considers that the potential of infection of mature apple fruit through pedicels or surface wounds would be more pronounced when the tree is severely blighted.

8.79 The United States notes that there is no scientific evidence to justify a measure restricting the eligibility of growers or packers based on concerns regarding spread of fire blight. Japan might have legitimate reason to restrict exports from certain states because of other plant diseases and quarantine pests. However, Japan has no grounds to restrict those exports under the auspices of a fire blight-specific measure.

8.80 Japan counters that the same measure applies to any state consistently with the Detailed Rules and the Operational Criteria. If the United States provides appropriate documentation of other quarantine pests and diseases, other states will be added to the eligible exporting locations.

8.81 The United States argues that the unjustified and unscientific nature of Japan's requirement is further demonstrated by considering that the requirement that orchards be free of fire blight means that a single fire blight strike on a single tree will disqualify all apple fruit in the orchard, even those tens, hundreds, or thousands of meters away from the source of inoculum.

8.82 Japan replies that scientists have recognized the risk of transmission of the disease from one tree to another adjacent tree. Japan argues that its definition is equivalent to the "(severely) blighted" condition referred to in the findings of the Original Panel.

8.83 The United States claims that the requirement for at least one inspection of both the orchard and the buffer zone at the early fruitlet stage to ensure that the orchard and buffer zone are free of fire blight bears no rational or objective relationship to the scientific evidence relating to apple fruit and fire blight.

8.84 In response, Japan states that the fruitlet stage is the best observation point for the fire blight infection of an orchard. If the orchard has already been (severely) blighted during the fruitlet stage, the orchard will likely produce a higher number of infected (immature) apples than otherwise. Similarly, the level of bacterial presence in a (severely) blighted orchard at the fruitlet stage may result in a higher probability of latent infection.

Analysis of the Panel

8.85 The four requirements referred to above are addressed together to the extent that they relate to the question whether a mature, symptomless apple harvested (a) from a blighted or severely blighted orchard; or (b) from an orchard where other blighted plants can be found could pose a threat with respect to the entry of fire blight into Japan.

8.86 We note that, before the Original Panel, the experts had expressed the opinion that "it would be appropriate not to export apples from (severely) blighted orchards"²¹³ and the Panel had interpreted this statement as evidence that some protection was justified by the state of the scientific evidence. In this proceeding, the experts further elaborated on the matter. Dr Smith noted that "it would not be possible to market successfully apples or pears from severely blighted orchards."²¹⁴ Dr Geider said "There may be no strict scientific basis to say that this is something that you should not do. On the

²¹³ Panel Report on *Japan – Apples*, para. 8.226.

²¹⁴ Dr Smith, Transcript, Annex 3, para. 183.

other hand there are practical reasons. I think this is what we say is good practice so it's good orchard practice not doing that."²¹⁵ Dr Geider added that:

will disqualify the orchard as a whole, cannot be c

"Why would we treat mature symptomless apple fruit by any disinfestation process, say a chlorine solution or something of that nature? There is no evidence of an epiphytic population, even less after storage at low temperature following the work of Hale. The only site on the apple fruit, mature symptomless fruit which Dr Hale has identified, is the calyx. The calyx is a protected site and a surface disinfestation process is not going to be effective because the calyx will not be reliably penetrated by the solution you are using to treat it."²²⁷

8.97 Having regard to the experts' opinions, we conclude that surface disinfection is not justified by scientific evidence to the extent that the existence of an epiphytic infestation of apple fruit by *E. amylovora* in quantities capable of reproduction and ultimately of infecting a host plant has not been established. Assuming that bacteria could be found in the calyx, the surface treatment required by Japan would not be effective in removing them.

(v) *The interior of the packing facility must be disinfected by a chlorine treatment*

8.98 The United States claims that there is no scientific evidence that apple fruit intended for export could be epiphytically contaminated with fire blight-causing bacteria in packing houses, much less that such contamination could then result in introduction of fire blight in Japan. Facility disinfestation is not standard in the US apple industry.

8.99 Japan argues that the disinfection of packing facilities by a chlorine treatment is a normal requirement in any process in that it only requires a level of sanitation typical in a commercial food production line.

8.100 The experts who expressed their views on the requirement that the interior of packing facilities be disinfected by a chlorine treatment queried how this requirement was different from the normal requirement of a certain level of sanitation.²²⁸ Moreover, Japan's legislation does not provide any particular detail on the requirement (e.g., regarding the frequency of disinfection).

8.101 We note that sanitation of packing facilities seems to be an established commercial practice.²²⁹ However, to the extent that the reason for such a requirement with respect to mature, symptomless apples is to avoid the transmission of epiphytic populations of *E. amylovora* to those apples during packing, there is no evidence that such transmission has ever occurred. Even if it were to occur, there is no scientific evidence that populations of *E. amylovora* would survive commercial handling and transport.²³⁰ Even assuming they would, completion of the pathway would require the completion of an additional sequence of events which is deemed unlikely and which has not been scientifically established to date.

8.102 As a result, we conclude that while proper sanitation may be required and seems to be established commercial practice, the scientific evidence does not justify chlorine disinfection of packing facilities in order to prevent contamination of mature, symptomless apples by *E. amylovora*.

(vi) *Fruit destined for Japan must be kept separate post-harvest from other fruit*

8.104 According to Japan, the separation requirement is not specific to fire blight but a natural extension of the other control requirements. Referring to a statement by Dr Hale²³¹, Japan also recalls

on whether the measure, treatment, or action the completion of which has to be certified is itself justified by scientific evidence.

- *Certification that exported apples are free of fire blight*

8.111 In respect of the requirement that US authorities certify that exported apples are free from fire blight, we first recall that fire blight is a recognized disease with serious consequences. The United States does not contest this. We also recall that fire blight does not currently occur in Japan. Japan is therefore r.6(m)7ot current8.4(e)-3.1(nt th)e71.Jap9(ho)-W 475 ent7(475 ing579 -1.1[(m)8.3(0h h.5(does n)3.6(o)-1

apples are free from fire blight as long as it does so in a manner compatible with the SPS Agreement, in particular Annex C thereof.

Chlorine treatment

8.117 In contrast, as far as the confirmation by Japanese officials of the certification of chlorine treatment of exported apples by US officials is concerned, we recall our findings regarding the scientific justification for chlorine treatment as such.²³⁷ this requirement is not scientifically justified. In application of our reasoning in paragraph 8.115 above, we conclude that a confirmation requirement applicable to a requirement which is itself not scientifically justified cannot be scientifically justified either.

- *Inspection of packing facilities by Japanese officials*

8.118 As far as the inspection of packing facilities is concerned, we also recall our findings regarding chlorine washing of apples, disinfection of packing facilities and separation of apples destined for Japan, which are to our knowledge the requirements that have to be complied with in the packing facilities.²³⁸ We recall that none of the above-mentioned requirements was found to be scientifically justified in relation to fire blight. As a result, we can only conclude that, to the extent that it relates to these requirements, inspection of packing facilities is not supported by scientific evidence.

(ix) *Summary of findings*

8.119 In conclusion, our findings in paragraphs 8.89, 8.94, 8.97, 8.102, 8.106, 8.111, 8.112, 8.116, 8.117 and 8.118 are that each element of the measure at issue, with the exception of the requirement that US plant protection officials certify that fruits are free from fire blight, and the related confirmation by Japanese officials, is not supported by sufficient scientific evidence.

4. Conclusion on Article 2.2 of the SPS Agreement

8.120 On the basis of the scientific evidence made available to us and the opinions of the experts, we conclude that the United States has made a prima facie case that the compliance measure at issue is not supported by sufficient scientific evidence. Japan has not rebutted this prima facie case.

8.121 This does not mean that no phytosanitary measure is justified. On the contrary, the United States claims to export mature, symptomless apples. To the extent that this constitutes a phytosanitary requirement, Japan would be entitled to verify that this is actually the case. We note that the need for verification that only mature, symptomless apples are exported has been confirmed by the experts.²³⁹

D. ARTICLE 5.1 OF THE SPS AGREEMENT

1. Approach of the Panel

8.122 nitary measure

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between the measure and the risk assessment. The consideration of whether there exists a risk

"[w]hen an export orchard is severely blighted, it appears not prudent to ignore the risk of *E. amylovora* entering Japan through: (A) mature apple fruit internally affected with *E. amylovora*; (B) immature apple fruit infected with *E. amylovora*; (C) wounded/decayed apple fruit infected with *E. amylovora*. Once the bacteria enters Japan in significant populations, the bacteria will likely establish and spread in Japan, and cause great damage with extremely high economic consequences."

8.136 As mentioned above, the Appellate Body in *EC – Hormones* agreed with the general consideration of the panel in that case that "Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2 of the SPS Agreement", including the obligation not to maintain a measure without sufficient scientific evidence. We recall that the scientific evidence which is being evaluated must support the conclusions of the 2004 PRA.²⁴⁶ Therefore, if the conclusions of the risk assessment are not sufficiently supported by the scientific evidence referred to in the 2004 PRA, then there cannot be a risk assessment appropriate to the circumstances²⁴⁷, within the meaning of Article 5.1.

8.137 In doing so, we are mi.-gv557 -3pe

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the real world. Even if the studies relied upon by

3. Is the measure at issue *based on* a risk assessment?

(a) Summary of the arguments of the parties²⁵²

8.148 The United States argues that Japan cannot claim that its new measure adopted in June 2004 is based on a risk assessment dated September 2004.

8.149 Japan responds that the PRA was available in mid-June, but the United States never requested it. Japan maintains that the only difference between the June PRA and the September revision is the reference to the status of studies which were more formally finalized after June.

8.150

8.156 Second, with respect to the argument of the United States that there is no rational relationship between the measure at issue and the 2004 PRA, we recall our finding above that the 2004 PRA does not amount to a risk assessment appropriate to the circumstances. We conclude, as a consequence, that Japan's compliance measure is not based on a risk assessment, within the meaning of Article 5.1.

4. Conclusion on Article 5.1 of the SPS Agreement

8.157 For the reasons mentioned above, we conclude that the United States has made a prima facie case that the compliance measure at issue is not "based on an assessment, as appropriate to the circumstances, of the risk to [...] plant life or health" in Japan, within the meaning of Article 5.1 of the SPS Agreement. Japan has not rebutted that prima facie case.

E. ARTICLE 5.6 OF THE SPS AGREEMENT

1. Introduction

8.158 Article 5.6 reads as follows:

"Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or

8.163 We now proceed with the review of the arguments of the parties for each of these elements which, as recalled by the Appellate Body, have to be applied cumulatively.

2. "Reasonably available taking into account technical and economic feasibility"

(a) Summary of the arguments of the parties²⁵⁹

8.164 The United States claims that a measure restricting imports to Japan to mature US apple fruit is reasonably available taking into account technical and economic feasibility. US federal laws (the US Export Apple Act) and regulations already ensure that export apple fruit are mature. US quality control measures for apple fruit involve several pre-harvest and post-harvest steps that ensure that the final exported product is mature apple fruit. The measures include: pre-harvest testing of soluble solids, starch-iodine and/or firmness to ensure that apple fruit meet requirements for storage as well as consumer demands; consultation with industry horticulturalists in making harvesting decisions; storage on arrival at the packing facility in regular cold rooms or controlled atmosphere cold rooms; packing according to one of two available protocols, "direct pack" or "pre-size"; and inspection by Federal and/or Federally-licensed State inspectors. US apple producers do not ship immature apple fruit since this type of shipment would be rejected by the importer, result in economic loss for the exporter, adversely affect the reputation of US apple fruit in export markets, as well as potentially run afoul of the provisions of the US Export Apple Act.

8.165 The United States further argues that the risk of failure of commercial quality controls is hypothetical. Indeed there was no evidence that the billions of apple fruit shipped internationally (a vast number of which were shipped without SPS measures for fire blight) have ever introduced fire blight into a fire blight-free area.

8.166 Japan argues that the United States proposes that products should meet "US No.1 Grade" specifications but does not include specifics about test methods for verification. By failing to provide test methods or ways to achieve the specification, the United States has not established any "measure" worth considering. The alternative measure proposed by the United States is nothing other than the "current commercial practice" which the industry applies elsewhere. Not only is there no evidence or assurance that the products from this process will be "mature [and] symptomless" in terms of their quality, but there is no evidence that the process specifications achieve Japan's appropriate level of protection (ALOP).

8.167 According to Japan, the concept of the mature, symptomless apple fails to take into account (potential) risks associated with (i) failure of the inspection mechanism at the shipping (release) stage, or (ii) the new discovery of non-observable potential infection inside the apple fruit.

8.168 Japan further argues that the United States seeks to rely on the previous export experience with other countries to which the United States previously shipped apple fruit without any phytosanitary measure and which did not suffer from the spread of fire blight from the shipments. Japan emphasizes that the natural environment of these areas (including Chinese Taipei) was significantly different from that of Japan. Japan also notes that US inspectors in charge of certification incur no risk of liability. Finally, Japan refers to instances where codling moth was identified in shipments of US apples to Chinese Taipei as an illustration of failure in the US apple export control.

²⁵⁹ A more detailed account of the arguments of the parties can be found in paras. 4.164-4.173 of this Report.

8.175 We also note that the US legislation defines maturity as:

"The apples have reached the stage of development which will insure the proper completion of the ripening process."²⁶²

8.176 Finally, we recall that the United States has informed us that quality controls for apple fruit involve several pre-harvest and post-harvest steps which, according to the United States, ensure that the final exported product is mature apple fruit. These controls include: pre-harvest testing of soluble solids, starch-iodine and/or firmness to ensure that apple fruit meet requirements for storage as well as consumer demands; consultation with industry horticulturalists in making harvesting decisions; storage on arrival at the packing facility in regular cold rooms or controlled atmosphere ("CA") cold rooms; packing according to one of two available protocols, "direct pack" or "pre-size"; and inspection by Federal and/or Federally-licensed State inspectors.

8.177 In light of the above, we consider that the United States has sufficiently demonstrated that such quality controls could provide sufficient guarantees to reasonably ensure that the product exported is mature, symptomless apples.

8.178 While we disagree with Japan, for the reasons given in our discussion of scientific evidence under Article 2.2, that mature apples could be internally yet not visibly infected, thus making the maturity requirement and the external control for symptoms insufficient, we cannot exclude that the inspection system put in place by the United States might, on some occasions, fail to guarantee that all exported apples are mature and symptomless. However, we note that there is no evidence that this has occurred in the past.²⁶³ In particular Japan, as the party claiming that such risk exists, did not provide evidence that this has ever happened. Japan only refers to the failure of US export controls in relation to codling moth presence in shipments to Chinese Taipei. However, we note that the Appellate Body agreed in the original case that there was no reason for the Panel to infer from the examples relating to codling moth that apples other than mature, symptomless ones had ever been exported from the United States to Japan.²⁶⁴ Finally, we note the difference between an apple infested by codling moth and an apple infected by *E. amylovora*. One will simply show a pin hole whereas the other one will be rotten or shrivelled.

8.179 We also note that Japan failed to provide sufficient scientific evidence that a contaminated apple was likely to complete the pathway and allow the establishment or spread of fire blight in Japan. In other words, even if the controls set up by the United States were to fail on a given occasion, the fact that the importation of something else than a mature, symptomless apple in a shipment destined for Japan could lead to the establishment and spread of fire blight is unlikely.²⁶⁵

8.180 Finally, we note that Japan may establish mechanisms appropriate to the circumstances and compatible with the SPS Agreement, to ensure that only mature, symptomless apples are imported into its territory.

8.181 For these reasons, we consider that the United States has demonstrated that the requirement that apples imported into Japan be mature and symptomless is an alternative measure that is reasonably available taking into account

3. "Significantly less restrictive to trade"

(a) Summary of the arguments of the parties²⁶⁶

8.182 The United States argues that a restriction of imports to mature US apple fruit would be significantly less trade-restrictive than the nine-measure import regime currently maintained by Japan. The extremely low level of US apple fruit imports to Japan and the corresponding high levels of economic risk to which US apple growers are exposed as a result of the measure at issue is evidence of its trade restrictive effect. For example, if a single fire blight strike is detected in a grower's orchard, or in the buffer zone surrounding the orchard, the grower's investment is lost as his apple fruit are no longer exportable to Japan. As a result of this risk, Japan's trade-restrictive apple fruit import regime has, over time, eliminated the incentive for US growers to attempt to export to Japan, thus protecting Japanese growers from competition.

8.183 The United States further notes that the proposed alternative measure of restricting imports to mature apple fruit is significantly less trade-restrictive. Under the proposed alternative, entire orchards would no longer be disqualified upon discovery of a single fire blight strike on a tree or in a buffer zone, and all mature apple fruit would be eligible for export to Japan. If imports were restricted to mature apple fruit, US apple growers would financially be able to compete to fill orders for export to Japan.

8.184 Japan recalls that even though the Original Panel found that "mature, symptomless" is a

spite of their desire to export apples to Japan, which seems to be at the origin of this case, US growers have not exported apples since 2002.

8.188 We conclude that the United States has demonstrated that the requirement to import only mature, symptomless apples would be "significantly less trade restrictive" than the measures at issue.

4. Achieving Japan's "appropriate level of [...] phytosanitary protection"

(a) Summary of the arguments of the parties²⁶⁷

8.189 The United States claims that, in light of the scientific evidence relating to mature apple fruit and fire blight, a measure restricting imports to mature apple fruit would achieve Japan's appropriate level of phytosanitary protection, a level of protection that would allow Japan to prevent the introduction of fire blight into Japan and maintain its fire-blight-free status.

8.190 Japan argues that its ALOP is the level of protection that provides a security level which will not compromise Japan's status as a fire blight-free country through commercial shipment of fresh apple fruit, in the absence of illicit acts. Individual travellers carrying small shipments (illegally) might pose a threat, but the risk is insignificant and inevitable. Japan's ALOP against fire blight has not changed even though the measure has been changed.

8.191 The United States argues that, as the Original Panel has found, scientific evidence does not establish that mature, symptomless apple fruit would be infected with or harbor endophytic populations of *E. amylovora*; that mature, symptomless apple fruit would be infested with epiphytic populations of *E. amylovora* capable of transmitting fire blight; or that apple fruit, regardless of its maturity, would serve as a pathway for the introduction of fire blight into Japan. Therefore, a measure requiring shipments to be mature US apple fruit would meet Japan's ALOP because mature apple fruit did not present a risk of introduction of fire blight into Japan.

8.192 Japan notes that the Original Panel's finding of completion of the pathway was made relative to the measure then in place, and should not be interpreted to imply a comprehensive denial of any risk whatsoever. Moreover, Japan's new evidence, as interpreted together with the previous evidence, signal a risk posed by apples from a (severely) blighted orchard, which might not be healthy or mature. The US proposal does not address the issues arising from permitting exportation of US apple fruit from a "(severely) blighted" orchard, or the risk of infection or sorting errors for apples from such an orchard.

(b) Analysis of the Panel

8.193 We first recall that it is for Japan to determine its ALOP, and that we should not question it. We note that Japan describes its ALOP as equivalent to the one that would result from an import ban on commercial apples. We have already addressed the question of the latent infection of mature apples and reached the conclusion that it had not been sufficiently scientifically established. Since there is no evidence that mature, symptomless apple fruit will complete the pathway for the entry, establishment or spread of fire blight into Japan, we agree that the requirement that apples be mature

there is no dispute that Japan's measures restrict imports of apples through means other than duties, taxes or other charges.

8.201 Japan argues that since the new measure is consistent with the relevant Articles of the SPS Agreement, it is presumed to be covered by Article XX(b) of GATT 1994, pursuant to Article 2.4 of the SPS Agreement.

2. Analysis of the Panel

8.202 We have found above that the measure taken by Japan to comply with the recommendations

H. OTHER CLAIMS INCLUDED IN THE REQUEST FOR THE ESTABLISHMENT OF THE PANEL

8.208 The United States request for establishment of a panel in the context of its recourse to Article 21.5 of the DSU also alleged the inconsistency of the measure at issue with Articles 2.3, 5.2, 5.3, 5.5, 6.1 and 6.2 of the SPS Agreement. Technically, these claims are part of our terms of reference. We note, however, that in order for us to make findings on these claims, the United States should have made a prima facie case for each of them. The United States did not develop any argumentation regarding these provisions in its subsequent submissions.

8.209 Under those circumstances, we refrain from making any finding regarding the consistency or not of the measure at issue with Articles 2.3, 5.2, 5.3, 5.5, 6.1 and 6.2 of the SPS Agreement.

IX. CONCLUSION

9.1 In light of the findings above, we reach the following conclusions:

- (a) Japan, by maintaining the phytosanitary measure at issue, violates Article 2.2 of the SPS Agreement not to maintain phytosanitary measures "without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5";
- (b) Japan, by reaching, in the 2004 PRA, conclusions that are not supported by the scientific evidence.