

**JAPAN – MEASURES AFFECTING
THE IMPORTATION OF APPLES**

Recourse to Article 21.5 of the DSU by the United States

Report of the Panel

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I. INTRODUCTION

1.1 On 10 December 2003, the Dispute Settlement Body ("DSB") adopted its recommendations and rulings in the dispute *Japan - Measures Affecting the Importation of Apples* (the "*Japan – Apples* Panel Report").¹ Having found Japan's phytosanitary measure for imported US apples to be inconsistent with its obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"), the DSB recommended that Japan bring its measure into conformity with that agreement. On 30 January 2004, the United States and Japan concluded an agreement pursuant to Article 21.3(b) of the Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU")² that the reasonable period of time available to Japan to implement the DSB's recommendations and rulings would expire on 30 June 2004.

1.2 On 19 July 2004, the United States requested authorization from the DSB to suspend tariff concessions and other related obligations with respect to Japan under the General Agreement on Tariffs and Trade 1994 (GATT 1994), pursuant to Article 22.2 of the DSU.³

1.3 At the meeting of the DSB held on 30 July 2004, Japan informed the DSB that it had amended its measures on 30 June 2004 to implement the DSB's recommendations and rulings within the reasonable period of time. At the same meeting, the United States requested the establishment of a panel pursuant to Article 21.5 of the DSU. The DSB agreed that the Article 21.5 request be referred to the Original Panel. The DSB also agreed, at the request of Japan, that the matter would be referred to arbitration to determine the level of suspension of concessions, pursuant to Article 22.6 of the DSU. Japan and the United States agreed that the arbitration proceedings would be suspended until after the adoption of the panel report under Article 21.5. If the Article 21.5 Panel found that Japan had acted inconsistently with its WTO obligations, then the Article 22.6 arbitrator would automatically resume its work.

1.4 Australia, Brazil, China, the European Communities, New Zealand and the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu reserved their third-party rights to participate in the Article 21.5 proceedings.

A. TERMS OF REFERENCE

1.5 The following standard terms of reference applied to the work of the Panel:

"To examine, in the light of the relevant provisions of the covered agreements cited by the United States in document WT/DS245/11, the matter referred to the DSB by the United States in that document and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in those agreements."⁴

B. PANEL COMPOSITION

1.6 The Panel was composed as follows:

Chairman: Mr Michael Cartland

¹ WT/DS/245.

² WT/DS245/9.

³ WT/DS245/12.

⁴ WT/DS245/14.

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. Infected fruit do not develop fully, turning brown to black, shrivelling, and becoming mummified, frequently remaining attached to the limb. Limbs and trunks of trees may also develop cankers, which, if disease development is severe, may result in plant death.

2.2 The most serious primary infection with fire blight is an over-wintering canker developed in the previous season. Fire blight bacteria over-winter exclusively in infected host plants. In the presence of warm, wet conditions in spring, the disease cycle begins when cankers on infected hosts exude a bacterial-laden ooze or inoculum. This inoculum is transmitted primarily through wind and/or rain and by insects or birds to open flowers on the same or new host plants. The bacteria may spread within the host plant, causing disease in blossoms and fruiting spurs, twigs, branches, or leaves.

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

2. Relevant technical and scientific terms

Abscission layer

2.4 The barrier of cells that develops across the stem at the base of a fruit as it approaches the time of falling from a plant. This specialized layer acts as the breaking point for separating the plant from its fruit.

⁵ The following description of the disease and list of defined terms has been adapted from the Original Panel report on *Japan – Apples* (WT/DS245/R).

Bioluminescence

2.5 The emission of light by living organisms.

Buffer zone

2.6 An area in which a specific pest does not occur or occurs at a low level and is officially controlled, that either encloses or is adjacent to an infested area, an infested place of production, a pest free area, a pest free place of production or a pest free production site, and in which phytosanitary measures are taken to prevent spread of the pest.

Canker

2.7 A lesion on the bark of a tree or shrub caused by infection. Fire blight cankers on limbs, stem, and trunks appear as sunken, discoloured areas that often exhibit deep cracks in the bark at the margins of the canker. A hold-over canker is one in which the pathogen may survive the winter and, if survival occurs, from which the inoculum for primary infections the following spring originate.

Desiccation

2.8 The process of becoming dried up.

Disease (of plant)

2.9 A disorder of structure or function in a plant of such a degree as to produce or threaten to produce detectable illness or disorder; a definable variety of such a disorder, usually with specific signs or symptoms.

Endophytic and epiphytic

2.10 With respect to *E. amylovora*, the term endophytic is used when the bacterium occurs inside a plant or apple fruit in a non-pathogenic relationship. The term epiphytic is used when the bacterium occurs on the outer surface of a plant or fruit in a non-pathogenic relationship.

Entry, establishment and spread (of a pest)

2.11 Entry refers to the movement of a pest into an area where it is not yet present, or present but not widely distributed and being officially controlled. Establishment means the perpetuation, for the foreseeable future, of a pest within an area after entry. Spread refers to the expansion of the geographical distribution of a pest within an area.

Infection

2.12 When an organism (e.g., *E. amylovora*) has entered into a host plant (or fruit) establishing a permanent or temporary pathogenic relationship with the host.

Infestation

2.13 Refers to the presence of the bacteria on the surface of a plant without any implication that infection has occurred.

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, GUIDELINES AND RECOMMENDATIONS

2.23 As in the Original Panel, the parties referred specifically to the International Standard for Phytosanitary Measures (ISPM) 11 on Pest Risk Analysis for Quarantine Pests, adopted in 2004.⁷ ISPM 11 describes the PRA process as consisting of three stages. Stage one involves (a) the identification of a pathway, usually an imported product, that may allow the introduction and/or spread of quarantine pests, and (b) the identification of a pest that may qualify as a quarantine pest. Stage two considers the identified pests individually and examines, for each one, whether the criteria for quarantine pest status are satisfied, that is, that the pest is of "potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled". Based on the information gathered under stages one and two, stage three determines the appropriate phytosanitary measure(s) to be adopted. The three stages are summarized in the PRA Guideline as: "initiating the process for analysing risk", "assessing pest risk" and "managing pest risk", respectively.

III. CLAIMS OF THE PARTIES

3.1 The **United States** recalled that on 10 December 2003, the DSB adopted its recommendations and rulings in the dispute *Japan – Apples* and found that Japan's phytosanitary measure on imported US apples was inconsistent with Articles 2.2 and 5.1 of the *SPS Agreement*. Two sets of conclusions about the scientific evidence had been central to these findings. First, the DSB concluded that the scientific evidence did not establish that mature, symptomless apple fruit:

⁷ *International Standard for Phytosanitary Measures No.11: Pest Risk Analysis for Quarantine Pests including Analysis of Environmental Risks and Living Modified Organisms*, FAO, Rome 2004.

- (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 this proceeding was not to consider whether potential future measures might comply with Japan's WTO obligations; it was to determine whether the measures Japan had already taken to comply were consistent with the provisions of the WTO Agreements cited in the US request for a panel.

4.2 **Japan** emphasized that the Operational Criteria had all the characteristics of a "measure" under the *SPS Agreement*. These Criteria were a "supplementary guideline" setting forth methods to implement the Detailed Rules although they did not take the form of an enforceable regulation. The Operational Criteria addressed in particular the matter of orchard inspection. These specifics of the Operational Criteria had been arranged with the United States in the form of a "Work Plan," and took the form of administrative criteria of the Japanese Government. Japan argued 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 its interpretation.

4.3 The Operational Criteria described the following procedures:

- (a) The objectives of the border zones of around 10-meter width were two-fold. First, it was designed to prevent branches of trees inside the "free area of fire blight" (as provided for by the Detailed Rules, hereinafter "orchard") from overlapping, or being in direct contact, with plants outside the orchard. The second objective was to delineate the boundary of the export orchard for which both authorities will ensure the absence of fire blight symptoms according to these criteria. The requirement would be automatically met when the orchard was surrounded by passageways, waterways or other equivalent zones of an around ten-meter width, as is normally the case. Consequently, if there were zones of the equivalent width inside one orchard at a certain location, each of the sections (blocks) surrounded by the zones would be considered an independent orchard.
- (b) No inspection of the border zone would be done as long as the border zone was not used as cultivating grounds of host plants of the disease. This requirement would also be met automatically when the orchard was surrounded by passageways or waterways.
- (c) The annual inspection by the US (including confirmation by the US and Japanese authorities) would be done only *once*, visually, by officials driving through an orchard using a buggy car, inspecting the exterior of apple trees inside the orchard.

⁸ Operational Criteria for the Exportation of US Apples to Japan (Exhibit JPN-2).

- (d) Inspection under (c) above was designed to detect only typical symptoms on large branch(es). Suspected symptoms would then be laboratory-tested before they are found positive.
- (e) When a heavily blighted tree was found, only the particular section (block) within the orchard would be disqualified, as long as the around 10-meter "border zone" (e.g., a passageway or a waterway) surrounded the section. The rest of the orchard would retain the status of a qualified export orchard and would be treated equally with other export orchards where no such tree was found.
- (f) As long as a particular growing lot was surrounded by a "border zone" of around 10 meters within an orchard, each such lot of any size would be considered an "independent orchard" or a "section" for the purpose of determination under (e) above, except for those varieties designated as "least resistant" to the fire blight disease by the USDA.⁹ Sections for these varieties would have to be surrounded by either a passageway, a waterway, a cliff or other natural barriers of around ten meters in width.

4.4 The Detailed Rules had been formulated according to the Japanese administrative law practice. The Japanese laws and regulations stipulated a general regulative mechanism, and government authorities stipulated rules, guidelines and directives within their mandate. In this respect, the Japanese laws and regulations were as consistent with the WTO Agreements, as those of the United States, or of any other Member, which contained similar generic provisions.

4.5 The **United States** argued that since the Criteria was not currently in effect, it had not been "taken" by the time of the establishment of the Panel and so could not be within the Panel's terms of reference.

4.6 **Japan** claimed that the Operational Criteria was a specific irrevocable offer and noted that if the United States consented to these criteria Japan would be obliged to implement them. Japan argued that the Operational Criteria was therefore a "draft measure" already offered to the United States, and had therefore been "taken". Japan noted that a mere possibility of inconsistency with the WTO Agreements of a measure did not make a *prima facie* case under the DSU; the "nullification and impairment" requirement could not be presumed without the presence of violation.¹⁰ If the government authorities in charge of the matter expressed their intent to implement the measure only in a manner consistent with the Agreements, the measure would be presumed to be consistent with them. In this case, as noted above, Japan had irrevocably expressed its intent to follow the Operational Criteria in relation to implementing the Detailed Rules.

4.7 The **United States** noted that the Operational Criteria were not among the "measures taken to comply with the recommendations and rulings" which Japan notified to the WTO, nor had Japan referred to them in its 29 July request for arbitration under Article 22.6 of the DSU nor in its 30 July statement to the DSB. Although Japan indicated that it had intended to discuss and agree to the Criteria with the United States, the United States had first learned of the Operational Criteria when it received Japan's first submission.

4.8 **Japan** responded that Operational Criteria were a supplementary guideline, not an independent legal instrument. Although the precise wording, documentation and dissemination of the Operational Criteria were completed as of the date of signature by the Director on 13 September 2004,

⁹ van der Zwet & Beer (1999). Disease cycle-Fire blight – Its nature, prevention and control. the US Government Printing Office, Washington D.C., at. 41.

¹⁰ DSU, Article 3.8.

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.

2. Scientific Experts

4.10 The **United States** argued that experts need not be consulted in this proceeding because the science relating to fire blight and apple fruit had not amended, clarified or altered the scientific evidence at issue in this dispute since it had been evaluated by the Original Panel. The United States claimed that Japan's four new studies relating to apple fruit and fire blight had failed to introduce any new scientific evidence relating to either fire blight disease or to mature, symptomless apple fruit exported from the United States.

4.11 **Japan** countered that Azegami *et al.* (2005) and Tsukamoto *et al.* (2005a) had presented a new discovery relating to a possible infection route, and Tsukamoto *et al.* (2005b) had demonstrated, under favorable ecological conditions, that the pathway for transmission of fire blight would be completed. The work of Kimura *et al.* (2005) had offered a fresh estimate of the probability of introduction and establishment of the disease in Japan.

4.12 The **United States** argued that if the Panel were to decide to consult experts in this proceeding, any such consultation should be limited to an evaluation of Japan's new studies rather than a re-evaluation of science previously reviewed. The United States noted that Japan's argument hinged entirely on this new "science" rather than on the extensive scientific record and the Original Panel's findings on that evidence

4.13 **Japan** noted that the revised PRA had taken into account evidence which had been available before the Original Panel, as well as the new pieces of evidence. Japan argued that the Panel must examine whether the evidence available at the time of the Original Panel as well as the new scientific evidence had a rational relationship with the new measure taken by Japan.

B. THE MEASURE (OR MEASURES) AT ISSUE

4.14 **Japan** stated that Japanese law and other Ministerial regulations delegated authority to the Director-General of the Ministry of Agriculture, Forestry and Fisheries (MAFF) in charge of food safety and consumer affairs to create phytosanitary rules which would apply to apples from the United States. In response to the recommendations and rulings of the DSB, the Director-General had modified the Detailed Rules, and, through the Director of the Plant Protection Division, had established the Operational Criteria. Modifications of other laws and regulations had not been necessary since the parties' disagreement focused on the Detailed Rules and the Operational Criteria.

4.15 Japan presented its revised measure as consisting of six elements: (a) designation of an export orchard; (b) a ten-meter border zone surrounding the orchard; (c) one annual inspection of the orchard and the border zone; (d) surface sterilization of fruit; (e) sterilization of packing facilities; and (f) sampling and export/import inspection.

4.16 The **United States** noted that Japan's original, WTO-inconsistent measure consisted of ten elements. The United States noted that the only element that had been entirely eliminated from Japan's import regime was the requirement that packing materials be sterilized, thereby leaving nine

of the ten elements of the original measure in place. The United States also noted that Japan's assessment of the number of elements of the measure at issue in this proceeding was inconsistent with the actual amendments it had made to its import regime for US apple fruit.

4.17 The United States noted that Japan had failed to include the requirement that apple fruit destined for Japan be segregated from other fruit post-harvest in its description of the elements included in its measure. The United States observed that by failing to address post-harvest separation of apple fruit in its submission, Japan had failed to rebut the *prima facie* case raised by the United States that the post-harvest separation requirement was maintained without sufficient scientific evidence for purposes of Article 2.2.

4.18 **Japan** argued that the United States had not made a case against the separation requirement, other than in relation to the disinfestation treatment. The separation requirement still applied, although it was not specific to fire blight but a natural extension of the other control requirements (i.e., the orchard requirement and the border zone requirement against fire blight and the fumigation requirement against codling moth).

4.19 The **United States** observed that Japan still maintained the requirement that a US Official certify that the apple fruit had been treated post-harvest with chlorine, and that Japanese officials must confirm that US official certification and inspect packing facilities.

4.20 **Japan** maintained that these requirements were normal administrative procedures and did not impose any additional restrictions on US apple exports.

C. ARTICLE 2.2

1. **General – Four new studies**

4.21 In its first submission, the **United States** claimed that it was unaware of any scientific evidence regarding apple fruit and fire blight that altered the evidence examined by the Panel two years previously, or the conclusions drawn from that evidence. As before, the scientific evidence did not establish that mature, symptomless apple fruit would either be infected with or harbor endophytic populations of *E. amylovora*, nor did it establish that mature, symptomless apple fruit would be epiphytically infested with populations of *E. amylovora* bacteria capable of transmitting fire blight.¹¹ Further, the scientific evidence did not establish that apple fruit would serve as a pathway for introduction of fire blight into Japan.¹² To the contrary, while the United States had shipped approximately 53.5 billion apples world-wide over the last 37 years, there was no evidence of apple fruit having introduced fire blight into a fire blight-free area.¹³ Japan's revised measures were maintained without sufficient scientific evidence in breach of Article 2.2.¹⁴

4.22 In its first submission **Japan** introduced four recently completed studies. The first study by Azegami *et al.* (2005) had been commissioned in March 2003, initiated 7 August, 2003 and completed 6 November, 2003.¹⁵ The Journal of General Plant Pathology had accepted this study on 11 August, 2004. The publication schedule had been changed from vol. 71, No.1, February 2005 to vol. 70, No.6, December 2004.

¹¹ Panel Report on *Japan – Apples*, paras. 8.136, and 8.171.

¹² Panel Report on *Japan – Apples*, paras. 8.168, 8.171, and 8.176.

¹³ 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 in the Original Panel.

¹⁴ Panel Report on *Japan – Apples*, paras. 8.136, 8.168, 8.171, and 8.176.

¹⁵ Azegami *et al.* (2005). Invasion and colonization of mature apple fruit by *E. amylovora* tagged with bioluminescence genes, J. Gen. Plant Pathol. (In press) (Exhibits JPN-6).

4.23 According to Japan the purpose of the Azegami study was to examine the existing belief that mature apples were immune from infection. Contrary to the traditional view which focused on the route through the calyx to the core,¹⁶ Azegami *et al.* (2005) had found that mature, symptomless apple fruit developed undetectable internal infection by the bacteria when inoculated with 10^4 cfu or 10^5 cfu of *E. amylovora* at pedicels and wounds. The bacteria spread and colonized along vascular bundles a few days after inoculation.

4.24 The second study submitted by Japan, Tsukamoto *et al.* (2005a), had been commissioned in March 2003, initiated 7 August 2003, and completed on 31 May 2004.¹⁷ This study had been received by the Journal of General Plant Pathology on 23 August 2004 and was in the process of a second peer review.

4.25 According to Japan, the Tsukamoto *et al.* (2005a) study examined the status of 142 apple fruit infected through inoculation and held in storage at five degrees Celsius. All but two of the 142 infected fruit had been still infected after one month of storage. Moreover, since the bacteria had been found to survive in a latent state over six months, survivability of the bacteria in mature apple fruit during cold storage and shipment had been conclusively established.

4.26 The third study submitted by Japan, Tsukamoto *et al.* (2005b), had been commissioned in March 2004, initiated 10 March 2004, and completed 31 May 2004.¹⁸ The Research Bulletin of the Plant Protection Service of Japan had accepted this study for publication on 21 October 2004.

4.27 According to Japan, in this laboratory study Japanese scientists had sought to find scientific evidence of spread of the disease from the apple fruit. They had found that (i) normal flies fed on apple fruit infected by fire blight bacteria and were later found to be contaminated by the bacteria, and that (ii) flies contaminated by the bacterial suspension were able to cause fire blight on young pear fruit and shoots through surface wounds.

4.28 The final study submitted by Japan, Kimura *et al.* (2005), had been commissioned in May 2004 and was composed of an overall review of the previous three studies rather than laboratory experiments. The Journal of General Plant Pathology had received this study on 8 September 2004 and it was currently undergoing its first peer review.¹⁹

4.29 The **United States** claimed that the four new studies contained no new scientific evidence. At best they repeated 50-year old results achieved under artificial conditions in Anderson *et al.*

¹⁶ Dueck (1974). Survival of *E. amylovora* in association with mature apple fruit, Can. J. Plant Sci. 54; Roberts *et al.* (1989). Evaluation of mature apple fruit from Washington State for the presence of *E. amylovora*, Plant Disease 73: 917-921; Roberts (2002). Evaluation of buffer zone size and inspection number reduction on phytosanitary risk associated with fire blight and export of mature apple fruit, Acta Horticulture (Exhibit USA-9). See also Hale *et al.* (1987). Occurrence of *E. amylovora* on Apple Fruit in New Zealand, Acta Horticulturæ 217: 33-38 (Exhibit JPN-7).

¹⁷ Tsukamoto *et al.* (2005a). Infection frequency of mature apple fruit with *E. amylovora* deposited on pedicel and its survival in the fruit stored at low temperature, J. Gen. Plant Pathol. (forthcoming 2005) (Exhibit JPN-8).

¹⁸ Tsukamoto *et al.* (2005b). Transmission of *E. amylovora* from blighted mature apple fruit to host plants via flies, Res Bull. Plant Protection Service Japan 41 (forthcoming 2005) (Exhibit JPN-9).

¹⁹ Kimura *et al.* (2005). The probability of long-distance dissemination of bacterial diseases via fruit, J. Gen. Plant Pathol. (forthcoming 2005) (Exhibit JPN-10).

(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 the findings and conclusions regarding "mature, symptomless" apple fruit of the Original Panel, in this proceeding the fundamental factual claim the United States should have made was that the US apple fruit *as produced and processed under the current US practice* would indeed be "mature, symptomless." In the absence of such evidence, the United States had neither established a *prima facie* case of violation of the SPS Agreement, nor proven the presence of nullification or impairment of its interests.

²⁰ Anderson, H.W., "Maintaining Virulent Cultures of *Erwinia amylovora* and Suggestion of Overwinter Survival in Mummied Fruit", Plant Disease Reporter, Vol. 36, No. 7 (July 15, 1952) (Exhibit USA-18).

(a) Mature, symptomless apples

4.34 The **United States** noted that in making its findings the Original Panel had analyzed the scientific evidence relating to apple fruit and fire blight. Its analysis was based in part on the written and oral statements of scientific experts on the scientific evidence on fire blight and apple fruit. The scientific experts had concluded that: there was no scientific evidence that mature apple fruit harbor endophytic populations of fire blight bacteria²¹ or that *E. amylovora* occurred as an endophyte in healthy-looking fruit;²² scientific evidence did not establish that a mature apple fruit could be infected with fire blight;²³ scientific evidence demonstrated that even apple fruit that were harvested very close to sources of inoculum were not infested with significant populations of epiphytic bacteria;²⁴ there was no scientific evidence that, in the rare event that a mature fruit was infested with bacteria in the calyx that the inside of the apple fruit would subsequently be infected;²⁵ there was no scientific evidence that calyx-infested apple fruit would transmit fire blight;²⁶ there was no scientific evidence that mature apple fruit had ever been the means of introduction of fire blight into an area free of the disease;²⁷ and the scientific evidence did not establish that any pathway for introduction of fire blight via apple fruit, whether mature or immature, would be completed.²⁸

4.35 **Japan** claimed that the new evidence, which had not been available at the time of the Original Panel, demonstrated that the probability of infection of mature apples was higher than expected, because mature apple fruit were not physiologically immune from infection through the pedicels. The probability of latent infection of mature apple fruit would depend on the physiological conditions and activities of the bacteria from August to the end of the maturing process. According to the evidence available, the physiological activity of the bacteria inside the trees did not appear to be declining during this season. For example, Norelli *et al.* (2001) had reported that the inoculation of scions in May resulted in recovery of the bacteria on 30 August from the internal tissue of the rootstock, suggesting the bacterial activity was still recognizable during the late growing season.²⁹ This could have explained recovery of *E. amylovora* from inside Utah apple fruit on 27 September.

4.36 The **United States** argued that Norelli *et al.* does not report the results relied on by Japan, and that the Norelli study simply does not stand for or support the notion that *E. amylovora* is moving about within the tree all year long. In fact, according to the United States, it is so well known that fire blight activity slows down as the summer progresses that it is difficult to find literature to specifically document the phenomenon. Primarily during discussions of the disease cycle, the authors mention,

²¹ Panel Report on *Japan – Apples*, para. 8.125; Panel Report on *Japan – Apples*, Transcript, Annex 3, paras. 28, 29 (Dr Hale), 54 (Dr Smith), 57 (Dr Geider), 59 (Dr Hale), 63 (Dr Geider), 75, 76 (Dr Hayward), 80 (Dr Geider), 82 (Dr Hale), and 360-363 (Drs Geider, Hale, Hayward, and Smith).

²² Panel Report on *Japan – Apples*, para. 8.126; Panel Report on *Japan – Apples*, Transcript, Annex 3, paras. 59 (Dr Hale), 76 (Dr Hayward), and 82 (Dr Hale).

²³ Panel Report on *Japan – Apples*, paras. 8.138-8.139, and 8.171.

²⁴ Panel Report on *Japan – Apples*, Transcript Annex 3, paras. 223-236 (Drs Hale, Geider, Smith, and Hayward).

²⁵ Panel Report on *Japan – Apples*, para. 8.117; Panel Report on *Japan – Apples*, Transcript Annex 3, paras. 364-367 (Drs Geider, Hale, Hayward).

²⁶ Panel Report on *Japan – Apples*, para. 8.147.

²⁷ Panel Report on *Japan – Apples*, Transcript, Annex 3, paras. 382-385 (Drs Geider, Hale, and Hayward), 332 (Dr Hayward); Panel Report on *Japan – Apples*, paras. 6.20-6.23, 6.31, and 6.37-6.40. The Original Panel noted that the experts "categorically stated that there was no evidence to suggest that mature apples had ever been the means of introduction (entry, establishment and spread) of fire blight into an area free of the disease." Panel Report on *Japan – Apples*, para. 8.149. Further, the Panel points out, as noted by Dr Smith, that "not only was there no evidence that fruits had ever introduced fire blight into an area, but there was no necessity to invoke such an improbable pathway since there were much more probable alternatives." Panel Report on *Japan – Apples*, para. 8.149, citing para. 6.31.

²⁸ Panel Report on *Japan – Apples*, paras. 8.149, 8.166, 8.168, 8.171, and 8.176.

²⁹ Norelli *et al.* (2000). Fire blight of apple rootstocks, *New York Fruit Quarterly* 8:1-5.

e.g., that "[r]enewal 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 Appellate Body, highlighting the difficulty of detecting every infection only from apparent symptoms in apple fruits, supported Japan's position that controls were necessary at the orchard level to address potential detection errors.

Azegami *et al.* (2005)

4.38 According to the **United States**, the fundamental flaw of the Azegami paper was its assertion that the results of the experiment demonstrated that *E. amylovora* would invade and colonize mature apple fruit. The Azegami study instead demonstrated that inoculation of (a) fruit pedicels that were cut more than four days after harvest, or (b) fruit-bearing twigs with mature fruit still attached, and therefore having uninjured fruit pedicels, *did not result in the movement of E. amylovora* into the stems or fruit cortex of mature apples. *Only by removing the abscission layer* from the end of fruit pedicels situated at the furthest point from the apple fruit and *then placing high levels of inoculum on the cut end* of the pedicel were the researchers able to demonstrate bioluminescence, and therefore the presence of the marked strain of *E. amylovora*, within the stem and fruit. The United States concluded that the Azegami study appeared to confirm that it was only under the experimental conditions of the study that *E. amylovora* bacteria could be isolated inside apple fruit.

4.39 **Japan** noted that Azegami *et al.* and the Tsukamoto *et al.* (2005a) studies did not use high levels of inoculum but showed infection with the bacteria at the level of 10^4 or 10^5 cfu. In addition, this was the level generally believed to be sufficient to infect pear flowers, least resistant hosts of the bacteria.

4.40 The **United States** explained that the abscission layer acted as a natural barrier to desiccation and invasion of the fruit by micro-organisms. The effectiveness of the abscission layer as a barrier had been demonstrated in the "Results and Discussion" sections of the Azegami paper, where it had been reported that, for the 60 fruit still attached to the (wound inoculated) fruiting spurs, "a luminous area was observed on the abscission layer of one fruit eight days after inoculation but not on any fruit" and that "pathogen progress stopped at this layer in the experiment." The United States concluded from these results that, because the apple fruit had been mature with intact abscission layers, the abscission zone had acted as a physical barrier to the movement of *E. amylovora* into the apple fruit. The Azegami paper's conclusion that "the possibility that the pathogen may pass through the layer cannot be excluded," was contradicted by the study's own data.

4.41 **Japan** explained that Azegami *et al.* (2005) showed that the water passed through vascular tissue and that this potential infection route would remain active until the formation of the abscission layer. Noting that the crucial issue therefore was the timing of formation of the layer, Japan referred

³⁰ van der Zwet, T. and Beer, S.V., Fire Blight – Its Nature, Prevention, and Control: A Practical Guide to Integrated Disease Management, USDA, Agriculture Information Bulletin No. 631. (Emphasis added).

³¹ Appellate Body Report on *Japan – Apples* (WT/DS245/AB/R), para. 160. This risk was found "legitimate" by the Original Panel.

to studies which showed that the abscission layer was formed and completed toward the final stage of ripening of apple fruit and that the vascular tissue would remain an active conduit for introduction of the bacteria into apple fruit until the very late stage.³² Japanese scientists conducted a further study on this matter, and demonstrated that fire blight bacteria can infect apple fruit latently from fruit bearing twig through abscission layer at the time of fruit maturation.³³

4.42 Japan also contended that contrary to the assertion of the United States, the activity of the bioluminescence genes inserted into *E. amylovora* had been observed inside the apple fruit after inoculation through the pedicels in this study. Since the bioluminescence genes were known to be active during the stage of logarithmic reproduction of the bacteria, this observation showed that the bacteria were actively reproducing in their colonies.

4.43 The **United States** noted that the Azegami paper purported to demonstrate the "invasion" of fire blight bacteria into the fruit. However Azegami had successfully introduced fire blight bacteria into the apple fruit through the pedicel only when the pedicel and its abscission layer were severed and a suspension of bacteria placed on the wound. US researchers had conducted an experiment demonstrating that transpiration (rather than active invasion) could cause a suspension applied to the severed pedicel to be sucked into the apple fruit. US researchers placed an inert dye (Methyl blue) on the cut pedicel of a mature apple fruit. While this non-living dye was incapable of "invading" an apple fruit, the dye, like the bioluminescence in Azegami *et al.* (2005), had entered the fruit and had spread into the vascular bundles. This result could only have been attributable to the dye being drawn into the fruit through transpiration, demonstrating that spread of either bioluminescence or dye into apple fruit was as likely a consequence of the cut-pedicel method and transpiration as a result of active colonization and invasion by bacteria.

4.44 **Japan** described the US dye study as an example of an additional route for fire blight passage into mature apple fruit, distinct from that observed in Azegami. Japan emphasized that Azegami *et al.* (2005) showed isolation of a far higher number of bacteria colonies from the apple fruit infected by this method and thus multiplication of the bacteria (infection).³⁴

Tsukamoto *et al.* (2005a)

4.45 The **United States** commented that like the Azegami *et al.* study, the Tsukamoto *et al.* (2005a) study had employed the cut-pedicel method to inoculate apple fruit. Although it cited Azegami *et al.* in support of its findings and conclusions, Tsukamoto *et al.* (2005a) made repeated reference to the inoculum being deposited on the fruit pedicel in the Azegami study *without referencing the fact that the abscission layer of the pedicel had been artificially removed*. The United States argued that the conclusion of Tsukamoto *et al.* (2005a) that "[t]his investigation showed that *E. amylovora* can infect mature apple fruit from pedicels and can survive more than six months at 5 degrees Celsius" was a misstatement.

4.46 **Japan** claimed that results from the Tsukamoto *et al.* (2005a) study showed that bacteria had the ability to survive the period of a few months under cold conditions, which corresponded to the

³² Takishita *et al.* (1992). Effect of 2, 4-DP on the formation of the abscission layer in mature apple pedicel. Bull. Fruit Tree Res. Stn. 23: 111-121 (in Japanese). Lang (1990). Xylem, phloem and transpiration flows in developing apple fruits, J. Experimental Botany 41: 645-651. Lang & Ryan (1994). Vascular development and sap flow in apple pedicels, Ann. Botany 74: 381-388. Oberly (1973). Effect of 2,3,5-triiodobenzoic acid on bitter pit and calcium accumulation in 'Northern Spy' apples, J. Amer. Soc. Hort. Sci. 98: 269-271.

³³ Azegami *et al.* (2004). Entry of *Erwinia amylovora* into apple fruit from fruit-bearing twig through abscission layer at the time of fruit maturation. Personal Communication (Exhibit JPN-16).

³⁴ The level is 3.5×10^7 to 6.3×10^8 cfu per 1 cubic centimeter of apple fruit. And 1.1×10^5 to 5.8×10^8 cfu per 1 cubic centimeter of apple fruit.

period and temperature conditions of US apple fruit during handling, cold storage and shipment to Japan.

4.47 The **United States** countered that in Tsukamoto *et al.* (2005a), the artificially inoculated fruit had been held under conditions of high relative humidity (in enclosed steel or plastic boxes) for nine days at 25 degrees Celsius before being placed under refrigeration at 5 degrees Celsius. It had long been recognized that a delay in cooling of this magnitude would have a severely deleterious effect on the quality and storability of commercial apple fruit.³⁵ The United States argued that the results of Tsukamoto *et al.* (2005a) could not be presumed to predict what would happen under commercial conditions because:

- (a) Commercial apple fruit were not wounded and artificially inoculated after harvest.
- (b) Commercial apple fruit were cooled to storage temperature (-1 to 4 degrees Celsius, but more fruit were stored at 0 to 2 degrees Celsius) as quickly as possible, with nearly all of the apple fruit being placed into refrigerated storage within 24 hours of harvest. In other words, they were not subjected to the nine-day incubation period as was the case with the apple fruit in Tsukamoto *et al.* (2005a).
- (c) Development of fire blight disease in mature, symptomless apple fruit was not known to exist.
- (d) Multiple scientific papers had reported the absence of *E. amylovora* inside thousands of mature, symptomless apple fruit harvested from or adjacent to severely blighted trees, indicating that the phenomenon of infection through the pedicel described in Azegami *et al.* and Tsukamoto *et al.* (2005a) was an artifact of laboratory experimentation.³⁶

4.48 **Japan** stated that Azegami *et al.* (2005) and Tsukamoto *et al.* (2005a) did not necessarily contradict the results of Roberts (2002), which had not isolated any bacteria from 100 apple fruit harvested from the blighted trees.³⁷ The results of the Roberts (2002) study showed that even apples harvested from blighted trees did not necessarily show bacteria inside their core. However, according to Japan, Roberts (2002) had not investigated the stem of apples, the likely part of infection when bacteria enter through the pedicels. Moreover, since the study had focused on mature, symptomless apple fruit, it had assumed that infection from surface wounds, a risk which would be more significant in a blighted orchard, would be detected.

4.49 The **United States** countered that, contrary to Japan's argument, several previous studies, including Roberts (2002), had in fact analyzed the stems, calyx tissues and cortex (flesh) tissues of mature apple fruit. Indeed, the Dueck and Roberts studies explicitly note that these tissues were analyzed.

³⁵ Hardenberg, R.E. *et al.* (1986), The Commercial Storage of Fruits, Vegetables and Florist and Nursery Stocks, Agriculture Handbook No. 66, United States Department of Agriculture.

³⁶ Roberts, 1989, 2000; Dueck, 1974.

³⁷ 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) (Exhibit USA-9).

(b) Pathway for transmission of the disease

Tsukamoto *et al.* (2005b)

4.50 **Japan** recalled that the Original Panel had concluded, on the basis of the evidence before it at the time, that it had not been established with sufficient scientific evidence that the last stage of the pathway (i.e. the transmission of fire blight to a host plant) would likely be completed (see paragraph 4.7). However Tsukamoto *et al.* (2005b) had demonstrated that the completion of the pathway in Japan was more likely than thought at the time of the Original Panel. In the context of this experiment, "mechanical injuries" of pear fruit represented normal scars or bruises resulting from accidental damages possibly through being hit or touched by twigs or branches.

4.51 The **United States** responded that the Tsukamoto *et al.* (2005b) paper had not demonstrated that: (1) greenbottle flies had acquired cells of *E. amylovora* from infected fruit of their own volition, i.e., that they had acquired bacteria when not artificially forced to associate with infected apple fruit; (2) the flies directly or indirectly vectored *E. amylovora* from the infected fruit to the susceptible host material; or (3) infection and disease development had been a result of a natural interaction between the flies and the host material (i.e., feeding injury), and had not been dependent on artificial mechanical injury. The methods employed in the study were so far removed from what might actually take place under production orchard conditions that the resulting data was not useful in assessing the risk of transmission of fire blight or determining a probabilistic estimate of a real world event.

4.52 **Japan** countered that three elements of the Tsukamoto *et al.* (2005b) experiment methodology captured natural ecological conditions. First, flies endemic to Japan were known vectors of fire blight disease.³⁸ Second, Japanese pear fruit, which were highly susceptible to *E. amylovora*, were cultivated in pergola training systems for commercial purposes and thus were realistically representative of Japanese host plants. Moreover, the timing of apple fruit importation/consumption and that of pear fruit growth coincided: US apple fruit were imported and distributed from January to July, while Japanese pears were either at the blossom stage, fruitlet stage or shoot stage during April to July. Japan argued that it was plausible to assume that a certain percentage of these fruits would be damaged during the growth phase, exposing the fruit juice which would attract flies. The choice of wounded pear fruits as the host plant thus reflected plausible ecological conditions prevailing in Japan. Finally, the level of contamination of flies by the bacteria in the second phase of the experiment was approximately equal to the level observed in insects found in blighted orchards in natural conditions.³⁹

4.53 Japan further commented that the major discoveries of this study were that (i) flies had easily fed on infected apple fruit and were subsequently contaminated by the bacteria at the level of 7.6×10^1 to 8.3×10^2 cfu, a level high enough for suitable host plants to be infected, and that (ii) contaminated flies had fed on suitable host fruit and left a sufficient number of bacteria to infect the new host. With these two discoveries, it was logical to conclude that the combination of (i) infected apple fruit, (ii) flies and (iii) suitable host plants posed a *risk* of completion of a pathway of the disease into Japan. In order to argue otherwise, Japan claimed, the United States would need to demonstrate that there was a methodological error in the experiment.

³⁸ Thomson (1992). Fire blight of apple and pear, in "Plant diseases of international importance, Diseases of fruit crops", vol. 3 (Kumar *et al.* ed), Thomson (2000). Epidemiology of fire blight, in Fire blight: The disease and its causative agents, *Erwinia amylovora* (Vanneste, ed.). In Tsukamoto *et al.* (2005b), 5.0×10^1 to 5.5×10^2 cfu (2.6×10^2 cfu on the average) of fire blight bacteria were recovered from flies using M-MS Plates, and the colony formation unit on flies is estimated to be 7.6×10^1 to 8.3×10^2 cfu (3.9×10^2 cfu on the average).

³⁹ Miller & Schroth (1972). Monitoring the epiphytic population of *Erwinia amylovora* on pear with a selective medium, *Phytopathology* 62: 1175-1182.

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 did not penetrate the pedicels of mature apple fruit.

4.58 **Japan** countered that the United States' central critique of Kimura *et al.* (2005) rested on its reliance on Azegami *et al.* (2005) and Tsukamoto *et al.* (2005a, b). As these studies were sound, contrary to the United States' critique, Kimura's conclusions remained valid to the extent they relied on these pieces of new evidence. For example, the United States argued, "[t]he Azegami study appears to demonstrate just the opposite by noting that bioluminescence did not penetrate the pedicels of mature apple fruit."⁴¹ On the contrary, the bioluminescence genes were observed to be active inside the apple tissue in this study. The genes were active during the stage of logarithmic reproduction, and this observation showed that the bacteria were actively reproducing inside the apple tissue. Similarly, the abscission layer was known to be formed and completed toward the final stage of ripening of apple fruit and the vascular tissue would remain an active conduit for introduction of the bacteria into apple fruit until the very late stage.

⁴⁰ van der Zwet & Keil (1979), Miller & Shroth (1972), Thomson (1992, 2000).

⁴¹ US Second Written Submission, para. 26.

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* did not move into mature apple fruit if the abscission layer of the pedicel had been left intact, unequivocally supported the results from Roberts *et al.* (1989), that *E. amylovora* were not present in mature apple fruit even when harvested from branches or fruiting spurs with fire blight disease.

4.61 **Japan** argued that Kimura *et al.* (2005) suggested an alternative explanation of the absence of the bacteria in the core of 1,555 apples in Roberts *et al.* (1989) – the bacterial introduction to apple fruit could be through pedicels, vascular tissue and cortex (flesh), rather than through calyx to the core. While Roberts *et al.* (1989) had probably studied part of cortex, its methodology had clearly not been designed to evaluate the potential introduction of bacteria from pedicels. There was no way to tell whether or not the bacteria were indeed not present inside the entire apple tissue. However, Japan argued, to make that assertion without evidence did not add any scientific weight to the US argument. Indeed, Kimura *et al.*, using the results from Tsukamoto *et al.* (2005b), had found that the quantitative risk of transmission of the disease by apple fruit was not insignificant.

4.62 The **United States** noted that Japan acknowledged that *E. amylovora* would not be isolated in the cores of mature, symptomless apple fruit, but rather in vascular bundles, or "flesh". At the same time, the Kimura study argued that the pathway for introduction of fire blight would consist of either discarded apple cores or apple peels because Japanese consumers consume the flesh (cortex) of the apple fruit, thus contradicting its own findings.

4.63 **Japan** contended that the conclusion of Kimura *et al.* (2005) did not contradict its findings. Both Azegami *et al.* (2005) and Tsukamoto *et al.* (2005a) showed a presence of the bacteria along the internal surface of apple fruit.⁴² It was customary in Japan to peel and eat apple fruit and discard the peel and the core as garbage, leaving the inoculum for the environment to feed on. Tsukamoto *et al.* (2005b) discussed the later stage of introduction and establishment in suitable hosts, with flies a possible vector, successfully demonstrating that, under plausible ecological conditions, the pathway would be completed.

4.64 The **United States** also claimed that Kimura *et al.* mischaracterized the results of Tsukamoto *et al.* (2005b) by stating that greenbottle flies "gathered" to blighted fruit. Rather, according to the methodology described in Tsukamoto *et al.* (2005b), flies had been imprisoned with blighted fruit inside a small enclosure, and were not allowed to forage freely. Kimura *et al.* further mischaracterized the Tsukamoto *et al.* (2005b) study by noting that the greenbottle flies "feasted" on infected apple fruit and then flew to pear fruitlets. Instead, greenbottle flies had been sedated and immersed in a suspension of inoculum before being exposed to wounded pear fruitlets in a small, enclosed space. Moreover, the flies that were trapped in an enclosed space with infected fruit had not transferred bacteria to host tissue.

⁴² Azegami *et al.* (2005) figure 1. (Exhibit JPN-6); Tsukamoto *et al.* (2005a) (Exhibit JPN-8).

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 item. The United States further commented that the Kimura study proposed a probability estimate for introduction of fire blight into Japan via apple fruit that was almost four times greater than the risk posed through importation of infected nursery stock (historically recognized as a potential pathway for the disease). Kimura *et al.* estimated the risk of nursery/root stock introducing fire blight into Japan at once every 1,898 years, once every 1,781 years in scions or buds, and "once every 565 years or so in fruit." Not only did this probability estimate attempt to demonstrate that apple fruit presented approximately four times the risk of introducing fire blight as nursery stock, it contradicted the study's own conclusion that "[a]ccording to our estimation of probabilities of establishment of fire blight, the descending order of magnitude is as follows. Nursery stock and/or rootstocks > Scions and/or buds > Fruit." The United States questioned also the assumed infection rate of imported apple fruit (100 per cent) and the assumed number of apple cores discarded out of doors by Japanese consumers.

4.66 **Japan** countered that the study had not assumed that "10 per cent of the total household garbage in Japan that was thrown out of doors consists of apple cores." The percentage used in the multiplicative model represented the parametric assumption that 10 per cent of the total households' garbage disposed of by households would be thrown away outdoors. The scenarios of Kimura *et al.* corresponded to the ones assumed by Roberts *et al.* (1998). In Kimura *et al.*, the risk of establishment of fire blight in Japan by apple fruit was once every 1,898 years or so in Scenario 1 (when the export orchard was surrounded by a 500-meter buffer zone; orchard inspections were conducted three times per a year, namely at the blossom season, the fruitlet season and the harvest season; and the chlorine treatment of fruit surface was conducted), once every 1,781 years or so in Scenario 2 (when no buffer zone was established; and one orchard inspection was conducted per year at the harvest season, and the fire blight strikes might occur on 1 per cent or less of the trees in the orchard, but apples from infected or adjacent trees could not be exported), and once every 565 years or so in Scenario 3 (no phytosanitary requirement implemented for *Erwinia amylovora*).

4.67 In addition, Japan claimed, Tsukamoto *et al.* (2005b) and Kimura *et al.* (2005) showed that completion of the pathway by flies was not a theoretical risk but a real one. The vector was capable of carrying a significant amount of bacteria to Japanese pears, a host which is widespread in urban areas, and the arrival and distribution of US apple fruit coincided with the flowering or fruitlet seasons of these hosts. Notably, the process of infection from infected apple fruit to Japanese host plants was the only part of the pathways, for which the Original Panel found that Japan's evidence was not sufficient to counter the argument of the United States. Japan argued it was the United States' responsibility to establish, with further evidence, that the pathway would nevertheless not be completed.

2. Scientific evidence and the components of Japan's measure

4.68 The **United States** claimed that in light of the scientific evidence and the DSB findings based on that evidence, it was clear that Japan's current measures on imported US apple fruit, whether considered cumulatively or singly, were maintained without any scientific evidence, let alone sufficient scientific evidence. Those findings indicated that the scientific evidence does not establish that mature, symptomless apple fruit, the commodity exported by the United States, would be infected by or harbour endophytic populations of fire blight bacteria, or infested with epiphytic populations of fire blight capable of transmitting the disease. Further, each of Japan's measures was premised on the unscientific, hypothetical scenario that a pathway for introduction of fire blight via apple fruit imported from the United States could be completed.

4.69 **Japan** noted that despite the strong rhetoric in the US submissions, the practical gap was not as large as it appeared. In this context, Japan requested that, should the Panel find any part of the new

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 United States Department of Agriculture upon application by the orchard owner. Currently, the designation is accepted only for orchards in the states of Washington and Oregon

4.70 The **United States** argued that the scientific evidence relating to fire blight and apple fruit did not establish that mature, symptomless fruit would be infected with, harbor endophytically, or be epiphytically-infested with populations of *E. amylovora* capable of transmitting fire blight. The same evidence did not establish that apple fruit would act as a pathway for introduction of fire blight. In fact, there was no scientific evidence that even fruit from a tree infected with fire blight posed a risk of transmission of fire blight if the fruit was mature (and therefore symptomless).⁴³ Therefore, the United States concluded, there was no rational relationship between the scientific evidence and Japan's requirement that apples be sourced from fire blight-free orchards. Accordingly, Japan's measure requiring fire blight-freedom in export orchards was maintained without sufficient scientific evidence within the meaning of Article 2.2.

4.71 The United States noted that Japan had attempted to include in its revised measures certain Operational Criteria which ostensibly amended Japan's "fire blight-free orchard" requirement to one of disqualification of an export orchard if a severely blighted tree was identified in a visual inspection. While the United States stressed that the Operational Criteria were not a part of the measure properly before the Panel in this proceeding (as described above), the Operational Criteria did not change the analysis of Japan's measure, because the inspection requirement set out by the Criteria essentially became a requirement of a fire blight-free orchard.

4.72 The United States emphasized that the same scientific evidence that did not support a requirement of fire blight-freedom in orchards did not support a measure restricting fruit from severely blighted orchards.⁴⁴ For example, even if an apple fruit harvested from a severely blighted orchard possessed epiphytic bacteria in its calyx, the scientific evidence did not establish that those bacteria would be present in populations capable of transmitting fire blight. Similarly, because the apple fruit harvested from the orchard would be mature, symptomless fruit, the scientific evidence did not establish that they would be infected with or harbour endophytic populations of *E. amylovora*.

4.73 **Japan** recognized that Azegami *et al.* (2005) and Tsukamoto *et al.* (2005a) did not establish that all US apple fruit posed an equally significant risk. The studies showed that the probability of infection from the pedicel or surface wounds of mature apple fruit depended on the conditions and activities of fire blight bacteria during the late season. If activities of the bacteria, which were known to peak during the flowering and fruitlet seasons, remained relatively dormant after the spring, apples which harboured the bacteria at a certain level would be likely to develop symptoms well in advance of maturity, as the Original Panel had noted.⁴⁵ However, no evidence suggested that this was the case,

⁴³ Panel Report on *Japan – Apples*, paras. 8.189, and 6.134-6.135 (Dr Hale noted that the 2000 joint study conducted by the United States and Japan had shown that "fruit harvested from blighted trees or adjacent to blighted trees had not harboured *E. amylovora*"). See 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) (Exhibit USA-9).

⁴⁴ Dr Hale's study had defined an orchard with 75 infected strikes per tree as being "(severely) infected".

⁴⁵ Panel Report on *Japan – Apples*, para. 8.138.

and the question of whether or not bacteria could still infect the apple fruit through the pedicels or wounds late in the season depended on various conditions. Japan concluded that the potential of infection of mature apple fruit through pedicels or surface wounds would be more pronounced when the tree was severely blighted. Indeed, the Original Panel found:

[T]he experts considered, *inter alia*, that it would be appropriate not to export apples from (severely) blighted orchards and that they would not be comfortable with a complete and immediate removal of the phytosanitary measures imposed by Japan, given the phytosanitary situation of that Member.⁴⁶ (footnotes omitted)

4.74 The **United States** commented that Japan's first written submission confirmed that its original and revised measures had not been and were not supported by the scientific evidence as evaluated by the Original Panel; Japan did not attempt to justify its measures based on the Original Panel's findings and the scientific evidence examined in the Original Panel proceeding. Rather, Japan relied on "new evidence" in the form of new studies in an attempt to show that its import regime for US apple fruit was rationally or objectively related to the scientific evidence. The United States noted that Japan stated that the new experiments provided "a scientific underpinning of the concern over (severely) blighted orchards," which had been expressed by the Original Panel based on the experts' opinions. The United States maintained that Japan needed to draw a clear distinction between the experts' opinions expressed at the meeting and the "scientific evidence" as is generally known.

4.75 **Japan** argued that if the opinions of the experts of the Original Panel did not constitute scientific evidence *per se*, they did reflect their interpretation of available scientific evidence. For instance, when Dr Hale had stated that one inspection was a reasonable requirement,⁴⁷ he was not talking about his personal preference but giving his scientist's judgment in the matter. Japan contended that the common concern expressed by the scientific experts over shipment of apple fruit from a (severely) blighted orchard indicated their common interpretation of the available evidence.

4.76 The **United States** argued that in conducting new studies on the scientific issues in this dispute, Japan appeared to have directed its efforts at supporting the conclusion that apple fruit should not be exported from severely blighted orchards. The United States noted that Japan referred to statements by some of the experts as "advising" this result, ignoring the views of those very same experts on the scientific evidence, and the ultimate panel findings on that evidence. Further, the United States claimed, Japan had not apparently cited the statements of some of the experts regarding severely blighted orchards as themselves constituting scientific evidence,⁴⁸ for indeed they are not – nor did the experts claim they were. In fact, one of those experts stated, "I am not sure this is something that has to be argued in scientific terms. It is a matter of public policy."

4.77 **Japan** countered that despite the US attempt to discount the experts' opinions regarding protection against a (severely) blighted orchard, this did not undermine the value of their statements in interpreting the available evidence. Japan emphasized that a measure would be scaled, under the SPS Agreement, according to the level of protection of the importing country, and it was natural for the experts to avoid judgment on a measure – as it could not be made on the basis of science alone.

4.78 Japan noted that since the findings of Azegami *et al.* (2005) and Tsukamoto *et al.* (2005a) indicated the difficulty of detecting every infection only from apparent symptoms in apple fruits, these

⁴⁶ Panel Report on *Japan – Apples*, para. 8.226.

⁴⁷ Panel Report on *Japan – Apples*, Transcript, Annex 3, para. 414.

⁴⁸ The Original Panel defined "scientific evidence" as "evidence gathered through scientific methods, excluding by the same token information not acquired through a scientific method", and further excluding "not only insufficiently substantiated information, but also such things as non-demonstrated hypothesis". Panel Report on *Japan – Apples*, paras. 8.92, 8.93, and 8.101-8.103.

studies supported Japan's position that errors or inability of detection would make it imperative to control the risk at the orchard level. It was also evident that apples from such trees would more likely contain something other than "mature, symptomless" apple fruit, leading to possible human errors in sorting. Japan also noted that Professor Thomson's discovery of *E. amylovora* from inside apples late during the maturing season in Utah was from a (severely) blighted tree.⁴⁹ Considered together, Japan argued these results demonstrated that the risk of contamination or infection from the bacteria was higher in a (severely) infected orchard.

4.79 Japan expressed concern that the US arguments had not demonstrated how the product the United States would export in the absence of the orchard requirement would indeed be identical to the conceptual "mature, symptomless" apple fruit. Nor had there been any discussion of effectiveness of the quality controls currently in place at the release stage, even though there was direct evidence that the quality control had failed at least once in the blighted pear shipment to Hawaii.⁵⁰ Rather, Japan argued, the United States sought to have the Panel endorse its current export practice, but without production process controls.

4.80 The **United States** clarified 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. In the 1940s, fruit, in particular pear fruit, was often packed directly in the orchard and packing facilities were used simply for cold storage purposes. Since that time, packing facilities had evolved to play a much greater role vis-a-vis quality controls and quality controls themselves had become much more sophisticated. For instance, sophisticated equipment such as optical scanners had only become available to the apple industry in the last decade.

4.81 The United States noted that no evidence existed that quality controls for exported apple fruit relating to fire blight had ever failed vis-a-vis shipments of mature, symptomless apple fruit, even in the 1940s, when quality controls were less technologically advanced and sensitive. The United States stated that neither relevant databases nor pertinent US Government and industry officials had indicated that foreign importers had ever rejected US apple exports for reasons of immaturity or infection/infestation with fire blight.⁵¹

4.82 **Japan** noted that Chinese Taipei had temporarily suspended imports of apples from Washington and the rest of the United States after a codling moth larva was found in a shipment from Oregon.⁵² Codling moth larvae were intercepted at import inspection of US apple fruit four times in 2004 after the previous interception in 2002 at Chinese Taipei. These repeated cases of failure indicate that there exists a genuine cause of concern over the quality of the export inspection by the US authorities.

⁴⁹ Letter from S.V. Thomson, Utah State University, to R.G. Roberts, USDA at 1 (August 23, 2002) (Exhibit JPN-13).

⁵⁰ University of California (1965). Do summer oil sprays favor fire blight development in pear fruit?, Calif Agric. Ext. Serv. Fruit Nut Grape Dis. Newsl. (Jan): 2; van der Zwet *et al.* (1990). Population of *Erwinia amylovora* on External and Internal Apple Fruit Tissues, Plant Disease 74: 711-716. (Exhibit JPN-11); van der Zwet (1994). The various means of dissemination of the fire blight bacterium *Erwinia amylovora*, EPPO Bulletin 24: 209-214.

⁵¹ The United States 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 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. The Foreign Notification of Non-Compliance database contains a limited time period of electronic entries, and paper records of export non-compliance/rejection which date back to the 1950s.

⁵² The Seattle Post Intelligencer, *Taiwan bans Washington apples*. Dec. 22, 2004.

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 Oregon was maintained without sufficient scientific evidence and bore no rational or objective relationship to the scientific evidence relating to apple fruit and fire blight as analyzed by the Panel. It did not matter, for fire blight purposes, where the apple fruit was grown. Nevertheless, MAFF Notification No. 354 required that apple fruit be produced "where US plant protection authority inspect for fire blight at proper times in the States of Washington and Oregon, USA." Japan's measure limiting eligible apple fruit to those produced in Washington and Oregon was maintained without sufficient scientific evidence within the meaning of Article 2.2.

⁵³ To the contrary, in the Original Panel proceeding, the Panel noted that the experts categorically stated that there was no evidence to suggest that mature apple fruit had ever been the means of introduction (entry, establishment and spread) of fire blight into an area free of the disease." Panel Report on *Japan – Apples*, para. 8.149. See also R.G. Roberts, *et al.* *The potential for spread of Erwinia amylovora and fire blight*, Crop Protection 17: 19-28, 20-24, at 22 (1998).

⁵⁴ Panel Report on *Japan – Apples*, para. 2.1.

4.88 In its first written submission, **Japan** argued that its geographical restriction on US apple exports was consistent with the SPS Agreement because it was "based on a procedural requirement" and that "[a]s long as the United States provides appropriate documentation of other quarantine pests and diseases" for other US States, those States might begin exporting apple fruit to Japan.⁵⁵

4.89 The **United States** noted there was no scientific evidence to support or justify a measure in any way restricting the eligibility of growers or packers to those in Washington and Oregon based on concerns regarding the hypothetical spread of fire blight. Japan might, in certain scenarios, have legitimate reason to restrict exports from these states because of other plant diseases and quarantine pests. However, Japan had no grounds to restrict those exports under the auspices of a fire blight-specific measure. In light of the scientific evidence, insofar as Japan's measures purported to mitigate hypothetical fire blight concerns, they should permit apple growers and packers from every apple-producing state to export mature, symptomless apple fruit to Japan.

4.90 **Japan** countered that there would be no discrimination in treatment of apple fruit from any State. The same measure would apply to any state consistently with the Detailed Rules and the Operational Criteria. Japan noted that as long as the United States provided appropriate documentation of other quarantine pests and diseases, MAFF Notification No.354 and the Detailed Rules would be amended, and other States would be added to the eligible exporting locations. Alternatively, the United States could demonstrate that the environmental conditions of other States were not different from those of Washington and Oregon and Japan would consider adding the entire United States to the list.

- (b) The export orchard must be free of plants infected with fire blight
- (c) The fire blight-free orchard must be surrounded by an approximately ten-meter buffer zone (or border zone) free of fire blight

4.91 The **United States** recalled the statements of the experts to the Original Panel with regard to the two conditions. One expert noted that "in the case of fire blight the possibility that fire blight should enter an orchard during a given growing season from outside the orchard . . . [and] infect fruit is almost impossible. . . [s]o for that reason I doubt whether a buffer zone is really necessary in the case of fire blight."⁵⁶ Another expert commented that the 2000 joint study conducted by the United States and Japan "had shown conclusively that no buffer zone of any size was justified by the existing scientific data, as fruit harvested from blighted trees or adjacent to blighted trees had not harboured *E. amylovora*."⁵⁷

4.92 The United States claimed that the unjustified and unscientific nature of Japan's measures was further demonstrated by considering that a requirement of fire blight-freedom in a buffer zone meant that trees tens, hundreds, or thousands of meters away from a potential source of inoculum would be disqualified for export to Japan. In this respect, decreasing the size of the buffer zone from 500 meters to ten meters was a hollow gesture – fruit growing significant distances from a source of inoculum was disqualified for export in both scenarios.

4.93 **Japan** argued that the introduction of a "border zone," replacing the previous buffer zone, was a fundamental and substantial modification. Japan observed that, in contrast to Japan's revised measure, the United States required Japanese *unshu* orange orchards to be surrounded by a 400 meters

⁵⁵ Japan's First Submission, para. 64.

⁵⁶ Panel Report on *Japan – Apples*, Transcript, Annex 3, para. 314 (Dr Smith).

⁵⁷ Panel Report on *Japan – Apples*, paras. 8.189, and 6.134-6.135 (Dr Hale, citing 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) (Exhibit USA-9)).

buffer zone. The relaxation of the measure would be economically significant for American growers who would subsequently be permitted to designate practically every orchard they owned. In addition, Japan claimed that the buffer zone was necessary to (i) clearly delineate and define an "export orchard," separate from the rest of the grounds and subject to phytosanitary requirements, and to (ii) prevent branches of trees inside the orchard from overlapping, or being in direct contact, with plants outside the orchard. The width of ten meters was not definitely required; the border zone requirement would be automatically met when the orchard was surrounded by passageways, waterways or other equivalent natural barriers or open space of a width of about ten meters.⁵⁸ Japan noted that most orchards were surrounded by driveways, waterways or other non-cultivation zones, and the requirement was not likely to impose an additional or unreasonable burden on producers.

4.94 Japan further noted that an exception to this rule was established for the "least resistant" varieties. Because fire blight was known to spread widely within a block or section for these varieties, sections for these varieties would need to be surrounded by a passageway, a waterway, a cliff or other natural barriers of about ten meters, and simple open space between growing lots of these varieties would not qualify as a border zone.

4.95 The **United States** countered that since neither mature fruit from resistant varieties nor mature apple fruit from less-resistant varieties had ever been shown to contain internal populations of *E. amylovora* despite extensive studies conducted for this purpose, scientific evidence did not support either form of buffer zone. Japan's attempt to impose varying requirements depending on varieties further complicated the export process and discouraged exports of apples.

4.96 **Japan** noted that its requirement barely met the internationally recognized concept of a "buffer zone," as defined by the International Plant Protection Convention (IPPC), which was "[a]n area in which a specific pest does not occur or occurs at a low level and is officially controlled, that either encloses or is adjacent to... a pest free production site, and in which phytosanitary measures are taken to prevent spread of the pest."⁵⁹ Indeed, a non-cultivation zone of some width was the concept that the experts referred to as a "buffer zone" at the meeting of the Original Panel.⁶⁰

4.97 The **United States** noted that Japan's argument failed to rebut the *prima facie* case established by the United States that a fire blight-free buffer/border zone requirement was not rationally related to the scientific evidence. In addition the United States noted that the requirement of a fire blight-free buffer zone appeared to contradict Japan's argument that export orchards should be inspected for severe or heavy blight. Without suggesting that the scientific evidence justified either requirement, the United States noted that it was impossible for the scientific evidence to support both propositions, by permitting a certain amount of fire blight in an export orchard, yet none in the zone surrounding the orchard.

4.98 The United States noted that the Detailed Rules defined the buffer/border zone as being ten meters wide and possessing "[n]o tree with fire blight symptoms." Further, all buffer/border zones would need to be inspected. Japan's first submission described border zones in greater detail, but only in the context of the Operational Criteria. The United States also claimed that the Operational Criteria required that least-resistant varieties be surrounded by "a passageway, a waterway, a cliff or other natural barriers" of at least ten meters width. According to this interpretation of the Operational Criteria, least-resistant varieties would not be eligible for an exception from the border zone requirement, but rather would be subject to a tightening of the fire blight-free requirement. Under the

⁵⁸ An example of a Commercial Orchard in Washington State (Exhibit JPN-4).

⁵⁹ IPPC Guideline No. 5: Glossary of Phytosanitary Terms 2002, FAO, Rome 2002.

⁶⁰ Panel Report on *Japan – Apples*, Transcript, Annex 3, para. 319. Dr Geider stated "... buffer zones have to be really strictly defined and all host plants which could be eventually harbouring have to be removed ..."

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 Criteria of the new measure, a tree would be presumed to be "(severely) infected" when readily observable symptoms were found on the tree exterior, as seen from the official in the inspection automobile. If such tree was found, any section, block or part of an orchard which was not surrounded by a "border zone" of an appropriate size to prevent overlapping or direct contact with outside host plants would be presumed to disqualify from exportation.⁶¹

4.103 Japan noted that the Operational Criteria, which provided guidance on how orchard inspections should be conducted, had been provisionally established in light of the scientific evidence and the revised PRA. Japan's new measure was designed to prevent imports of US apple fruits from (severely) blighted orchards, as advised by the expert who were consulted in the Original Panel proceedings.⁶² Japan intended to modify the criteria depending on further evidence and the results of the present Panel.

4.104 The **United States** argued that the Operational Criteria, while not a measure taken to comply for purposes of this proceeding, equated severely or "heavily blighted" with a scenario where "readily observable symptoms were found on the tree exterior, as seen from the official in the inspection automobile." The United States noted that under this standard, a single, "readily observable" fire blight strike on a single tree which the inspection regime proposed in the Operational Criteria would be no more relaxed than the fire blight-free inspection/disqualification proposed in Japan's Detailed Rules of 30 June 2004 or fire blight-free inspections conducted by Japanese inspectors in the past. The Operational Criteria proposed the disqualification of an orchard or export block when an inspector, in a buggy car, observed "readily observable" fire blight symptoms on an apple tree.

⁶¹ Japan described this condition as most likely equivalent to Dr Hale's definition of "severe infection".

⁶² Panel Report on *Japan – Apples*, paras. 8.153 and 8.226.

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 1995, experts conducted buggy car inspections for visible signs of fire blight, and disqualified entire orchards on observation of a single fire blight strike.

4.110 The United States claimed 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 were free of fire blight bore no rational or objective relationship to the scientific evidence relating to apple fruit and fire blight.⁶⁵ The Original Panel had summarized the views of the scientific experts on the subject of inspections, noting that "[e]ven with uninspected orchards the experts thought the risk to Japan of the entry, establishment or spread of fire blight was very low as surface *E. amylovora* was found only rarely on apples even from severely infected orchards."⁶⁶ The experts' conclusion and the Panel's finding that the scientific evidence did not establish that calyx-infested apple fruit would harbour populations of bacteria capable of transmitting fire blight,⁶⁷ confirmed that there was no rational relationship between an orchard and buffer zone inspection and the scientific evidence.

4.111 The United States also contended that Japan's arguments regarding apple fruit infection contradicted the proposed "early fruitlet" timing of the orchard and buffer zone inspections. In support of its contention that mature apple fruit might become latently infected with fire blight, Japan

⁶³ Observation by MAFF Plant Quarantine Officials (Exhibit JPN-15).

⁶⁴ Panel Report on *Japan – Apples*, Transcript, Annex 3, para. 294.

⁶⁵ Panel Report on *Japan – Apples*, paras. 8.168, 8.171, and 8.176.

⁶⁶ Panel Report on *Japan – Apples*, para. 8.196.

⁶⁷ Panel Report on *Japan – Apples*, paras. 8.171 and 8.176.

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 cardboard which had no opportunity to become contaminated with *E. amylovora*. In light of the US apple industry's use of new, disposable crates, there was no possibility of containers previously contaminated by exposure to pears harvested from blighted orchards being re-used for harvesting apple fruit for export to Japan.

⁶⁸ First Written Submission of Japan, para. 39.

⁶⁹ Detailed Rules (April 1, 1997), § 1(4); Detailed Rules (June 30, 2004), § 1(4).

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 evidence that such an event occurred, and no new evidence was presented to facilitate evaluation of any of the other suggested means of dissemination. The strongest statement the authors could make about the "evidence" was "[t]he possibilities suggested rely heavily on circumstantial evidence but they cannot be ruled out."

4.119 **Japan** argued that the US argument regarding post-harvest measures was incongruous with its own "mature, symptomless" criteria – and current export practice. Japan's new measure were designed to address two sources of risk: (i) the risk of accidental shipment of observably infected apple fruit and (ii) the risk of latent infection. Japan contended that inspections at export/import stages would offer security for the former risk and inspections at the importation stage would be beneficial for detecting symptoms which had developed during shipping.

4.120 The **United States** noted that the Export Apple Act and its grading standards were one of numerous requirements and practices that assured that exported apple fruit were mature. For example, commercial considerations require that growers, packers and shippers, through their pre- and post-harvesting procedures, test apple fruit for maturity and subject fruit to visual and sensitive electronic scanning for grading and defects that would result in the culling of any hypothetically immature fruit. In addition the United States observed that the information listed on phytosanitary certificate addressed plant health concerns, and the specific requirements that had to be met on the certificate were dictated by the importing country. Unlike quality requirements under the Export Apple Act, the United States did not have a fixed, required form for a phytosanitary certificate. Rather, these certificates will vary on both commodity-by-commodity and country-by-country bases.

4.121 The United States noted that in order to export apple fruit to Japan, US apple growers and shippers had to satisfy each of the numerous requirements of Japan's import regime for US apple fruit. Participation in this programme was complicated, burdensome and costly, ultimately exposing the grower to the cost-prohibitive risk that a grower's harvest would be rejected or declared ineligible for export to Japan due to a failure to meet any one of Japan's scientifically unjustified requirements. Each element of Japan's import regime for US apple fruit imposed significant costs on the growers and shippers. Against these costs, growers and shippers assumed the risk that their entire investment would be lost as a result of a single fire blight detection that, given the nature of the programme, might be on a plant that was not even within the grower's legal or physical control (*e.g.*, if he or she

⁷⁰ The United States referred to Panel Report on *Japan – Apples*, paras. 6.33-35, 6.166, 6.168, and 6.169.

⁷¹ Billing, E. and Berrie, A.M. (2002), A Re-Examination of Fire Blight Epidemiology in England, Proc. 9th Intl. Workshop on Fire Blight, Acta Horticulturae 590: 61-67.

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 spread of the disease, bore no rational or objective relationship to the scientific evidence.

4.124 **Japan** argued that neither the experts nor the Original Panel found surface disinfestations to be inconsistent with the SPS Agreement. As epiphytic bacteria would not be removed by inspection at the orchard, it was prudent to sterilize the surface, even if the risk from these bacteria were not high.⁷² This treatment would decrease the incidence of the bacteria from collected apple fruit which might have been infected from surface wounds in a manner similar to that demonstrated by the Azegami *et al.* (2005) and Tsukamoto *et al.* (2005a) studies. In addition, the washing process using chlorine deactivated the bacteria. Japan indicated that washing of apple fruit was part of the normal commercial pre-shipment treatment of US apples and hence posed no additional burden on US exporters.⁷³

- (f) The interior of the packing facility must be disinfected by a chlorine treatment

4.125 The **United States** claimed that there was 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. Further, when viewed in light of the statements of an expert that another required Japanese post-harvest treatment – chlorine dip – alone would adequately remove any hypothetical risk of epiphytic contamination of apple fruit, it was impossible to demonstrate a rational relationship between Japan's sterilization measures and the scientific evidence.⁷⁴ Accordingly, the United States argued, Japan maintained its additional post-harvest measures without sufficient scientific evidence in breach of its obligations under Article 2.2.

⁷² Panel Report on *Japan – Apples*, para. 8. 136.

⁷³ Oral presentation by Mr. P. McGowan, at the first substantive meeting of the Original Panel.

⁷⁴ Panel Report on *Japan – Apples*, Transcript, Annex 3, para. 323 (Dr Smith) ("Indeed, it could be argued that such a disinfection treatment is quite adequate to remove the phytosanitary risk by itself.").

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
- (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.

4.128 The United States maintained that in light of the scientific evidence, there was no justification for the requirement that apple fruit destined for export to Japan be kept physically separate from other apple fruit. The United States observed that by failing to address post-harvest separation of apple fruit in its submission, Japan had failed to rebut the *prima facie* case raised by the United States that the post-harvest separation requirement was maintained without sufficient scientific evidence for purposes of Article 2.2.

4.129 **Japan** argued that the United States had not made a case against the separation requirement, other than in relation to the disinfestation treatment. The separation requirement was not specific to fire blight but a natural extension of the other control requirements (i.e., the orchard requirement and the border zone requirement against fire blight and the fumigation requirement against codling moth). In addition, Japan recalled comments by Dr Hale, specifically that separation of fruit destined for Japan would not be difficult given that many fruit exporters already had the capacity to separate fruit destined for different markets all over the world. Dr Hale had noted that in New Zealand fruit exports were separated in the process of packing into categories based on size, colour, type of fruit, and variety.

4.130 Japan noted furthermore that inspections at export/import stages would offer security for the risk of accidental shipment of observably infected apple fruit and inspections at the importation stage would be beneficial for detecting symptoms which had developed during shipping. These inspections and the issuance of phytosanitary certificates were standard regulatory practice and did not result in any burden to US exporters. As phytosanitary measures, the requirement was necessarily procedural. Moreover, Japan noted that the United States and other Members had a similar requirement for quarantine pests and their host plants. Japanese pre-shipment inspections were designed to counter not only the risk of fire blight but also of codling moth and other pests and diseases of quarantine concern.

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.

between the evidence and the measure, consistent with Article 2.2. In the PRA, Japan identified "US apple fruit" as a possible pathway for introduction of fire blight. The revised PRA then examined the probability of infection of US apple fruit, the survivability of *E. amylovora* during handling, storage and shipment and finally the completion of the pathway.

4.136 The **United States** noted that the Original Panel had found that Japan's PRA failed to evaluate the likelihood of introduction of fire blight into Japan. It had reached this conclusion in part because Japan's 1999 PRA was "not sufficiently specific to the matter at issue" in failing to examine the risk from apple fruit.⁷⁹ Japan's September 2004 PRA suffered from the same flaw by failing to address the commodity actually exported by the United States – mature, symptomless apple fruit – and instead relying on the existence of a commodity that did not exist in nature – mature, symptomless, yet latently infected apple fruit.

4.137 **Japan** argued that the requirement of specificity of the risk assessment identified in the Original Panel report (paragraph 8.271) had been fully met as indicated in the First Written Submission of Japan. The revised PRA did address the risk from "the commodity actually exported by the United States," which the United States had defined (but had not proved) to be "mature, symptomless" apple fruit. Japan's PRA had taken into account that such apple fruit under the current US export practice might or might not be actually "mature" in the horticultural sense or "healthy" in the pathological sense, and addressed these risks accordingly.

Probability of fire blight being associated with the pathway at origin

4.138 The **United States** commented that, in its 2004 PRA, Japan recognized that there was "consensus among foreign fire blight experts that mature, symptomless apples are unlikely to be infected by the disease. Since *E. amylovora* have not been detected from apple fruit which were sampled from infected trees or orchard, Dueck 1974, Roberts *et al.* 1989 and Roberts (2002) concluded that the mature apple fruit is not infected with *E. amylovora*. This conclusion was additionally supported by the available literature that the pathogen would infect (immature) apples at an early stage of growth, preventing the normal development of infected apples, so that by the time apples became mature, only healthy apples would remain at harvest time."

4.139 **Japan** claimed that the United States had mischaracterized Japan's argument by selectively citing only one part of the PRA. In the subsequent sections the PRA stated that the risk of latent infection might be higher than thought at the time of the Original Panel, and that inadvertent shipment of infected apple fruit would pose a risk, as new evidence demonstrated that the pathway could be completed.

4.140 The **United States** noted that because Japan appeared to recognize that mature, symptomless apple fruit did not pose a risk of introducing fire blight, the revised 2004 PRA instead examined the risk from a non-existent commodity – mature, symptomless, but latently infected fruit. The United States commented that Japan relied on the contention that Azegami *et al.* refuted the previous scientific evidence on apple fruit and fire blight. The United States had previously noted that the Azegami study had not succeeded in refuting this evidence. As a result, the 2004 PRA failed to examine the actual risk – as established by the scientific evidence – from mature, symptomless apple fruit.

4.141 **Japan** noted that apple fruit might be infected or infested by the bacteria in orchards. Though the risk of surface contamination was relatively insignificant, potential/actual infection of apple fruit posed a risk of introduction of the disease. Japan argued that since the new evidence indicated that the risk of latent infection of mature, symptomless apple fruit from a "(severely) blighted orchard"

⁷⁹ Panel Report on *Japan – Apples*, para. 8.271.

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 2004 PRA failed to provide any (new) evidence that the hypothetical pathway would be completed.

4.147 **Japan** contended that the United States had failed to note that the revised PRA had addressed two different risks: (i) the risk of erroneous shipment of infected apple fruit and (ii) apple fruit latently infected. Even though a latently infected mature fruit is found only under experimental conditions, Azegami *et al.* (2005) showed that apple fruit was not resistant to the bacteria even when they were mature and that the only protection against the infection was the abscission layer, as the United States argued. Completion of the pathway using infected apple fruit had also been demonstrated under conditions consistent with the Japanese environment.

⁸⁰ The United States referred to "An example of the pathways that Japan considers" (Exhibit JPN-12).

⁸¹ Hale and Taylor (1999). Effect of cold storage on survival of *Erwinia amylovora* in apple calyxes, *Acta Horticulturae* 489: 139-143 (Exhibit USA-16).

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 Panel nor the Appellate Body absolved Japan from its obligation to present evidence that the risk of failure of US apple fruit quality controls was more than just hypothetical. In fact, the Appellate Body had been careful to observe that the Original Panel's and experts' discussion of export controls was a discussion of those controls "in general," rather than an evaluation of the specific controls for apple fruit in place in the United States.

Probability of transfer of fire blight to suitable host

4.150 **Japan** claimed that the revised PRA had reviewed the results of Tsukamoto *et al.* (2005b) and found that this study confirmed the probability of infection by US apple fruit from a "(severely) blighted orchard" of the suitable hosts in Japan through flies. It had also been found that flies could carry bacteria to these hosts, which were widespread in urban areas, and that the arrival and distribution of US apple fruit coincided with the flowering or fruitlet seasons of these hosts.

4.151 The **United States** noted that although Azegami *et al.* (2005) purported to demonstrate the existence of a mature, symptomless, yet latently infected fruit, it failed to establish that such a thing exists. Similarly, while Tsukamoto *et al.* (2005b) concluded that flies are a vector of *E. amylovora*, it only achieved this result by failing to address real world, and real orchard, conditions. In fact, the flies inoculated with *E. amylovora* as a result of entrapment with blighted fruit failed to vector the inoculum to host plants. Further, although Kimura *et al.* purported to illustrate the probability of introduction of fire blight via apple fruit, it would only do so by relying on the Azegami and Tsukamoto studies, and even then its results contradicted its conclusions. The United States countered that Japan could not prove that the hypothetical pathway would be completed by relying on its new studies which neither augmented nor changed the conclusions of existing scientific evidence on fire blight and apple fruit.

4.152 **Japan** noted that the argument of the United States was based on categorical denial of the new evidence. Azegami *et al.* (2005) did show that mature apple fruit were not immune from infection of the bacteria, and Tsukamoto *et al.* (2005b) showed completion of a pathway from infected (whether latently or not) apple fruit using common flies as a vector in an environment consistent with Japanese fauna. Kimura *et al.* (2005) discussed the probability of these events in a comprehensive discussion of the risk of introduction and establishment of the disease into Japan. Japan noted further that the US critique boiled down to rejection of the conclusion of the revised PRA, and was not a valid critique of the methodology of the analysis, particularly since each of the requirements raised by Dr Hale had been fully met.⁸² The fact that the United States did not like the conclusion would never make a *prima facie* case under Article 5.1.

⁸² Panel Report on *Japan – Apples*, para. 8.279.

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 June, 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).

identify any scientific evidence supporting these premises. In the absence of any scientific evidence of a fire blight-risk posed by mature, symptomless apple fruit, any risk analysis which concluded otherwise would not "take into account available scientific evidence,"⁸⁶ and would not meet the requirements for a risk assessment under Article 5.1. The United States claimed that since Japan had failed to validate its revised measures through the production of the new PRA, its revised measures were not based on a risk assessment and were maintained in breach of Article 5.1.

4.161 The United States argued that the probability of introduction of fire blight via imported mature US apple fruit was essentially zero because the scientific evidence did not demonstrate that mature, symptomless apple fruit had ever introduced fire blight into a fire blight-free area, despite, in many cases, unrestricted trade in apple fruit. The evidence did not establish that mature apple fruit would harbour endophytic populations of fire blight bacterium or be infected by fire blight, or that mature apple fruit would harbour epiphytic populations of bacteria capable of initiating the disease. Because the scientific evidence confirmed that imported US apple fruit did not pose a risk to plant life or health in Japan, and when that scientific evidence failed to demonstrate a likelihood or probability of introduction of fire blight via mature apple fruit, the result of the risk assessment could not reasonably support, or sufficiently warrant, Japan's revised fire blight measures.

E. ARTICLE 5.6

4.162 The **United States** suggested that a measure restricting imports to mature US apple fruit would more than meet Japan's ALOP for fire blight because the scientific evidence did not establish that mature, symptomless apple fruit would be infected with fire blight or harbor endophytic populations of bacteria; that mature, symptomless, apple fruit would harbor epiphytic populations of bacteria capable of transmitting fire blight; or that apple fruit, regardless of its maturity, would serve as a pathway for introduction of fire blight.⁸⁷

4.163 The United States noted that the Appellate Body in *Australia – Salmon* found that in order to raise a successful claim under Article 5.6 of the SPS Agreement, the complaining party must demonstrate that (1) a measure exists that was "reasonably available taking into account technical and economic feasibility"; (2) the measure must be able to achieve "the Member's appropriate level of sanitary and phytosanitary protection"; and (3) the measure must be "significantly less restrictive to trade than the SPS measure contested."⁸⁸ The proposed alternative measure in an Article 5.6 argument was by necessity a measure to be implemented by the responding party due to the fact that the WTO-consistency of the responding party's original measure was being challenged. The United States proposed that a Japanese measure requiring that imported apple fruit be mature, and therefore symptomless was supported by both the Original Panel's findings and the voluminous scientific evidence on fire blight and apple fruit, and would satisfy each of the conditions of this three-prong test.

(a) Reasonably available taking into account technical and economic feasibility

4.164 The **United States** claimed that a measure restricting imports to Japan to mature US apple fruit was reasonably available taking into account technical and economic feasibility. US Federal laws and regulations already ensured that export apple fruit were mature. In fact, almost all fire blight-free areas to which the United States exported apple fruit imposed only a mature, symptomless fruit requirement for apples, thereby allowing US apple fruit meeting US export standards to be exported without the various pre-harvest restrictions or post-harvest treatments currently required for

⁸⁶ SPS Agreement, Article 5.2.

⁸⁷ Panel Report on *Japan – Apples*, paras. 8.168, 8.171, and 8.176.

⁸⁸ Appellate Body Report on *Australia – Salmon*, (WT/DS18/AB/R), para. 194.

export to Japan.⁸⁹ US apple growers and packers had complied with these laws and regulations and had met the standards of export markets by employing a series of effective commercial quality controls that ensured apple fruit maturity. The horticulturalists, machinery, trained packing facility workers and trained Federal and/or Federally-licensed State inspectors were available and used for US exports to international markets. Because these measures were in effect and regularly applied to US apple fruit exports, a measure restricting exports to mature fruit was reasonably available and technically and economically feasible.

4.165 The US Export Apple Act required that exported fruit meet minimum Federal grade standards.⁹⁰ Exported apple fruit must have satisfied, at a minimum, the requirements for "US No. 1 grade",⁹¹ which required that apples were:

mature but not overripe, carefully hand-picked, clean, fairly-well formed; free from decay, internal browning, internal breakdown, bitter pit, Jonathan spot, scald, freezing injury . . . and broken skin or bruises except those which are incident to proper handling and packing[;] free from damage caused by . . . sunburn or sprayburn, limb rubs, hail, drought spots, scars, stem or calyx cracks, disease, insects, [or] damage by other means.⁹²

4.166 The United States noted that violators of the provisions of the US Export Apple Act might be debarred from receiving export certificates and fined.⁹³ Debarment would render a facility's apple fruit ineligible for export, thereby placing the facility at dire economic risk in the event that its commercial quality controls should hypothetically fail. The United States emphasized that the risk of failure of commercial quality controls was hypothetical.

4.167 **Japan** countered that the United States proposed that products should meet "US No.1 Grade" specifications but did not include specifics about test methods for verification. By failing to provide test methods or ways to achieve the specification, the United States had not established any "measure" worth considering. The concept failed 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. Japan claimed that the United States argued in essence that the maturity of apple fruit was irrelevant and that the United States should be allowed to ship whatever apple fruit it found fit for export under its current shipping practice.

⁸⁹ The United States exports apple fruit to 61 countries that impose no measures on US apple fruit for fire blight, other than requiring a phytosanitary certificate indicating that the fruit is free from harmful organisms, including fire blight.

⁹⁰ US Export Apple Act, 7 USC. § 581 (Exhibit USA-11).

⁹¹ Apples and Pears Regulations, 7 C.F.R. § 33.10 (Exhibit USA-12).

⁹² United States Standards for Grades of Apples, 7 C.F.R. §§ 51.301, 51.302 (requirements for US No. 1 same as for "US Fancy," except for "color, russeting, and invisible water core"). (Exhibit USA-13). For purposes of these Standards, "mature" means that "the apples have reached the stage of development which will insure the proper completion of the ripening process." 7 C.F.R. § 51.312.

⁹³ 7 USC. § 586 ("After opportunity for hearing the Secretary is authorized to refuse the issuance of certificates ... for periods not exceeding ninety days to any person who ships or offers for shipment any apples in foreign commerce in violation of any of the provisions of this chapter. Any person or any common carrier or any transportation agency knowingly violating any of the provisions of this chapter shall be fined no less than \$100.00 nor no more than \$10,000 by a court of competent jurisdiction.") (Exhibit USA-11); United States Regulations for Fresh Fruits, Vegetables and Other Products (Inspection, Certification, and Standards), 7 C.F.R. § 51.46 ("Any or all benefits of the act may be denied any person for any of the following reasons: . . . (d) any willful violation of the regulations in this subpart may be deemed sufficient cause for debarring the person found guilty thereof from any or all benefits of the acts, after notice and opportunity for hearing has been accorded him.") (Exhibit USA-15).

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 by a measure equivalent to an import prohibition. In light of the scientific evidence relating to mature apple fruit and fire blight, a restriction of imported apple fruit to mature apple fruit would be an equivalent measure to an import prohibition, thereby achieving Japan's ALOP.

4.175 **Japan** commented that Japan's ALOP was the level of protection that would provide a security level which would 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 was insignificant and inevitable. Japan's ALOP against fire blight had not changed even though the measure was changed: a level equivalent to import prohibition.

4.176 The **United States** argued that a measure restricting apple fruit imports to mature US apple fruit would more than achieve Japan's ALOP because, as the Original Panel had found, scientific evidence did 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.⁹⁶ 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.

4.177 The United States commented that scientific evidence and history supported the conclusion that restricting import to mature US apple fruit satisfy Japan's ALOP. This conclusion stems from the comprehensive and time-tested quality controls employed by the US apple industry and the absence of evidence that the United States had shipped anything other than mature apple fruit. In addition, no scientific evidence indicated that unrestricted trade in apple fruit had ever been the means of introduction of fire blight.⁹⁷ Further, even if an immature fruit hypothetically had escaped US quality controls, the scientific evidence did not establish that any pathway for introduction of fire blight into Japan would be completed by apple fruit, regardless of its maturity.⁹⁸ Accordingly, Japan's ALOP would still be met even in the event of a hypothetical breakdown of US quality controls.

4.178 **Japan** noted 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, signalled a risk posed by apples from a (severely) blighted orchard, which might not be healthy or mature. The US proposal did 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.

4.179 Japan claimed furthermore that the United States mischaracterized the finding of the Original Panel, because the Original Panel's discussion of completion of the pathway was not limited to the

⁹⁶Panel Report on *Japan – Apples*, paras. 8.136, 8.168, 8.171, and 8.176.

⁹⁷ Regarding the potential for failure of quality controls in general, the panel of experts noted that the risk was "remote", "very remote", "negligible" and "extremely low so I think altogether it is not an essential question that we have to rely on." Panel Report on *Japan – Apples*, Transcript, Annex 3, paras. 329, 331 (Drs Smith and Hale), and para. 330 (Dr Geider), para. 332 (Dr Hayward).

⁹⁸Panel Report on *Japan – Apples*, paras. 8.168, 8.171, and 8.176.

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).

4.186 The United States argued that a range of alternative measures existed that were both less trade-restrictive and would more than achieve Japan's ALOP. Alternatives could include requiring that imported mature fruit be accompanied by a declaration on the export certificate that, pursuant to current sampling protocols, zero immature fruit were detected in the shipment. Or, apple fruit for export to Japan could be subjected to additional maturity testing, as proposed by the United States in the negotiations with Japan that took place during the during reasonable period of time. Pursuant to this testing programme, should a hypothetical shrivelled fruit be detected in a lot for shipment to Japan, the fruit would be subjected to starch/iodine testing to determine whether the shrivelling was due to apple fruit immaturity. Should it be determined that the shrivelling was a result of apple fruit immaturity, the lot would be disqualified for export to Japan.¹⁰¹ In addition, an alternative might include the import of mature apple fruit coupled with a phytosanitary certificate. Because the scientific evidence did not establish that mature, symptomless apple fruit would be infected with, or harbor endophytic populations of *E. amylovora*; that mature, symptomless apple fruit would harbor epiphytic populations of bacteria capable of transmitting fire blight; that apple fruit would serve as a pathway for introduction of fire blight; or that, despite billions of apple fruit shipped world-wide,¹⁰² apple fruit had ever transmitted fire blight, all of these alternatives would by definition be less trade-restrictive than Japan's current import regime and would more than meet Japan's ALOP.

4.187 However, because these alternative measures would not be scientifically justified, and would more than achieve the level of protection, the United States was not suggesting that these measures would be consistent with the SPS Agreement. Rather, the United States was using them to illustrate that Japan's measures were far more trade-restrictive than required.

4.188 **Japan** noted that the United States claimed that the "alternative measure" was the one which would restrict importation to "mature, symptomless apple fruit." Even though the Original Panel found that the "mature, symptomless" was a "relatively objective concept,"¹⁰³ it never found that what the US apple industry ships would be "mature, symptomless" apple fruit. The issue of how to ensure that quality, or the relevant specifications and test methods, was therefore an entirely open issue in this proceeding.

4.189 Japan stressed that "mature, symptomless apple fruit" was a "product specification." These types of specifications typically described (i) required qualities/parameters and (ii) test methods to ensure the qualities together with acceptable allowances.¹⁰⁴ The United States had not provided the "mature, symptomless" specifications. Instead, it described the "multiple processes" to ensure the quality of apple fruit shipped by US growers and equated these processes with the specifications. The United States was calling the apples produced through a process compliant with these specifications as "mature, symptomless," without regard to their true quality. As such, the "mature, symptomless" apples as defined by the United States might or might not match the definition of mature, symptomless apple fruit.

4.190 Japan noted that whereas the United States sought to rely on the security offered by the industry practices taken at the harvest ("end of the line") stage, Japan sought to ensure the quality at the orchard (production) level. Japan's approach was consistent with the caution expressed by the experts of the Original Panel regarding apple fruit from a "(severely) blighted" orchard, while the US

¹⁰¹ The United States argued that these additional steps would be further assurances that the exported fruit would be mature apple fruit. The United States stressed, however, that its current industry practices were such that we simply did not encounter shriveled or immature fruit at the "end of the line", *i.e.*, once harvested fruit had been subjected to the numerous quality controls currently utilized by the US apple industry.

¹⁰² Panel Report on *Japan – Apples*, paras. 8.136, 8.168, 8.171, and 8.176.

¹⁰³ Panel Report on *Japan – Apples*, para. 8.113.

¹⁰⁴ Japan referred to Standard for apples marked within the State of Washington (<http://www.leg.wa.gov/WAC/index.cfm?fuseaction=chapterdigest&chapter=16-403>). The standard explicitly accepts immature fruit up to 10 per cent.

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
- the Panel's consideration of scientific information and need to consult scientific experts.

5.2 Australia noted that the characterisation and interpretation of the scientific material presented by Japan was a strongly contested issue and stated that the Panel should have recourse to scientific experts to assist it in relation to the material presented by Japan. Australia requested the Panel ensure

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 completed after the 30 June Detailed Rules. The revised measure taken by Japan apparently did not fulfil the requirements of Article 2.2 because there was not a "rational or objective relationship between each restriction and the scientific evidence".

C. CHINA

1. Scientific experts

5.6 Because the new studies had played an important role in Japan's revised PRA, and formed the foundation of Japan's revised measure, China believed that Panel should consult experts on the new scientific issues in order to evaluate whether four new studies introduced by Japan constituted scientific evidence. In China's view, most elements of Japan's revised measures had also been included in the original measure. China argued that the scientific validity of the new studies would determine whether Japan should further amend its SPS measures affecting the importation of apples from the US.

2. Article 5.6 of the SPS Agreement

5.7 China believed that if (1) a measure could be identified; and (2) such a measure was under implementation, the measure was reasonably available taking into account technical and economic feasibility. The United States in its first written submission had defined its alternative measure as restricting trade to mature US apple fruit. China noted that the US industry already employed a series

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 the scientific evidence remained unchanged since the Original panel proceeding, then the alternative measure introduced by the United States could meet Japan's level of protection.

D. EUROPEAN COMMUNITIES

5.9 The European Communities noted that the DSU envisaged the possibility of dispute settlement progressing in stages:

- (a) an initial Panel proceeding;
- (b) appeal to the Appellate Body;
- (c) recommendations and rulings by the DSB;
- (d) disagreement as to the existence or consistency with a covered agreement of "measures taken to comply" with the original recommendations and rulings;
- (e) compensation or the suspension of concessions; and
- (f) binding arbitration.

5.10 The European Communities noted that an Article 21.5 proceeding was subject to procedures that were different from an Original Panel and brought the Parties one step closer to the possibility of the suspension of concessions. The possibility that Parties could agree to continue to suspend arbitration pending a second Article 21.5 DSU panel would not in itself prevent one party from proceeding to the arbitration stage, following a first Article 21.5 DSU proceeding.

5.11 A "measure taken to comply" could be attacked in the context of Article 21.5 DSU proceedings even in relation to provisions of the covered agreements not invoked in the original proceedings.¹⁰⁵ The need for prompt settlement of disputes meant that a Member could not indefinitely delay the progression foreseen in the DSU towards the possibility of the suspension of concessions by replacing one unlawful measure with another unlawful measure, albeit unlawful for different reasons.¹⁰⁶

5.12 On the other hand, a complaining Member could only move to the pre-suspension phase of an Article 21.5 DSU procedure if it had first secured a DSB recommendation or ruling that the defending Member must implement; and only insofar as there was disagreement as to the existence or conformity of measures taken to comply. In this context, the Appellate Body had made it clear that the question of what was the measure must be distinguished from the question of what was the claim,

¹⁰⁵ Appellate Body Report on *US-Shrimp (Article 21.5 - Malaysia)*, paras. 84-86; Appellate Body Report on *Canada – Aircraft (Article 21.5 - Brazil)*, paras. 39-41.

¹⁰⁶ Panel Report on *Australia – Salmon (Article 21.5 – Canada)*, para. 7.10, point 9.

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 principle, this Panel should assess the "measures taken to comply" by Japan with the "recommendations and rulings" [of the DSB] in the original dispute, for consistency with the provisions of the covered agreements invoked by the United States in its request for the establishment of this Panel, and in its first written submission.¹¹¹ The European Communities suggested that Japan had waived its rights regarding consultation.¹¹²

(b) Recommendations and rulings, findings and conclusions

5.20 The words "recommendations and rulings" in Article 21.5 DSU referred to the recommendations and rulings of the DSB in the original dispute. In the original dispute, by adopting the Appellate Body Report and the Panel Report as upheld by the Appellate Body Report including the Panel Report to the extent that it was not appealed, the DSB had accepted the recommendations and rulings contained in those documents as its own.

5.21 Various provisions of the DSU confirm that "rulings" might also be "adopted" by the DSB, in the same way that "recommendations" of a Panel or the Appellate Body might be adopted by the DSB, providing strong contextual support for the proposition that Panel Reports and Appellate Body Reports might also contain "rulings" within the meaning of Article 21.5 DSU.¹¹³ Various other provisions of the DSU referred expressly to rulings adopted by Panels or the Appellate Body.¹¹⁴ The European Communities argued that it was perfectly consistent with the DSU that Panel and Appellate Body Reports might also contain rulings, which, when adopted by the DSB, would become recommendations and rulings of the DSB for the purposes of Article 21.5 DSU. Further confirmation was provided by the fact that the "ruling" vocabulary had been consistently used by the Appellate Body in its original report in this case,¹¹⁵ as in previous cases.

5.22 The words "find" and "conclude" in adopted reports might be generally considered synonymous with the word "ruling". When the DSB adopted a Panel or Appellate Body finding or conclusion, it became a DSB ruling. Thus, if the Appellate Body upheld a finding by a Panel that a Member had acted inconsistently with one of its obligations under the covered agreements, and the DSB adopted the Reports, then the DSB had, in effect, given a "ruling" that the Member had acted inconsistently with its obligation, and accordingly also adopted the Panel and Appellate Body recommendation that the Member be requested to bring its measure into conformity.

¹¹⁰ Japan First Written Submission, paras. 81 to 89.

¹¹¹ Appellate Body Report on *US – Shrimp (Article 21.5 - Malaysia)*, paras. 84 to 86; Appellate Body Report on *Canada – Aircraft (Article 21.5 - Brazil)*, paras. 39-41.

¹¹² Appellate Body Report on *Mexico – Corn Syrup (Article 21.5 – US)*, para. 63.

¹¹³ DSU, Articles 21.3(b), 21.3(c) and 22.8.

¹¹⁴ DSU, Articles 26.1, and 26.2 (twice).

¹¹⁵ Appellate Body Report on *Japan – Apples*, paras. 4, 85, 92, 123, 128, 132, 136, 149, 159, 186, 217, and 243.

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 the SPS Agreement, into conformity with that Agreement".¹¹⁶ For the purposes of implementation and Article 21.5 DSU proceedings, all the recommendations of the Original Panel and Appellate Body, including all the findings and conclusions on which they are necessarily based, as adopted by the DSB, as DSB recommendations and rulings, were relevant.¹¹⁷

(c) Judicial economy by the Original Panel and the original measure at issue

5.24 The Original Panel concluded that it should consider all the ten elements together as the measure at issue in the original dispute, and this decision was not contested on appeal. With regard to Article 2.2, the Panel reached findings and conclusions in relation to certain elements (the 500 meter buffer zone and three yearly inspection) of the measure at issue that it had considered were "most obviously maintained without scientific evidence".¹¹⁸ It did not make any specific findings or conclusions of inconsistency with Article 2.2 in relation to the other elements of the measure at issue, considered in isolation. Instead the Panel stated that its more general findings rendered the measure as a whole inconsistent with the SPS Agreement.

5.25 The European Communities noted that neither the United States nor Japan had appealed either on the question of what constituted the original measure at issue, or on the absence of specific determinations on individual elements of the measure.¹¹⁹ Nevertheless, the European Communities noted, the United States called for the compliance Panel to evaluate specific elements of Japan's revised import regime on apple fruit to support a prompt and effective resolution of this dispute.

(d) Measures taken to comply

5.26 The European Communities noted that the Panel might need to make a preliminary determination about what are the "measures taken to comply" in order to determine the scope of these proceedings.¹²⁰ Of the four original pieces of Japanese legislation, only the Detailed Rules, which were modified by the 30 June Detailed Rules, had changed. The European Communities argued that if this Panel found that the entirety of those parts of the 30 June Detailed Rules dealing with fire blight were "measures taken to comply", then it would need to assess the entirety of that new measure for consistency with the provisions of the covered agreements invoked by the United States in its request for establishment of this Panel. If, on the other hand, this Panel found that the "measures taken to comply" were only those elements of the 30 June Detailed Rules that were different from its predecessor, then it would have to find that these proceedings were more limited in scope. In that case, the United States should request a fresh panel to address those elements of the original measure at issue for which judicial economy had been exercised, not an Article 21.5 DSU procedure.

5.27 The European Communities commented that absent any import restriction, the mere existence of a risk assessment with which another Member disagreed would not, in itself, be sufficient for the

¹¹⁶ Appellate Body Report on *Japan – Apples*, para. 244.

¹¹⁷ As submitted by Canada in *Australia - Salmon*, with the implied agreement of the Appellate Body : Appellate Body Report on *Australia - Salmon*, paras. 222-226.

¹¹⁸ Panel Report on *Japan – Apples*, paras. 8.123-8.176.

¹¹⁹ As Canada did, for example, in *Australia - Salmon* : Appellate Body Report, *Australia - Salmon*, paras. 217 and 279 (h); and as India failed to do in the *EC-Bed Linen* case : see Appellate Body Report, *EC - Bed Linen (Article 21.5 - India)*, paras. 71, 80, 81 and 92 to 96. See also Appellate Body Report, *Mexico – Corn Syrup (Article 21.5 – US)*, paras. 78 to 79.

¹²⁰ Appellate Body Report, *EC-Bed Linen (Article 21.5 - India)*, para. 78: "If a claim challenges a measure which is not a "measure taken to comply", that claim cannot properly be raised in Article 21.5 proceedings".

purposes of commencing dispute settlement proceedings. However, given that Article 5.1 required SPS measures to be based on a risk assessment, it followed that in circumstances where there was an SPS measure, any risk assessment on which it was said to be based necessarily fell within the scope of dispute settlement. Consequently, insofar as the DSB recommendations and rulings in the original dispute concerned the original measure at issue, they might also concern the risk assessment on which the original measure was purportedly based. It followed that when, in order to comply with the DSB recommendations and rulings, the risk assessment was changed or a new risk assessment was carried out, and put forward as the basis for the "measures taken to comply", then the risk assessment was also within the scope of subsequent Article 21.5 DSU proceedings.

5.28 The European Communities suggested that the submission by Japan of allegedly new scientific evidence could be handled in two ways. The first approach would treat the new scientific evidence as facts not previously considered by any Panel. In these circumstances, if a Member adopted a new SPS measure based on new scientific evidence, it might not be taking a measure to comply with DSB recommendations and rulings, but rather adopting a new measure in response to new facts. In this case, if the original complaining Member wished to submit the new measure to dispute resolution, it would need to do so via a fresh panel, and not via Article 21.5 DSU.

5.29 Alternatively, the new studies submitted by Japan could be the subject of these Article 21.5 DSU proceedings. The Panel might reach this conclusion on the basis that the 30 June Detailed Rules was a measure taken to replace the original measure at issue, and to comply with the original DSB rulings. The Panel might also take into account whether or not the defending Member had itself undertaken or commissioned the research resulting in the new scientific evidence.¹²¹ However, because of the nature of Article 21.5 DSU proceedings, this Panel should not simply assume that the new scientific evidence submitted by Japan was within the scope of this Panel, but should make an objective assessment of this issue, and explain the reasons for any findings or conclusions it reaches.

5.30 The European Communities also noted that it was not clear from the United States submission whether it was alleging the non-existence of compliance measures. If the United States would allege, for example, the non-existence of measures taken to comply by Japan in relation to certain findings of the Original Panel, such as the findings in paras 8.123 to 8.176 of the Original Panel Report, then that might bring these matters within the scope of these Article 21.5 DSU proceedings. However, the basic question would still remain: were the findings of the Original Panel on these points sufficiently complete and precise to allow the process to move into the implementation phase?

(e) Final Dispute Resolution

5.31 According to Article 21.5 of the DSU proceeding, this Panel might not lawfully re-consider findings or conclusions in the Original Panel Report upheld on appeal, or not appealed. The parties could not make the same claim in respect of the same element of a measure taken to comply, if such claim was disposed of in the original dispute by the Panel or Appellate Body.¹²²

3. Article 2.2

5.32 This Panel must assess whether or not the new elements of the 30 June Detailed Rules adopted by Japan are consistent with Article 2.2. Depending on what was the "measure taken to comply" this Panel might also need to assess whether or not elements of Japan's measure other than those "most obviously" not based on sufficient scientific evidence were consistent with Article 2.2. In

¹²¹ Panel Report on *Japan – Apples*, para. 8.46.

¹²² Appellate Body Report on *Canada – Aircraft (Article 21.5 – Brazil)*, paras. 40 and 41; Appellate Body Report on *US – Shrimp (Article 21.5 – Malaysia)*, paras. 84 to 110; Appellate Body Report on *EC – Bed Linen (Article 21.5 – India)*, paras. 79-99.

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 other international instruments. According to the definition of risk assessment given in paragraph 4 of Annex A to the SPS Agreement and paragraphs 2 and 3 of Article 5, Members should take into account not only scientific but also economic and regulatory considerations. The list of factors to be taken into account in making an "assessment of the risks" was not exhaustive.

5.35 "Based on" does not mean the same thing as "conform to."¹²³ The same risk assessment might "sufficiently warrant" more than one possible SPS measure, depending, inter alia, on the specific circumstances of the legislator. Responsible and representative governments might act on mainstream scientific opinion as well as on divergent scientific views.

5. Article 5.6

5.36 The Original Panel exercised judicial economy in respect of the United States claim under Article 5.6.¹²⁴ The words "and confirmed by the Appellate Body in this dispute" in paragraph 38 of the United States first written submission were therefore factually inaccurate. The United States had not appealed the Original Panel's exercise of judicial economy in relation to Article 5.6.

5.37 A finding of inconsistency with Article 5.6 pre-supposed that a complaining Member could present *prima facie* evidence that at least one other measure existed that was less restrictive than the measure at issue, and which achieved the Member's appropriate level of protection. Footnote 3 of the SPS Agreement confirmed that a panel must find that "there was another measure" in order to find an inconsistency with Article 5.6. Footnote 415 of the Original Panel Report did not change this analysis.

¹²³ Appellate Body Report on *EC - Hormones*, para. 166.

¹²⁴ Panel Report on *Japan - Apples*, paras. 8.299-8.303; Appellate Body Report on *Japan - Apples*, para. 4.

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 for the entry, establishment or spread of fire blight in Japan was central to the DSB's ruling.¹²⁵

5.40 The revised measure presented to the DSB on 30 June 2004 was contained in the Detailed Rules for Plant Quarantine Enforcement Regulation Concerning Fresh Fruit of Apple Produced in the United States of America of 30 June 2004, which amended the 1997 document of the same name ("Detailed Rules of 30 June 2004").¹²⁶ The adjustments to the rules related to three requirements. First, the requirement for a 500 metre buffer zone had been reduced to a 10 metre buffer zone. Second, the inspection requirement had been amended from a requirement of three inspections to at least one inspection per year at the early fruitlet stage.¹²⁷ And finally, the requirement that the harvesting crates be disinfected had been dropped.

5.41 New Zealand argued that Japan's revised measure was substantially equivalent to the original measures in that the changes were of a minor nature and all other trade restrictive and scientifically unfounded aspects of the original measure had been left intact. This included the requirement for certification of export orchards as fire blight-free, that designated export orchards be in Washington and Oregon, for disinfection of apples and harvesting containers and post harvest separation of fruit destined for Japan from other fruit, and the administrative requirements regarding United States official certification and Japanese confirmation of this certification.

5.42 Nothing about the revised measure addressed the point that apple fruit as commercially traded did not pose a risk of transmission of fire blight. Therefore, the revised measure continued to breach WTO obligations and could not be justified on the basis of the record of evidence before the Panel.

2. Japan's justification for the new measure

5.43 Japan had provided new scientific studies and a new risk assessment, which, it submitted, was the basis of the revised measure. Japan did not attempt to justify its revised measure based on the Panel findings and the scientific evidence before the Original Panel proceedings. Instead it brought forth "new evidence" in an endeavour to re-open the key factual findings of the Panel. However, New Zealand contended that Japan had not demonstrated that the evidence was genuinely new or pertinent to the key findings of the Panel. New Zealand agreed with the United States that the new studies failed to contradict or to amend the reams of peer-reviewed and time-tested science on apple fruit and

¹²⁵ Panel Report on *Japan – Apples*, paras. 8.169-8.176.

¹²⁶ New Zealand agrees with the United States' position set out in the Preliminary Request of the United States of 27 September 2004 that the "Operational Criteria" cannot be considered part of the revised measure.

¹²⁷ As noted by the United States, the Detailed Rules can be construed as also requiring a second inspection by Japanese officials. See First Written Submission of the United States, page 9, footnote 16.

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 most vulnerable to natural infection. Secondary spread of fire blight was often concurrent with a flush of new highly susceptible shoot growth. When the fruit approached maturity in late summer, natural populations of *E. amylovora* in apple tree tissue were in decline and had never been recorded as near levels used by Azegami *et al.* (2005), and fruit tissues became less susceptible to *E. amylovora* as they aged.

5.53 The scenario which the study sought to demonstrate could only have occurred naturally when fruit had been damaged by hail in close proximity to high levels of inoculum which were not available in late summer. Damaged fruit were not export quality and were culled out of the harvest in the orchard and packhouse.

5.54 Scientists were unable to infect a mature apple with *E. amylovora* using method c. Azegami *et al.* (2005) were unable to demonstrate the movement of *E. amylovora* across the abscission layer into the mature fruit. They tried to explain this important result by stating that the twigs were drying out after they were taken from the tree and water flow across the layer became limited. In fact the research actually confirmed the findings of Gowda and Goodman (1970)¹³³ that demonstrated that the abscission layer acted as a natural barrier to desiccation and invasion of apple fruit by microorganisms. The failure of Azegami *et al.* (2005) to infect mature apples through the abscission layer in the third experiment was consistent with published scientific evidence that the pathogen primarily moved in the phloem, downwards away from the fruit.¹³⁴ For example, infected scion wood would readily infect associated rootstocks,¹³⁵ whereas infected rootstocks were slow to infect associated scion wood and in such cases trees might not show symptoms of fire blight until the following spring.¹³⁶

5.55 For the circumstance hypothesised by Azegami *et al.* (2005) to occur outside of the laboratory, the high levels of inoculum (that had never been demonstrated to occur in plant tissue in

¹³³ Gonzalez-Carranza *et al.*, 1998. Recent developments in abscission: shedding light on the shedding process. Trends in Plant Science, Vol. 3, No. 1, pp. 10-14 (Exhibit NZ-1).

¹³⁴ Gowda S.S. & Goodman R.N., 1970. Movement and persistence of *Erwinia Amylovora* in shoot, stem and root of apple. Plant Disease Reporter 54, 7. 576-580 (Exhibit NZ-2).

¹³⁵ Wilcox 2004: <http://www.nysaes.cornell.edu/pp/extension/tfabp/firepm.shtml> (Exhibit NZ-3).

¹³⁶ Steiner 2004: http://www.caf.wvu.edu/kearneysville/disease_descriptions/omblight.html (Exhibit NZ-4).

late summer) would have had to cross the abscission layer (which had never been demonstrated to occur) in the two to three day period between the time the fruit became mature and was harvested. The paper did not present evidence to challenge the findings of the experts in the Original Panel that "there was not sufficient scientific evidence to conclude that mature, symptomless apples would harbour endophytic populations of bacteria".¹³⁷

- (b) Tsukamoto *et al.* (2005a) "Infection frequency of mature apple fruit with *Erwinia amylovora* deposited on pedicel and its survival in the fruit stored at low temperature" (Exhibit JPN-9).

5.56 Tsukamoto *et al.* (2005a) sought to extend the hypothetical circumstances described by Azegami *et al.* (2005). They suggested that, in the highly unlikely event that a mature apple fruit harbouring endophytic populations of *E. amylovora* was exported, the bacteria would survive the cool chain process. Tsukamoto *et al.* (2005a) demonstrated that populations of *E. amylovora* could be extracted from the artificially inoculated mature apple fruit held at the atypical storage temperature of 5 degrees Celsius for up to six months. These results could not be extrapolated to commercial circumstances and should be disregarded.

5.57 Once again scientists imposed a series of unnatural circumstances. First, mature apples were inoculated with high concentrations of bacteria through a cut pedicel, thus circumventing the abscission layer. Then, before being stored, the inoculated fruits were held at 25 degrees Celsius for up to nine days giving the bacteria optimal conditions to multiply before being put into cool storage. In contrast, in commercial circumstances, to ensure optimal fruit quality, fruit were cooled to remove the field heat as quickly as possible after harvest. Harvested fruit were processed quickly through the packhouse and rapidly placed in cool stores, or, if fruit could not be packed immediately, it was put into the cool stores in field bins directly from the field until it could be packed.

5.58 Azegami *et al.* (2005) was the only research that purported to show that endophytic populations of *E. amylovora* could be found in mature apple fruit. All published research demonstrated that the only place where populations of *E. amylovora* had consistently been detected on apples being prepared for commercial export was on the calyx. Despite strenuous efforts by many scientists, endophytic populations had never been detected naturally infecting mature apples, and populations of *E. amylovora* had never been shown to survive for long on the surface of apples.

5.59 Taylor and Hale (2003)¹³⁸ demonstrated conclusively that populations of *E. amylovora* on the calyx were in continuous decline and were commonly well below the numbers needed to initiate infection in a susceptible host. Their research showed that even artificially inflated population levels of 10^6 CFUs declined over a 20 day period of cool storage (2 degrees Celsius) to $<10^2$ CFUs, a level insufficient for spread to a susceptible host and to initiate an infection.

5.60 Tsukamoto *et al.* (2005a) stated: "Therefore it is considered that if the migrating *E. amylovora* in the tissues of apple tree can invade the fruit through pedicel, the fruit may become mature without showing any symptoms on the tree. It is highly possible that the symptomless mature fruit harvested from the blighted shoot is infected latently with *E. amylovora*." This statement contained two errors. First, it implied that latently infected mature fruit were a common occurrence whereas they had never been demonstrated other than in the laboratory of Tsukamoto *et al.* Secondly, all previous evidence showed that if *E. amylovora* enters apple fruit before it becomes mature then the fruit does not mature.

5.61 Endophytic populations of *E. amylovora* capable of transmitting fire blight had never been demonstrated in mature fruit and Azegami *et al.* (2005) failed to demonstrate that *E. amylovora*

¹³⁷ Panel Report on *Japan – Apples*, para. 8.128.

¹³⁸ Taylor, R.K. and Hale, C.N. (2003) Cold storage affects survival and growth of *Erwinia amylovora* populations on the calyx of apple. *Letters of Applied Microbiology*. 37 (4): 340-343 pp (Exhibit NZ-5).

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;
- Holding the inoculated mature fruit at a constant 26 degrees Celsius for 38 days; and
- Confining twenty three surface sterilized flies against the cut surface of the inoculated fruit for six hours

5.64 Despite imposing such unnatural conditions Tsukamoto *et al.* (2005b) reported extracting only an average of 2.6×10^2 CFUs from the entire body of the flies. This concentration was insufficient to spread and initiate an infection in a susceptible host.¹⁴⁰

5.65 Undaunted by this result Tsukamoto *et al.* (2005b) then reported that surface sterilized flies were soaked in a bacterial broth of *E. amylovora* at the unnaturally high concentration of 10^9 CFUs/ml for ten minutes. Then these flies were confined with a range of damaged immature apple and pear fruit and plant parts for an unspecified period. Unsurprisingly Tsukamoto *et al.* (2005b) reported that these flies had been able to transmit *E. amylovora* bacteria to the damaged plant parts and immature apple and pear fruit.

5.66 This approach suffered from a number of problems including:

- Concentrations of 109 CFUs/ml of *E. amylovora* had never been reported in the field in late summer. Populations of *E. amylovora* in ooze are short lived.
- When flies came into contact with ooze or rotting fruit, they only contacted the material with their feet and mouth parts.
- The exterior of flies were not sterile; in fact flies were well known to be infested with a vast range of microorganisms many of which would have been antagonistic to *E. amylovora*.

¹³⁹ Taylor, R.K., Hale, C.N., Gunson, F.A. and Marshall, J.W. (2003) Survival of the fire blight pathogen, *Erwinia amylovora*, in calyxes of apple fruit discarded in an orchard. *Crop Protection* 22 603-608 (Exhibit NZ-7).

¹⁴⁰ Taylor, R.K., Hale, C.N., Henshall, A.J.L. and Marshall, J.W. (2003b) Effect of inoculum dose on infection of apple (*Malus domestica*) flowers by *Erwinia amylovora*. *New Zealand Journal of Crop and Horticultural Science*. 31 : 325-333 pp (Exhibit NZ-10).

- 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 probabilities of transmission of fire blight by apple fruit were higher than previously considered.

5.70 Given that, Azegami *et al.* (2005), Tsukamoto *et al.* (2005a) and Tsukamoto *et al.* (2005b) failed to demonstrate their hypotheses, it was difficult to see how Kimura *et al.* (2005) could assign probabilities to these events. Nevertheless, the paper ascribed probabilities to these events while interspersing these probabilities with bona fide probabilities for the movement of *E. amylovora* on planting material, giving the estimated probabilities from Azegami *et al.* (2005), Tsukamoto *et al.* (2005a) and Tsukamoto *et al.* (2005b) an aura of validity by association.

5.71 However, the contrived nature of the endeavour continued to be evident. For example, Kimura *et al.* (2005) stated under "p5 = Probability that infected fruit are discarded", that "Japanese people pare apples, remove cores and consume remaining flesh".¹⁴¹ Yet the hypotheses of Azegami *et al.* (2005), Tsukamoto *et al.* (2005a) and Tsukamoto *et al.* (2005b) were that populations of *E. amylovora* in artificially infected mature fruit were harboured only in the flesh and not in the core. Thus, if the flesh of mature apples could harbour populations of *E. amylovora*, the remaining bacteria would be destroyed when the flesh was consumed.

¹⁴¹ Exhibit JPN-10, Page 18, line 3.

5.72 Similarly, Kimura *et al.* (2005) used the laboratory studies in Tsukamoto *et al.* (2005b) to estimate "p6 = Probability that *E. amylovora* adhere to one or more vector insects". Kimura *et al.* (2005) completely ignored the findings of Taylor *et al.* (2003).¹⁴² This latter paper used very sensitive PCR technology (sensitive enough to detect 10CFUs of *E. amylovora* per insect sampled) to try to detect populations of *E. amylovora* on the bodies of 177 insects of various types collected in an orchard containing discarded infested apples. However, despite the sensitivity of the method *E. amylovora* were not detected on any of the insects collected.

5.73 Further, Kimura *et al.* (2005) defined "p8 = Probability that host plants will be infected with *E. amylovora*", using the results of Tsukamoto *et al.* (2005b) as if they applied to natural field populations. Yet, as discussed, Tsukamoto *et al.* (2005b) had not demonstrated the transmission of *E. amylovora* by flies from rotting fruit to susceptible hosts initiated infection. These results could not generate probabilities that bear any relationship to natural conditions. The four new studies had not established with sufficient scientific evidence that fire blight would be transmitted to a host plant (for either mature or immature fruit).¹⁴³

4. Japan's revised measure and scientific evidence

5.74 Given the failure to displace the record of scientific evidence before the Original Panel, Japan's revised measure continued to be maintained without sufficient scientific evidence. New Zealand agreed with the United States that regardless of whether each requirement was considered singly or the measure was examined as a cumulative whole, the revised measure was maintained without scientific evidence in breach of Article 2.2. The scientific evidence demonstrated that mature, symptomless apples, the commodity that was traded, were not infected with fire blight and that there was no vector for fire blight to be transmitted from infected apples to host plants.

(a) Prohibition of fruit from orchards in which fire blight is detected

5.75 New Zealand submitted that there was no scientific evidence to support this element regardless of whether this element was interpreted as a requirement of fire blight-free status or a requirement that the orchard not be "severely blighted". There was no rational and objective link between the requirement and the scientific evidence. The established evidence did not support a link between commercial trade in apples and the transmission of fire blight. The Original Panel had made the conclusion that there was not sufficient scientific evidence that apple fruit were likely to serve as a pathway for the entry, establishment or spread of fire blight.¹⁴⁴ This was because mature, symptomless apples (i.e. the commodity that was traded) were not infected with fire-blight and because even with regard to apples other than mature, symptomless apples, there was not sufficient scientific evidence that the last stage of the pathway would be completed.

(b) Prohibition of fruit from orchards in which fire blight is detected in a 10-metre buffer zone surrounding the orchard

5.76 New Zealand submitted that there was even less scientific justification for the "buffer zone" requirement than for the requirement that the export orchard to be fire blight-free. Further, as noted by the United States in its second submission, there was an inconsistency in requiring the buffer zone to be blight-free while the export orchard must avoid being "severely blighted". Japan seemed to justify the buffer zone as a necessary requirement to "clearly delineate and define the export orchard", and suggested that in many cases such buffer areas would already or naturally be present in orchards.

¹⁴² Taylor, R.K., Hale, C.N., Gunson, F.A. and Marshall, J.W. (2003) Survival of the fire blight pathogen, *Erwinia amylovora*, in calyxes of apple fruit discarded in an orchard. *Crop Protection* 22 603-608.

¹⁴³ Panel Report on *Japan – Apples*, para. 8.168.

¹⁴⁴ Panel Report on *Japan – Apples*, para. 8.176.

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

(c) Requirement that export orchards be inspected at the early fruitlet stage

5.77 The established scientific evidence did not support the idea that calyx infested apple fruit would harbour populations of bacteria capable of transmitting fire blight. Thus the rational and objective relationship between the scientific evidence and the requirement was missing. In addition, if it was assumed that the point of the inspections was to identify "severely blighted" orchards, the inspection requirement appeared flawed given the lack of clarity around what a "severely blighted orchard" might be.

(d) Requirement that surface of apple fruit be disinfested with sodium hypochlorite (chlorine)

5.78 The requirement that the apples be disinfested with a chlorine solution bore no rational or objective relationship to the scientific evidence that mature, symptomless apples would not harbour fire blight bacteria capable of transmitting fire blight. The suggestion that such chlorine treatments might be an existing part of the United States export process did not obviate the need for Japan to demonstrate a sound scientific basis for its required inclusion as part of the measure.

(e) Prohibition of imported apple fruit from US States other than Washington or Oregon

5.79 New Zealand submitted that this element of the measure was self-evidently not based on scientific evidence. In New Zealand's view, Japan's claim that this was merely a procedural requirement did not assist the Panel in considering whether or not the requirement was based on sufficient scientific evidence, as required by Article 2.2.

(f) Prohibition of imported apples unless other production, harvesting, and importation requirements are met

5.80 New Zealand submitted that the additional requirements of sterilising of the packing facility, post-harvest separation of fruit destined for Japan, and export and import inspections were not maintained on the basis of sufficient scientific evidence. A rational and objective link between the SPS requirements and the scientific evidence was required. The established evidence was that apple fruit did not transmit fire blight because mature, symptomless apples were not infected with fire blight and because there was no vector for transmission of the disease to host plants. As the United States claimed, mere assertions that the "requirements are easily met" or are "procedural in nature" were not enough to demonstrate this link.¹⁴⁵

5. Article 5.1

(a) 2004 Revised Pest Risk Analysis

5.81 New Zealand submitted that the Japan revised measure continued to be in violation of the requirement that SPS measures be based on a valid risk assessment for a number of reasons. It defied logic and credibility to suggest that the revised measure notified to the DSB on 30 June 2004 had been in fact based on a risk assessment not finalised until September 2004 and had been based on scientific studies completed in September 2004, and prospectively dated for publication in 2005.

5.82 The revised PRA was little more than an amplification of the Pest Risk Analysis presented to the Original Panel in 2003 using the results presented in Azegami *et al.* (2005), Tsukamoto *et al.*

¹⁴⁵ Second Written Submission of the United States, para. 48.

(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 for production of symptoms at a later stage.

6.10 **Dr Hale** noted that it was surprising that Japan's submissions and new Pest Risk Analysis were based on new evidence from four research studies (Azegami *et al.* 2005; Tsukamoto *et al.* 2005a,b; and Kimura *et al.* 2005) that: a). which were still in the process of peer review; b). were, as yet, unpublished; and c). contained conclusions that were not substantiated by the data contained in the unpublished manuscripts. Information from a fifth study (Exhibit JPN-16) had been presented on 11 November 2004 together with "Japan's Replies to the Panel's Questions". As such, these manuscripts did not meet the criteria usually applicable in the field of science in providing relevant scientific evidence.

6.11 Dr Hale added that in terms of peer review: the submissions and new Pest Risk Analysis appeared to assume that the outcomes of the peer review would be favourable and that this was an assumption that could not be made if the papers were being peer reviewed by international reviewers who would undoubtedly question the experimental methodology and conclusions drawn from the results presented. This was particularly so as it related to the highly artificial conditions imposed experimentally and the outcomes suggested that differed markedly from previously published information e.g. Thomson (2000), Taylor *et al.* (2003).

6.12 Dr Hale stated that in terms of publication: the submitted manuscripts would undoubtedly require major revision and rigorous editing before they could be considered as acceptable by an international journal. From the timetable submitted relating to the manuscripts it appeared that only the Azegami *et al.* (2005) manuscript had been accepted for publication. However, it could not be assumed that publication of the information in the other manuscripts was inevitable.

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) Exhibit JPN-10 Kimura *et al.* (2005) "The probability of long-distance dissemination of bacterial diseases via fruit." Journal of General Plant Pathology (submitted). Undergoing peer review.
- (e) Exhibit JPN-16 Azegami *et al.* "Entry of *Erwinia amylovora* into apple fruit from fruit-bearing twig through abscission layer at the time of fruit maturation" (Azegami II).

6.14 Dr Hayward added that the fifth investigation (e) had not been subjected to peer review; the methods, results and conclusions had not been critically evaluated by an independent third party. Accordingly these had to be regarded as preliminary results in the category of a "personal communication".

6.15 Dr Hayward stated that the first study a) had been peer-reviewed and was to appear in December, 2004; the second and fourth studies b) and d) were still undergoing peer-review. The third study had been accepted for publication in the Research Bulletin Plant Protection Service Japan. He did not know whether papers accepted for publication in this periodical were independently peer-reviewed in addition to meeting acceptable editorial standards.

6.16 Dr Hayward commented that one of the five studies (Azegami I) met the criteria expected for relevant scientific evidence in that there had been independent peer review, presumably by two referees; the other studies were either still being peer-reviewed, might in one case have been accepted without any peer review and in the case of Azegami II consisted of a preliminary report not subjected to any critical evaluation.

6.17 Dr Hayward noted in regard to Editorial/Refereeing policy that the Journal of General Plant Pathology published by Springer-Verlag Tokyo, had an Editor-in-Chief supported by 19 Associate Editors of whom three are from the United States, two from Korea and one from Thailand, with the remainder from the host country. For most papers in most scientific journals there would be two, sometimes three, referees chosen at the discretion of the Editor, or by a designated Associate Editor, depending on the policy of the journal. In almost all cases the Editor/Associate Editor would take care to protect the anonymity of the referees and the referees reports were regarded as confidential information. There would be variation in the rigour with which papers were reviewed between scientific journals. A journal with a large editorial board and extensive international representation was likely to be one in which papers were reviewed by referees' selected from a wide catchment area, and with the necessary expertise in the subject area of the paper under review.

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 of the Dispute. They would have gained in authority if they had all been accepted for publication, but the fact that they were at different stages in the process did not disqualify them as scientific evidence. The main criticism that could be made of the first three papers was that, in the conduct of a normal research programme, the questions which they left open would have been further investigated, and more results obtained, before the overall results were submitted for publication. The papers individually represented only a small volume of research, and did not go into depth (but one understood why this was so). The fourth paper was in a different situation, because it was addressing a different question (providing specific input to the PRA). It was debatable whether calculations of risks associated with different pathways in a PRA needed to be published at all; they could be considered as an integral part of a PRA.

Question 2: Please comment on New Zealand's categorization of the new studies relied upon by Japan in these proceedings (para. 20 of New Zealand third party Submission).

6.19 **Dr Geider** stated that direct or fly-mediated fruit contaminations could be done under laboratory conditions and that they might even occur in orchards. He personally considered accidental contamination during harvest of fruits most crucial. All arguments about disease carriers such as flies might touch a minor impact. Insects might visit rotten fruits and carry bacteria to other locations. These flies would not typically visit flowers. To be safe, fruit processing for export had to be reliable for the origin of apples and fruit inspections should confirm the good conditions of the apples. The chance of fire blight dissemination by healthy looking fruits seemed to be extremely low or even zero.

6.20 **Dr Hale** noted that under extremely artificial experimental conditions it might well be possible to produce the results claimed in Japan's submission for apple infection, contamination of flies, and transmission of bacteria in no choice situations. However, these conditions did not relate to the real-life situations likely to be encountered. It was unlikely that high levels of *E. amylovora* inoculum were associated with mature apples at harvest time, there was no scientific evidence of high concentrations of *E. amylovora* associated with flies, and the no choice situations imposed in the experimentation did not relate in any way to nature. The results of the experiments reported did not provide convincing scientific evidence that mature fruit could be infected, or that flies could complete the disease pathway for introduction and establishment of fire blight under the normal environmental conditions likely to be associated with commercial apple production.

6.21 **Dr Hayward** stated that he agreed with the New Zealand assessment of the Azegami I and Tsukamoto II studies in paragraph 20 a), b) and c) of the Third Party New Zealand submission dated October 19, 2004.

6.22 **Dr Smith** pointed out that the New Zealand categorization related to the significance and relevance of the results of the new studies, which was covered by the questions under 3 below. Implicitly, it also questioned whether the results were "new". However, the results were clearly new, in any ordinary sense. What was in question was whether they shed new light on the risks associated with importing mature, symptomless apples.

Infection of fruit

Question 3: With respect to the Azegami study (2005):

- (a) **Does the scientific evidence demonstrate that an intact abscission layer is effective in preventing the spread of the bacteria into fruit?**

- (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 experiments could not easily be designed to answer the question. A mature apple with a low amount of *E. amylovora* might have been infected as a flower. It was impossible to show absence of *E. amylovora* in an apple at one time and colonization by the bacteria later, because the assays relied on destruction of the fruit.

6.25 Addressing question d, Dr Geider noted that again this was experimentally difficult. The sources of a fire blight infection in a narrow area could be multiple. Nevertheless, concerning invasion of *E. amylovora* from a twig, several points about natural infections should be considered. Fire blight was mostly established in a host plant by pathogen transmission to flowers. To a lesser extent, young shoots could become infected by contaminated insects resting or feeding on the succulent tissue. The disease then would migrate from the infection site into lower parts of the plant. It had not been clearly shown if the bacteria actively moved by swimming against the vascular water flow or if they were absorbed when the flow was reversed in some situations during a day. This might occur after environmental changes of temperature and humidity.

6.26 Dr Geider noted that with respect to host plant species, many cultivars of European pear could develop systemic symptoms, ie. *E. amylovora* spread to most or all parts of the tree. For apple trees, symptoms were mostly restricted to branches adjacent to the infection site. At all times, pathogen invasion was largely promoted by young plant tissue, with Spring as the shooting season. In late Summer, the risk and occurrence of new fire blight incidence decline. Migration of *E. amylovora* from an infested branch into a disease-free branch and then into apple fruits seemed unrealistic from the known infection steps. Pears might be more open for wide pathogen invasion on trees, but certainly not apple trees. Apples ripen on seasonally old twigs expanded in Spring. Late infection of those branches from adjacent plant tissue was unlikely to occur in a late growth season.

6.27 **Dr Hale** noted that for question a, when fruit was mature the abscission layer was intact. In Azegami *et al.* (2005) the evidence suggested that *E. amylovora* did not pass through the abscission layer into the pedicels and into the mature fruit. Internal *E. amylovora* had only been isolated from fruit when inoculations had been made on cut pedicels. Azegami *et al.* (Exhibit JPN-16) suggested that *E. amylovora* could pass from twigs, through the abscission layer into pedicels, and into mature

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 could serve as a useful guide in seeking to detect latent infections under natural conditions, but the study did not provide any results on latent infection under natural conditions. The fact that the spread in the flesh was a purely physical process and not an active "invasion" did not alter the fact that bacteria entering through the pedicel spread within the flesh. The Azegami study and the other infection study did usefully confirm that bacteria latently (though unnaturally) present in fruits could remain there alive for relatively long periods of storage.
- (d) The only relevant experiment on this point in Azegami (I) had given a negative result. Other experiments could be designed to investigate this point further, but the scientific evidence presented in Japan's first submission did not demonstrate that bacteria in a twig could infect mature fruits at any time. Azegami (II), introduced at a later stage, was such an experiment. It contradicted Azegami (I) in that bacteria were found in the fruits, the main difference in the experimental conditions being that the fruits were examined 3-4 weeks after the twigs were inoculated, not one week. The US Comments on these results were pertinent, and the situation was now confused. A more substantial study was needed to clarify what is going on.

Question 4: Does the scientific evidence, taking also into account the Azegami study, support Japan's statement that "If activities of the bacteria, which are known to peak during the flowering and fruitlet seasons, remain relatively dormant after the spring, apples which harbour the bacteria at a certain level will be likely to develop symptoms well in advance of maturity, as the Original Panel found. However, *there is no evidence to suggest that this is the case, and the question of whether or not bacteria will still infect the apple fruit through the pedicels or wounds at the late season will depend on various conditions.*" (para. 14 of Japan oral statement - emphasis added)

6.33 **Dr Geider** stated that he was not aware of such evidence, but fruits could become infected late by wounding and that local necrosis developing into soft-rot predominantly be caused by microorganisms other than *E. amylovora*. The experiments by Azegami *et al.* (2005) confirmed old data of Dueck (1974) about persistence of *E. amylovora* in artificially inoculated apple tissue.

6.34 Dr Geider added that in the Azegami study apples were not only inoculated at the surface but also applied to the apple stem. Twig inoculation might get closer to trees, but it should be realized that bacteria brought to wounds of detached plant parts might become sucked into the tissue by the water flow driven by evaporation on the large surface of the fruit. This passive movement of cells had even been discussed for shoot tip inoculations. Wild type strains distributed differently from non-pathogenic mutants or even latex particles, because virulent *E. amylovora* cells were able to grow in young host tissue.

6.35 **Dr Hale** noted that the activities of *E. amylovora* were well known to peak during flowering and fruitlet development periods (Thomson 2000). The most probable origin of inoculum to enable the fire blight cycle to commence in spring was the spread of bacteria from overwintering cankers to open flowers. Once flowers had been infected, infection of fruitlets could take place together with secondary spread of the bacteria to give shoot infections during late spring and early summer. Further secondary spread was from these infected tissues providing inoculum for spread to other newly emerging susceptible shoots. Fruitlets harbouring high levels of *E. amylovora* would develop symptoms and were likely to abort or show abnormal development resulting in shrivelling well before maturity. It had been shown that very lightly infected flowers might develop into mature fruit and *E. amylovora* may survive in the calyxes of these fruit (Hale *et al.* 1987).

6.36 Dr Hale stated, however, until the new information provided by Azegami *et al.* (2005) there had been no suggestion that apple fruit were infected late in the season when apples were mature and ready to be harvested. Azegami *et al.* (2005) suggested that inoculation of cut pedicels resulted in latent infection of mature apple fruit by active movement of *E. amylovora* through the vascular tissue and into the fruit. However, it was possible that the bacteria applied to the cut surfaces of the pedicels were drawn into the fruit by transpiration rather than by an active invasion of fruit tissues. Azegami *et al.* (2005) also showed that mature fruit could be infected through wounds by artificial surface inoculation. This had also been reported by McLarty (1923) and Anderson (1952). However, there were no published scientific reports of natural infection of mature fruit through pedicels, and fruit infection from surface inoculation did not appear to be a common phenomenon in mature fruit under natural orchard conditions.

6.37 Dr Hale noted that in a severely blighted orchard, infection of trees was most likely in the spring as a result of flower and shoot infection. Fruit that were infected either through the pedicel in the early part of the growing season, or from secondary spread in the orchard would be immature and would not develop into mature fruit. Therefore harvesting of mature, symptomless fruit from severely infected orchards was unlikely.

6.38 **Dr Hayward** replied that the available scientific evidence did not support the statement by Japan. That there could be a late season infection event in a severely infected orchard as a consequence of storm activity was a plausible hypothesis. Roberts (2002) had not provided any evidence of such rare, hypothetical events. Storm activity sufficient to lead to infection through a damaged fruit spur or abscission layer would probably also lead to damage to fruit which would be culled out prior to export.

6.39 Dr Hayward commented that in general epidemiological studies on sources of inoculum and modes of dissemination were best carried out under field conditions in countries or regions where a disease was endemic. In a country where the disease did not occur work, if it was contemplated at all, should be contained and limited to a PC3 laboratory or to a quarantine glasshouse, as in the case of Azegami I and II and Tsukamoto I and II. Their studies were carried out under highly artificial conditions. Fundamental questions about disease epidemiology could be answered on an agreed collaborative basis between countries affected or threatened by the disease.

6.40 **Dr Smith** noted that Japan's statements suggested that apples might acquire bacteria early in the season and, rather than develop symptoms, remain latently infected to maturity. There was, however, a considerable body of evidence that *E. amylovora* was not isolated from mature apples. This did not altogether exclude the possibility that a small number of such latent infections do occur, but no new evidence was given on this point. The question whether mature apple fruits could be infected at a late stage through the pedicels was addressed by the contradictory results of Azegami (I) and Azegami (II) (cf. above). The evidence available still did not show that latently infected mature fruits existed at all under natural conditions, but the Azegami results provided a basis for further research to determine this.

Question 5: Do you concur with the US statement that "if ... the pedicel is a conduit for entry of bacteria into maturing apple fruit, the numerous earlier studies on mature, symptomless apple fruit harvested from severely blighted trees would have isolated bacteria within the fruits' tissues"? (para. 18 of US oral statement)

6.41 **Dr Geider** stated it was thought that fruits get fire blight from flower infections followed by bacterial migration into the developing fruit and not from stem infections.

6.42 **Dr Hale** noted that if *E. amylovora* enter fruit through the pedicel as they mature it was almost certain that the detailed studies conducted (Roberts *et al.* 1989; Dueck 1974) would have

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 distinction between the core and the cortex of an apple? Please comment on Japan's arguments that previous studies regarding the existence of *E. amylovora* inside of apple fruit relied on examinations only of the core of apples and not of the cortex. Please comment on the relevance, if any, of the studies by Roberts (2002), Roberts (1989) and Dueck (1974) in this regard. (See para. 27 of US second submission, US reply to Question 5 of Japan and Japan's comment on the US reply.)

6.45 **Dr Geider** stated that the cortex of plants was defined as exodermis of tissue, such as the cortex involved in water uptake of roots or the bark of stems. Core should be the center part of an organ. The definition might be expanded to apples (skin/apple core). A gradient of *E. amylovora* within inoculated fruits could be shown using gfp-labeled bacteria. A gradient would exist from the inoculation site of *E. amylovora* to other parts of the apple tissue.

6.46 **Dr Hale** noted that there was a distinction between core and the cortex of an apple. However, it should be noted that these two areas of the apple fruit were connected by their vasculature as the vascular bundles of the cortex and core tissues were contiguous.

6.47 **Dr Hale** commented that Roberts *et al.* (1989) had, in fact, examined both core and cortex tissue, the stem, and calyx tissue of apple fruit from severely blighted trees and had been unable to detect *E. amylovora* in any of these tissues. This confirmed the result of Dueck (1974) who had also found that *E. amylovora* was not isolated from the internal tissues of mature apples harvested from severely infected trees. Although Japan commented that both Dueck (1974) and Roberts *et al.* (1989) had targeted the core tissue it seemed clear that vertical cores taken through the fruit included stem, cortex, core, and calyx tissues. Although Roberts (2002) had examined mainly core tissue, cortex tissue was likely to have been associated with the core tissues sampled.

6.48 **Dr Hayward** replied that insofar as the vascular tissue of the apple fruit cortex was contiguous with the vascular tissue of the apple fruit core there was no clear physiological distinction between the core and cortex of the apple. It was not possible to make a separate estimation of the bacterial population of the core of the apple distinct from that of the apple cortex or "flesh", at least not under routine conditions. In the work of Roberts (2002) mature apple fruit had been surface sterilized by immersion in hypochlorite, sonicated, rinsed in sterile water, and the core of the fruit removed with a sterile cork borer. The stem and calyx ends of the sample had been excised with a sterile scalpel and discarded. The remainder of the core sample would have included a portion of the cortex and "flesh" of the apple. The argument from Japan that previous studies regarding the existence of *E. amylovora* inside of apple fruit were not comparable to Azegami I and Tsukamoto I, because the latter studied only "flesh" populations and the earlier studies only core populations, was not supported.

6.49 **Dr Smith** noted that there was a clear anatomical difference. It was not clear what was meant by a physiological difference or why this should be relevant. Both Roberts (1989), and Dueck (1974) explicitly referred to the sampling of cortex tissue. Roberts (2002) referred only to the sampling of

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 recovered from the internal tissues of fruits.

Question 8: In the light of the Azegami study or any other recent scientific developments, would you wish to modify your reply to Questions 2 and/or 10 from the Original Panel proceedings?

6.55 **Dr Geider** stated that artificial inoculation had to result in fruit with bacteria. Tissue of apples was a sterile environment, suited for persistence of *E. amylovora*. No defense reactions of fruits were known to quickly diminish the *E. amylovora* population as in HR lesions of non-host plants

6.56 **Dr Hale** noted that the results of Azegami *et al.* (2005), although suggesting that mature fruit could be invaded by *E. amylovora* after artificial inoculation of cut pedicels, did not provide convincing evidence that mature fruit were likely to become infected under natural conditions in an orchard. Low level flower infection could lead to *E. amylovora* infestations of calyx tissues (Hale *et al.* 1987). However, this did not result in fruit infection. As a consequence there was no published evidence to suggest that mature apple fruit had been shown to be infected internally under natural conditions, or that they had ever been implicated in the introduction and establishment of fire blight in an area free of the disease.

6.57 Dr Hale commented that apart from the unpublished Azegami *et al.* (2005) study of cut pedicel inoculations there was no evidence to suggest that mature, symptomless apple fruit had been endophytically contaminated with *E. amylovora*. Consequently, endophytic *E. amylovora* were extremely unlikely to be responsible for the establishment of new disease outbreaks.

6.58 Dr Hale concluded that the evidence provided did not suggest that mature, symptomless fruit were a source of endophytic *E. amylovora* in nature, or that they were involved in the spread of the disease.

6.59 **Dr Hayward** replied that he had not been persuaded by the studies of Azegami I, Azegami II or Tsukamoto I, or any other scientific developments, to change his answers to Questions 2 and 10 of the Original Panel proceedings.

6.60 **Dr Smith** stressed that he stood by what he replied in the Original Panel proceedings. The suggested scenario of Japan was that bacteria might enter mature fruits, from infections on twigs, through the pedicels, and be carried by the vascular system of the fruit to the cortex, where they might persist as a latent infection. There was no direct evidence that this happened under natural conditions. It seemed implausible that earlier studies on the isolation of bacteria from inside fruits, which included cortex, somehow had failed to detect these infections.

Contamination in orchards

Question 9: In the September 2004 PRA, Section 2-3-1-1(2)(A) indicates that "...the physiological activity of the bacteria inside the trees does not appear to be declining during the seasons (sic)". However, the section then makes reference to Norelli et. al (2001) which mentions that "... the bacterial activity is still recognizable during the late growing season". That bacteria can still be found does not appear to confirm a statement of no decline in bacterial activity. Please explain. (See Japan's reply to Question 23 of the Panel and US comments on Japan's reply.)

6.61 **Dr Geider** clarified that due to the limited amount of data in his lab about events spreading fire blight in orchards, he could only add a few personal remarks.

6.62 Dr Geider stated that usually, the most active starters for fire blight in Spring were oozing cankers on stems. There had been a claim that an *E. amylovora* population inside trees did not result in spread of the fire blight provided that all cankers had been removed or protected against insects. It could be asked how *E. amylovora* persisted in trees apart from tissue with symptoms. Cankers were oozing heavily in Spring and declined later in season with lower root pressure. Bacterial activity could be defined as spread in plant tissue, which was associated with young shoots or leaves. Second bloom of pears might have provided a boost of bacterial activity, but this might not have affected invasion of fruits if any.

6.63 **Dr Hale** noted that there did appear to be some confusion in these statements. That bacterial activity was still recognisable did not necessarily suggest that this was an important factor in the

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 evidence did not support the concept of continuous movement of the bacterium through the plant throughout the growing season.

6.65 **Dr Smith** noted that "activity" of the bacteria was a vague concept. Here were some things that bacteria could do: multiply; produce enzymes or other substances which damage the host tissues and cause local symptoms; move within the plant; multiply to such an extent, with production of extracellular polysaccharide, that a "bacterial ooze" was secreted on the surface of the plant; be carried to other plants; just survive. They could also die out. Most of these activities happened in spring. Later, bacteria generally stopped causing damage and stopped oozing, and thus stopped spreading to other plants, but they might still multiply to a certain extent, they might still move in the plant, and they certainly survived (at least some of them). It was by no means clear what the PRA meant by activity, or what Norelli *et al.* meant by activity. Hence the confusion.

Question 10: Japan contends that the fire blight freedom requirement is applicable not necessarily at the orchard level but at a sub-orchard (production site) level as long as this sub-unit is surrounded by a fire blight-free border zone (para. 43 of Japan's second submission and the Operational Criteria). How is an orchard defined for export purposes? Is this based on international agreement(s) or common practice, or does it differ for different fruits, and/or different countries? Please comment on any scientific evidence or literature relating to border zones and their effect on the fire blight status of an orchard (or sub-orchard). Does it depend on the "varieties" of apple trees in terms of their susceptibility to fire blight? (See US and Japan's replies to Question 5 of the Panel and Japan's comment on the US reply.)

6.66 **Dr Geider** stated freedom from fire blight could not be rigorously shown in an orchard. Border zones were mostly connected with the distance of bee flight, but there were all kinds of transitions possible including fire blight susceptibility of apple cultivars.

6.67 **Dr Hale** noted that there did not appear to be a clear definition of an orchard based on any international agreement. The term orchard in common practice usually referred to a production area under a single management structure. For export purposes in many countries orchards were registered with a grower organisation with a number that appeared on packaging, and even on each piece of fruit, that could be used for traceability purposes by regulatory authorities, wholesalers, and supermarkets. Within an orchard there were likely to be different fruits and different varieties of fruits being grown. These were commonly designated as orchard blocks in many countries.

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 Criteria for the Exportation of US Apples to Japan (Exhibit JPN-2) proposed an annual inspection from a buggy car designed to scan the exterior of apple trees inside the orchard for typical symptoms on large branch(es). The assumption was made that identification of a single fire blight strike was predictive of severe fire blight throughout the entire orchard. An orchard could not be designated as severely blighted without a thorough examination of the orchard. It was entirely possible that an orchard in which one infected tree had been identified was lightly infected rather than severely blighted.

6.76 **Dr Smith** stated that such procedures certainly existed in Europe, since orchards falling within fire blight buffer zones (for nurseries) had to be monitored. But he did not have details. On the whole, nurseries with fire blight host plants were not set up anywhere near orchards; it saved trouble.

Question 12: Is there a commonly accepted definition in the scientific literature of what is a "blighted" orchard with respect to fire blight? A "severely blighted" orchard? (See Japan's reply to Question 14 of the Panel.)

6.77 **Dr Geider** stated that there should be no severely blighted commercial orchards. In that case, the orchard was not suited for fruit production and the trees had to be removed. An orchard with only one fire blight strike was a blighted orchard and should be handled with care for fruit trade to fire blight-free countries.

6.78 **Dr Hale** noted that there did not appear to be commonly accepted definitions in the scientific literature of "blighted" or "severely blighted" orchards. Hale *et al.* (1987) had used the term "severely blighted" for orchards containing an average of 75+ fire blight strikes per tree. However, the authors had not been specifically attempting to provide a definition of the severity of blight in an orchard for inspection purposes. They had been providing a numerical value to show the numbers of strikes per tree in an orchard and the relationship with the presence or absence of *E. amylovora* associated with the surfaces and calyxes of mature, symptomless fruit. It should be noted that *E. amylovora* had not been detected on the surfaces of any fruit from an orchard with 75 fire blight

strikes per tree, and only from calyxes of <1 per cent of the mature, symptomless apples harvested. *E. amylovora* had not been detected on the surfaces or in the calyxes of any of the fruit from orchards with an average of 1-2 fire blight strikes per tree.

6.79 Dr Hale commented that it should be mentioned that an orchard with 75 strikes per tree would, in fact, require very little inspection, as this level of infection in trees would be very obvious by even a cursory glance. Consequently, the comments from the Japanese inspectors (Exhibit JPN-15), who found orchards with "an apple tree with a symptom of fire blight" did not suggest that the orchards would have been "severely infected (blighted)" - despite the lack of a commonly accepted definition.

6.80 **Dr Hayward** replied that a severely blighted apple orchard was one in which there are 75 infections per tree (Hale, McRae and Thomson, 1987) or 50-100 strikes per tree (Exhibit JPN-13 Letter from Sherman Thomson to Rodney Roberts, August 23, 2002). A lightly infected orchard would be one in which there were 1-2 terminal shoots infected per tree (Hale, McRae and Thomson, 1987).

6.81 **Dr Smith** stated that there were no such definitions (though Dr Hale had suggested one at the time of the Original Panel). Simplistically, one could consider, since *E. amylovora* was a quarantine pest, that a blighted orchard was one where any fire blight had been detected. A severely blighted orchard could be one where symptoms of the disease could be found without difficulty in any part of the orchard. But these were just suggestions.

Question 13: Does the available scientific evidence demonstrate that imports of mature apple fruit from severely blighted orchards could complete a pathway for introduction of fire blight into an orchard?

6.82 **Dr Geider** stated that due to a rare long distance spread of fire blight, only plant trade could be connected with the introduction of fire blight.

6.83 **Dr Hale** noted that the available published scientific evidence suggested that imports of mature, symptomless apple fruit from "severely blighted" (75 strikes per tree) orchards would not provide a pathway for the introduction of fire blight into an orchard. Hale *et al.* (1987) had shown that *E. amylovora* had been isolated only from <1 per cent of the calyxes of mature, symptomless fruit harvested from a "severely" blighted orchard. Hale *et al.* (1996) and Taylor *et al.* (2002, 2003) had found no evidence that *E. amylovora* in the calyxes of mature, symptomless fruit could be disseminated to susceptible host tissues in an orchard under natural conditions.

6.84 **Dr Hayward** replied that the available scientific evidence did not demonstrate that imports of mature apple fruit from severely blighted orchards could complete a pathway for introduction of fire blight into an orchard.

6.85 **Dr Smith** commented that in theory, the pathway as far as the entry into Japan of an apple carrying living bacteria could be achieved in two ways: a) by bacteria being splashed onto the apple from the severely blighted tree and then persisting epiphytically (which they would do for a limited period only, and which could be prevented by surface disinfestation); b) by the establishment of a latent internal infection (as noted above, it remained controversial whether this could happen at all; accumulated scientific evidence strongly suggested that, if it could, this remained a rare phenomenon). The completion of the pathway into the orchard then depended on a succession of conjectural events whose reality was still not demonstrated.

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 *E. amylovora* that were capable of disseminating fire blight. The unpublished information presented in Azegami *et al.* (2005) was from work carried out under artificial inoculation conditions and could not be considered to be relevant to the issue under dispute. Finally there was no scientific evidence that mature, symptomless apple fruit had ever been involved in the introduction and spread of fire blight worldwide despite many decades of trade in the commodity. Consequently, no buffer zones of any size were justified as a means of reducing the risk of fire blight transmission on mature, symptomless apple fruit.

6.88 **Dr Hayward** replied that none of the new scientific evidence in his possession was sufficient to change his answer to Question 24 from the Original Panel, or sufficient to discount the evidence of Roberts (2002).

6.89 **Dr Smith** stated that he would not modify his answer. But it did seem that Japan had responded to the experts' views on this point by reducing the width of the buffer zones from 500 to 10 m. With the addition of the idea that the working unit was a production site within the place of production (see 10 above), the area which was disqualified for export as a result of a single find of fire blight was very much less in the new measure than in the old (contrary to the suggestions of the US submission).

Post-harvest treatment of apple fruit

Question 15: According to Japan's MAFF Notification No. 354, US apples "must be treated with pulp temperature at 2.2 degrees for 55 days in a cold treatment facility" (item 4(1)a, in Exhibit USA-7). New Zealand contends (paras. 41-43 of its third party submission) that the Tsukamoto study (2005a) is not representative of commercial circumstances since, in the experiment, artificially infected apples were subject first to a temperature treatment of 25 degrees for up to 9 days before being stored at 5 degrees for up to 6 months. To what extent are the results of the Tsukamoto study (2005a) relevant given Japan's post-harvest cold treatment requirement? (See Japan's replies to Questions 9 and 17 of the Panel, US replies to Question 9 of the Panel and Question 7 of Japan, and New Zealand's reply to Question 5 of the Panel.)

6.90 **Dr Geider** stated that the preprints by Tsukamoto *et al.* and by Azegami *et al.* show persistence of *E. amylovora* in artificially inoculated apples at various temperatures. If apples became contaminated by chance, *E. amylovora* would survive for a long time. Too many requirements had to be realized to establish fire blight from these fruits in an orchard. An example could be given from a commercial apple orchard in the Heidelberg area of Germany. A small lot of quince trees had been heavily fire-blighted. They had confirmed the presence of *E. amylovora* by several detection methods, and could not find a difference to other "fruit tree" strains. The diseased lot had been kept in this stage for several years due to labor shortage. The adjacent apple trees in 5 m distance had not developed fire blight during that time or later, probably due to different blooming periods of apple and quince.

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 reused.

6.100 **Dr Hayward** replied that there was no new evidence showing that contaminated fruit boxes would infect/infest apple fruit since the Original Panel proceeding; accordingly he saw no reason to change his response to Question 31. Unused, disposable cardboard boxes were used by US industry. Wooden crates had ceased to be used long ago. There was still speculation about the involvement of blighted pears and wooden crates in the first outbreak in the UK in 1955-57, but no new evidence (Billing and Berrie, 2002).

6.101 **Dr Smith** noted that the 2004 PRA referred back to old ideas about fruit boxes. His reply to Q 31 still applied: these ideas were conjectures in the first place, and had been in practice disregarded ever since (except by repetition in reviews), since practically no research has been done on this possibility. It was not enough for PRAs to quote possibilities from old scientific literature; they also had to be technically evaluated in the light of more recent information. Note that there was a recent article - Ceroni *et al.* (2004), Survival of *Erwinia amylovora* on pears and on fruit containers in cold storage and outdoors, *Bulletin OEPP/EPPO Bulletin* **34**, 109-115 - on the duration of survival of *E. amylovora* on wood and plastic containers and on packing materials. This gave a maximum figure of 77 days survival on wooden boxes in cold store. The article did not investigate whether such contamination can in fact lead to spread, or to the contamination of fruits.

6.102 **Dr Smith** added that in the present context, it was also interesting to refer to the article of Billing & Berrie (2002) A re-examination of fire blight epidemiology in England. *Acta Horticulturae* no. 590, 61-67. Though the article was mainly concerned with how fire blight spread in England, it also re-examined how it might have arrived, and raised several issues that were very relevant to the points under discussion. The article suggested again that fruit boxes had been involved. However, it further suggested that 1954 was a severe blight year in California, leading to some post-harvest rotting. It suggested that lots of pears imported into southern England included some rotting fruits, or rotted in transit, that these lots had been discarded in rubbish dumps and that *E. amylovora* had then spread to host plants by insects or birds. Thus, the suggestion was that the pathway in question in this Dispute had in fact been completed (at least on pears) in the 1950s when fire blight first arrived in England. However, the only new element in this suggestion was the fact of the severe fire blight outbreak in California in 1954. It was only conjectured that: *E. amylovora* rotted the pears (though *E. amylovora* was not normally understood to cause any post-harvest rotting, so other organisms had presumably been responsible); that it had survived transit in rotted pears and discarding to rubbish dumps; that such discarding actually took place to a significant and unusual extent; that there had been then a pathway to hosts. The article also indicated that pears had been imported from USA to

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** noted that whilst a level of sanitation was likely to be the normal situation in most packing/sorting facilities there was no reason for it to be a mandatory requirement as there was no published scientific evidence to suggest that mature, symptomless apple fruit could be infected with fire blight from contact with packing/sorting lines.

6.105 Dr Hale noted that it was possible that mature, symptomless apple fruit from "severely blighted" orchards (75+fire blight strikes per tree) might be infested with small populations of *E. amylovora* in calyxes (Hale *et al.* 1987). However, there was no scientific evidence of surface contamination of fruit from these orchards. Consequently, there was very little likelihood of contamination of packing/sorting lines or other fruit, and no likelihood of infection from these sources.

6.106 **Dr Hayward** replied that he had no comment to the first question. To the second, he had not been able to find any scientific evidence that *E. amylovora* had been spread through packing/sorting lines to non-contaminated fruit. Since the cardboard boxes used for packing apples in the United States were being used for the first time there was no possibility of infestation/infection of apples occurring through contact with the surface of the box.

6.107 Dr Hayward noted that upon rereading the evidence on this subject, and the description of the procedures used by the United States he would change the last two sentences in para. 6.151 of the Original Panel proceedings to read as follows: If apples were harvested either from a disease-free orchard or one in which there was a low level of infection a post-harvest treatment should be avoided, unless required for other reasons.

6.108 **Dr Smith** noted that he was not in detail familiar with the cleaning procedures of packing facilities. Nor did the Japanese requirements seem very specific (disinfection of the "interior" with sodium hypochlorite prior to use and whenever necessary). Maybe this hardly went further than normal good-practice cleaning. In the PRA, the purpose and effectiveness of disinfection of facilities was hardly touched on. The path from a contaminated fruit to a healthy one was not explored (in fact mere contact seems insufficient; there would have to have been movement of liquid from one surface to another, e.g. during washing). The problem in packing facilities was much more that fruits from an uncertified source should accidentally be mixed with fruits for export, and exported (disinfection is of no relevance to this). There was no scientific evidence that *E. amylovora* had spread to non-contaminated fruits through packing/sorting lines.

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 endophytic populations of *E. amylovora*, were cooled immediately after harvest and cool stored immediately after packing. Any delays in cooling of apple fruit after harvest could have a major impact on the storage life of cool stored fruit (Hardenberg *et al.* (1986) – as suggested in the United States response to Question 9 from the Panel. In fact, Hale & Taylor (1999) had showed that cool storage of mature, symptomless apple fruit reduced the survival of *E. amylovora* in calyxes of both naturally infested and artificially infested fruit. Taylor & Hale (2003) also had reported that, although *E. amylovora* had the ability, in nutrient media, to multiply at low temperatures, populations of *E. amylovora* in the calyx tissue had declined with time spent in cold storage.

6.111 Dr Hale commented that there was no scientific evidence presented that changed the response to questions from the Original Panel proceeding relating to the likelihood of *E. amylovora* associated with apple fruit surviving normal commercial shipping and export procedures.

6.112 **Dr Hayward** replied that Taylor and Hale (2003) had provided new evidence, to add to that of Hale and Taylor (1999), that cool storage of mature, export quality apples in either the laboratory at 0 degrees +/- 0.5 degrees Celsius or a commercial pack house (2 degrees +/- 0.5 degrees Celsius) reduced the survival of *E. amylovora* in calyxes of both inoculated and naturally infested fruit. The new scientific evidence presented by Japan purported to show that there could be mature, symptomless, latently infected fruit, but the occurrence of such an entity under natural conditions was unproven. The calyx of the fruit was the only known protected site for survival of residual low level populations of the pathogen but these might have been eliminated during cold storage.

6.113 **Dr Smith** stated that it was no longer quite clear to him what was meant by "normal commercial procedures" in this context, and whether this involved any disinfection. But the new evidence did not significantly change the situation on survival of bacteria on fruit. The bacteria survived a certain time but progressively died out, more quickly on the surface than when protected, e.g. in the fruit calyx. The effect of temperature and of position in the fruit remained to be fully explored.

Potential pathways for transmission of *E. amylovora* via apple fruit

Question 19: In paragraphs 30-31 of its second submission, referring to the Pathway Study (Tsukamoto 2005b) Japan mentions that flies contaminated by bacteria in a beaker did not directly become the source of infection. Japan then makes reference to the two major discoveries of the study and concludes that the combination of infected apple fruit, flies and suitable host plants pose a risk of completion of a pathway of the disease. Do you concur with Japan's argument that this is the "logical" conclusion from the Pathway Study, and that this identifies a scientifically probable risk? (See also Japan's reply to Question 19 of the Panel.)

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 blighted pear orchard carried *E. amylovora* and had been probably involved in secondary spread of fire blight as they visited flowers in search of nectar. Taylor *et al.* (2003) had not found *E. amylovora* contaminating trapped insects in a flowering orchard in which heavily infested mature apple fruit had been discarded. Pollinating insects had been reported as major distributors of fire blight (Hildebrand *et al.* 2000). However, these insects were unlikely to visit both infected fruit and susceptible plant tissues such as blossoms.

6.119 Dr Hale noted that to date the available information could not be shown to support the conclusion that there was a scientifically probable risk that a pathway could be completed.

6.120 **Dr Hayward** replied that the Pathway Study (Tsukamoto II) had been carried out under highly artificial laboratory conditions. *E. amylovora* was a bacterial pathogen which did not produce resistant resting cells; the vegetative cells were subject to the effects of desiccation, and to the effects of cyclical wetting/drying found in the natural environment (which lead to deleterious changes in water activity). UV irradiation and heat exposure and diurnal temperature variation were other adverse factors in the environment. There were also biotic factors involved including predation or antagonism by other microorganisms. *E. amylovora* did not compete well with its saprophytic relatives such as *Erwinia herbicola* (synonym: *Pantoea agglomerans*) which occurred commonly as secondary invaders in moribund plant tissue. Insect species had characteristic patterns of behaviour, substrate and host preference. The Tsukamoto II experiments eliminated all of the critical factors of

the natural environment. In view of the artificiality of the experiment he could not accept the logicity of the conclusion that the pathway apple fruit, flies, suitable host plants had been established.

6.121 Dr Hayward further noted that there was a very extensive literature on the role of insects in secondary dissemination of fire blight from cankers to flower blossoms (Thomson, 2000; Schroth *et al.* 1974).

6.122 **Dr Smith** commented that it was interesting to note that the mention of Japan ("that flies contaminated by bacteria in a beaker did not directly become the source of infection") was not directly supported by the reported results of the Pathway Study. There was no record in the Study that this possibility had been investigated. One would certainly have expected this experiment to have been done (and the reply to Question 19 suggested that it was, though it was not reported). In any case, the lack of such a result much weakened the claim that a pathway had been demonstrated. The two discoveries were indeed new, but the results obtained were not altogether surprising. By suitable adjustment of bacterial numbers, time of exposure, containers, etc., it was possible to recover bacteria from flies which had been in contact with an infected fruit, and to transfer bacteria from a deliberately contaminated insect to wounded fruits. These results were what might be expected in the early stage of an investigation which should go on to investigate conditions more closely corresponding to those of the hypothetical pathway.

Question 20: Do you concur with Japan's contention that the conditions to which the flies were subjected to in the Tsukamoto study (2005b) relate to "plausible ecological conditions" (see paras. 32-33 of Japan's second written submission, Japan's reply to Question 18 of the Panel and US comments on Japan's reply). Please explain.

6.123 **Dr Geider** stressed that it was a theoretical situation and that even without phytosanitary fire blight inspections in Germany, he had never seen an apple with fire blight symptoms in a local fruit shop.

6.124 **Dr Hale** noted that the experimental conditions to which the flies had been subjected in the Pathway study (Tsukamoto *et al.* 2005b) did not bear any relationship to "plausible ecological conditions". (See also response to Question 19 of the Panel above).

6.125 **Dr Hayward** replied that he could not agree that the Tsukamoto II experiments were carried out under "plausible ecological conditions" for the reasons given in the response to Question 19. In the natural environment many biotic and abiotic factors interacted which would affect the survival of the bacterial pathogen and the behaviour of the insects. Because of the wide and random spatial separation of the hypothetical oozing apple, flies and suitable host plants, there was time for the biotic and abiotic factors to exert their effects. The Tsukamoto II experiments eliminated the spatial separation of the elements but forced them together.

6.126 **Dr Smith** noted that the conditions used were not "plausible" because they did not allow at all for the natural behaviour of the insects, which were put in a no-choice situation. They might just as well have been dead insects, shaken in the respective containers with the fruits. More plausible conditions could have been devised, even within a cage in a quarantine facility, allowing the insects to choose to feed on the infected fruits and to choose to settle on the healthy ones.

Question 21: Do you concur with the US and New Zealand's statements regarding flies as possible vectors for the spread of fire blight (paras. 23-25 of US second submission; paras. 50-54 of New Zealand third party submission, New Zealand's replies to Question 4 of the Panel and Question 3 of Japan, and US comments on Japan's reply to Question 19 of the Panel)? Please comment on the article by Taylor *et al.* (2003) referenced in both submissions.

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

on paras. 26-32 of US second submission, paras. 56-62 of New Zealand's third party submission, including the reference to Taylor *et al.* (2003) as well as on the US and Japan's replies to Question 20 of the Panel.

6.133 **Dr Geider** stated that he had no objections to the mathematics. Statistical considerations depend on basic assumptions. Even Kimura *et al.* concluded there was a low probability to distribute fire blight with fruits.

6.134 **Dr Hale** noted that evidence to date on long distance transmission of fire blight attached significant importance to nursery stock, scions and buds as the likely causes of long distance dissemination of the disease (Roberts *et al.* 1998). Despite this Kimura *et al.* (2005) estimated the risk posed by the import of apple fruit to be significantly greater than for the generally accepted means of long distance dissemination. The corrigendum to Exhibit JPN-10, supplied by Japan, did not appear to alter the conclusions reached by Kimura *et al.* (2005). The probabilities estimated by Kimura *et al.* (2005) appeared to rely heavily on the unpublished information in the Infection Study (Azegami *et al.* (2005) and the Pathway Study (Tsukamoto *et al.* 2005a,b) that did not provide any evidence that the pathway for disease, from infected fruit to susceptible host tissues, could be completed under natural ecological conditions. The fact that Kimura *et al.* (2005) assumed that the pathway could be completed by flies under natural ecological conditions was not borne out by the published information (Taylor *et al.* 2003) that insects did not become contaminated with *E. amylovora* from infested fruit discarded in an orchard when susceptible host tissue was in abundance. Hale *et al.* (1996) had also reported that there was no detectable spread of *E. amylovora* from heavily infested calyxes and fruit surfaces to blossom clusters, immature, or mature fruit. Taylor *et al.* (2003a) also found that the population levels of *E. amylovora* required for infection of susceptible host tissues under orchard conditions far exceeded the levels likely to be present in infected apple calyxes at harvest and after cold storage.

6.135 **Dr Hayward** replied that Kimura *et al.* (2005) (Exhibit JPN-10) had concluded that the probability of dissemination of *E. amylovora* via fruit was low but not negligible, in three scenarios differing in stringency of inspection frequency and size of buffer zones. They had based their study in part on the results and conclusions of Azegami I and II and Tsukamoto I and II. In view of the artificiality of these experiments, as described above, he could not support the change in probability from negligible to low. Azegami II, a study in which the methodology and conclusions had not been critically evaluated by an independent third party, claimed to show that infection could occur from an injured fruit spur through the pedicel to the maturing fruit. There might be a window of opportunity for a late infection event to occur if injury occurred to the spur just prior to completion of formation of the abscission layer in the presence of available inoculum, but the probability of occurrence of such a late infection event might be close zero.

6.136 **Dr Hayward** agreed with the statements in the US second submission and the New Zealand third party submission on the Kimura study.

6.137 **Dr Smith** stated that the probability estimates of Kimura *et al.* (2005) were twofold. There were those presented in section 2, which related to the probability that, from a single infected item (rootstock, scion, or fruit) entering Japan, fire blight established in that country. These figures, for fruit, were closely based on the results of the other New Studies. Then there were estimates made in the discussion (section 3), based in addition on the probability that a single exported fruit had been infected, as calculated by Roberts *et al.* (1998), adjusted according to Yamamura *et al.* (2001). The three scenarios which had been compared in the latter case (as later indicated in Japan's corrected sheet) related to three different types of measures applied to fruit orchards, and had nothing to do with rootstocks or scions. The calculation of the latter estimates was not presented in detail, so it was difficult to make any judgements about it. To the extent that the calculation took into account the number of apple fruits shipped annually, and the probability of a fruit being infected, the figures

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 *E. amylovora*. Billing and Berrie (2003) referred to circumstantial evidence that migrant birds (starlings) might have served to spread the disease from southern England to hawthorns on the continent in the mid-1960s.

6.141 **Dr Smith** stated that there was no evidence that crows themselves were vectors. Though they might feed on discarded fruits, they did not behave in a way which would then transmit any acquired bacteria to host trees. The argument that they scattered garbage, making it accessible to other smaller vectors (if any such exist), seemed reasonable. It was surprising that Japan had not rather drawn attention to the possible role, presented by the PRA, of bulbuls and whiteeyes, birds which were well recognized in the ornithological literature to feed on fruit and to suck nectar from flowers. The PRA asserted that these birds suck the nectar of fire blight host plants. He wondered if this was as specifically known as it was written in the PRA. His impression from ornithological books was that these birds feed on larger flowers. In any case, this particular pathway seemed to have the ecological plausibility that some other suggested pathways lack, and might merit further investigation.

Question 24: In the light of the Pathway Study (Tsukamoto 2005b), would you modify your reply to Questions 9 and/or 16 from the Original Panel proceedings regarding the completion of the pathway?

6.142 **Dr Geider** stated that the events were possible, but not realistic for fruit trade. Of course, flies became contaminated crawling on blighted fruits. Pears, especially sliced, were very susceptible to *E. amylovora* and developed symptoms with low amounts of bacteria. There was almost no chance that the anticipated pathway will occur in orchards.

6.143 **Dr Hale** noted that there was no published scientific evidence to suggest that mature, symptomless apple fruit could be infected with *E. amylovora* under natural conditions. The unpublished data from the Pathway Study (Tsukamoto *et al.* 2005b) did not provide any scientific evidence for the possible completion of the disease pathway. There was no published scientific evidence to suggest that the pathway for fire blight to infect susceptible host tissue from mature, symptomless fruit could be completed. The only published scientific evidence for contamination of mature, symptomless fruit related to calyx infestation (Hale *et al.* 1987) and Taylor *et al.* (2003) showed that there was a discontinuity in the pathway from infested fruit to susceptible host tissue, and that the disease pathway was not completed under natural environmental conditions. Finally there was no reported evidence of mature, symptomless apple fruit having ever been involved either in dissemination of *E. amylovora* or in an outbreak of fire blight in a previously disease-free area.

6.144 **Dr Hayward** replied that there was no new scientific evidence which would persuade him to change his responses to Questions 9 and 16 from the Original Panel proceedings.

6.145 **Dr Smith** commented that the situation has not changed from the Original Panel proceedings. Studies had shown that trees did not become infected by spread from discarded fruits, under reasonable experimental conditions. No study had shown that such transfer occurred. Investigations remained to be done on plausible vector species. In any case, it appeared that such transfer had to be rare and difficult to demonstrate.

Japan's September 2004 Pest Risk Assessment

Question 25: How does Japan's September 2004 PRA compare with the IPPC Pest Risk Assessment standard of 2001 (attached)?

6.146 **Dr Geider** stated that he was not well acquainted with PRA considerations. Fire blight seemed to be a one-hit event to become established in a remote area, and a PRA might not be applicable. All proposed measurements might decrease the risk further, but other events besides official plant or fruit trade might be a more serious risk. Once established, it was very difficult to interfere with sequential spread of fire blight to adjacent areas.

6.147 **Dr Hale** noted that the contents table of the IPPC Pest Risk Analysis for Quarantine Pests standard of 2001 was identical to that of the Standards for Phytosanitary Measures – Pest Risk Analysis for Quarantine Pests, Including Analysis of Environmental Risks and Living Modified Organisms (ISPM 11) produced by IPPC in 2004. It was on the basis of this standard that the Japan "Pest Risk Analysis Concerning Fire Blight Pathogen (*Erwinia amylovora*) – Fresh Apples Produced in the United States of America – September 2004" had been prepared.

6.148 **Dr Hale** noted that the Japan PRA had been revised to take into account the identification and biology of *E. amylovora*, and Japan's views on the identification of a possible pathway for entry into and establishment of *E. amylovora* in Japan, the economic consequences to Japan, and a review of measures against *E. amylovora* related to apples from the United States. The PRA discussed the probability of fire blight being associated with the pathway at origin, the probability of survival of the pathogen during storage and transport, and the probability of transfer to a suitable host. However, the PRA was based on the assumptions that the export commodity is mature, symptomless apples that were latently infected with *E. amylovora*, that decayed or damaged fruit harboured *E. amylovora*, that the pathogen survived in latently infected fruit, and that a disease pathway from mature, symptomless, latently infected apples actually existed. The evidence presented to justify these assumptions was, as yet, unpublished, and was not considered to be convincing scientific evidence as neither latent infection, nor the suggested pathway involving decaying fruit, and transfer from this fruit to susceptible hosts had ever been completed under natural environmental conditions. It should be noted that there was little information on fruit rots in mature apples being caused by *E. amylovora*. With all

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 *et al.* 1998; Taylor *et al.* 2003).

6.161 **Dr Hayward** replied that he could not find any evidence that the circumstances in Question 27 above would provide a pathway for the introduction, establishment and spread of fire blight in Japan.

6.162 **Dr Smith** replied that it was not likely that *E. amylovora* would multiply or spread in store or transit (provided that the apples remain under proper storage conditions). All that could happen was that small numbers of bacteria might be transferred from the surface of apples carrying a few bacteria to others which did not do so originally. This did not create a new pathway. If "internally infected mature fruits" were present (the existence of such fruits being in any case disputed), there was no pathway for these internal bacteria to infect other apples. In any case, the export phytosanitary inspection was not the only check that consignments did not contain damaged fruits.

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 France (pattern type Pt 4) was observed. Pt3 could have developed in Belgium/Northern France and had been transmitted to Northern Italy and Central Spain most likely by import of infested plants to nurseries. In Northern Italy, no fire blight symptoms had been found in the suspicious nursery at the time of the first outbreaks. Pt1 in Germany, Poland, Austria, Switzerland and Eastern France was another example of sequential spread. Fruit trade in Europe was not restricted by quarantine measures concerning fire blight. Nevertheless, the PFGE pattern types seemed to be undisturbed. In summary, a novel establishment of fire blight was very rare in spite of many human and environmental activities that were assumed to favour long distance spread of the disease including the trade issues discussed here. May be, the parties could find compromises about trade restrictions. It should be emphasized that with or without trade restrictions, there was a permanent threat to establish fire blight in a remote clean area by many unpredictable events of daily life.

VII. INTERIM REVIEW

A. INTRODUCTION

7.1 On 24 March 2005, Japan and the United States requested the Panel to review, in accordance with Article 15.2 of the DSU, precise aspects of the interim report that had been issued to the parties on 10 March 2005. Neither Japan nor the United States requested a further meeting with the Panel. On 31 March 2005, in accordance with our timetable, both parties submitted comments on each other's communications of 24 March 2005.

7.2 What follows is a discussion of the arguments made at the interim review stage, in application of Article 15.3 of the DSU.

7.3 The Panel has modified aspects of its report in light of the parties' comments where it considered it appropriate, as explained below. Consequently, the findings of the Panel have to be read in conjunction with this section.

7.4 The Panel has also made certain editorial modifications either at the suggestion of the parties or of its own initiative for the purpose of clarity and accuracy.

7.5 References to paragraph numbers relate to those in this final report.

B. ORIGINAL COMMENTS OF THE UNITED STATES AND COMMENTS BY JAPAN ON THE UNITED STATES' ORIGINAL COMMENTS

7.6 The United States has requested us to modify the description of the nature of Japan's Operational Criteria made in the second sentence of paragraph 8.19 in order to match the description

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 and commercial risks attached to the compliance with Japan's measure at issue.¹⁴⁸ Japan has argued that the potential benefits for US exporters of participating in the export programme under Japan's current import regime outweigh the expected costs and risks,¹⁴⁹ thus implicitly acknowledging that the exported apples will find clients to buy them at a remunerative price. This argument does not support Japan's position at the interim review stage that Japanese consumers are not attracted to US apples. Furthermore, the fact that the costs of inspection are ultimately borne by the US exporters rather than by the US Government confirms the argument of the United States that the measure at issue is burdensome and costly for US exporters. We see no reason to modify our findings in this respect.

7.20 Finally, Japan makes comments of a much less specific nature in relation to our findings under Article 2.2.

¹⁴⁷ See also GATT Panel Report on *Japan – Leather II (US)*, paras. 51-55.

¹⁴⁸ United States reply to additional questions of the Panel, 25 January 2005.

¹⁴⁹ Japan comments on the United States' answer to additional questions of the Panel, 1 February 2005.

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 suggestion amounts to re-arguing the validity of the measure at issue as a whole from a different angle, by presenting the elements of the measure at issue as a "production process control" necessary to *verify* that the exported product is mature, symptomless apples. We believe that the interim review is not the appropriate stage for rearguing the case on new grounds.

7.24 For these reasons, we are of the view that we should not address Japan's comments which do not relate to specific paragraphs of our findings, since Japan failed to comply with the requirements of Article 15.2 of the DSU in this respect.

7.25 Even if we were to consider those arguments, and even if we were to agree with Japan that we should look at the measure from the angle it suggests, this would not affect our findings that most elements of the measure at issue are maintained without sufficient scientific evidence, within the meaning of Article 2.2 of the SPS Agreement.

7.26 We note that Japan relies on a statement made by Dr Smith in the course of our hearing of the experts.¹⁵² However, what Dr Smith said in the paragraph quoted by Japan was limited to a requirement that orchards be blight-free. He did not address other aspects of the measure at issue. In addition, we did not quote Dr Smith's statement in the context of our analysis under Article 2.2 because, in this statement, Dr Smith explicitly avoids claims that his opinion is based on scientific evidence. Rather, he acknowledges that "I don't know whether I have produced a scientific argument or if that is a technical argument."

7.27 Dr Smith's statement referred to by Japan does not affect our conclusion in paragraph 8.89 that available scientific evidence does not support the view that mature, symptomless apples harvested from blighted orchards, whether severely blighted or not, would harbour populations of *E. amylovora* capable of spreading fire blight disease.

¹⁵⁰ Panel Report on *Australia – Salmon*, para. 7.3.

¹⁵¹ See, e.g., Panel Report on *Japan – Apples*, paras. 8.158-8.161.

¹⁵² Dr Smith, Transcript, para. 135.

7.28 At best, Dr Smith's suggestion could represent an alternative to Japan's current measure within the meaning of Article 5.6 of the SPS Agreement. We recall, however, that Japan does not refer to Dr Smith in relation to our findings under Article 5.6, but in relation to our findings under Article 2.2 of the SPS Agreement. Moreover, Japan never argued this point during the proceeding in relation to Article 5.6 and it is not for us to make a case for Japan. We recall in this respect that the United States proposed an alternative measure to the measure at issue, which we considered.

7.29 We note that the experts consulted by the Panel acknowledged that verification through samples may not give full certainty that only mature, symptomless apples will be exported. We nonetheless recall that there was not sufficient scientific evidence that apple fruit can complete the pathway for fire blight.

7.30 As a result, even if we were to admit Japan's comments regarding our findings under Article 2.2 of the SPS Agreement, we would see no reason to modify those findings.

7.31 We also took into account the relevant editorial suggestions made by Japan.

VIII. FINDINGS

A. INTRODUCTORY REMARKS

8.1 The United States claims that Japan has failed to implement the Dispute Settlement Body's (DSB) recommendations and rulings by failing to bring its phytosanitary measures on imported US apples, which restrict the import of such apples in connection with fire blight and the fire blight disease-causing organism, *Erwinia amylovora*, into compliance with its obligations under the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement).¹⁵³

8.2 The United States claims in substance that Japan's phytosanitary measures at issue are not compatible with Articles 2.2, 5.1 and 5.6 of the SPS Agreement, as well as with Articles 4.2 of the Agreement on Agriculture and Article XI of GATT 1994.

8.3 As a preliminary remark, we recall that Articles 2.2, 5.1 and 5.6 of the SPS Agreement are interrelated and that our findings under one of these provisions would be of relevance to our findings on the others.

8.4 We would also like to stress that the role of a panel under Article 21.5 of the DSU is, like that of the Original Panel, limited to finding whether the party concerned failed to comply with its WTO obligations. A panel may legitimately restrict its findings to what is strictly necessary to determine whether the measure at issue is in breach of the Member's WTO obligations.¹⁵⁴ It is for the party found in breach of its obligations to make all the appropriate changes to bring its legislation fully into conformity with its obligations. However, we are mindful of the specific nature of Article 21.5 proceedings, which come after the party found in breach of its obligations in the original proceeding has been given a reasonable period of time to bring its legislation into conformity and should have normally taken measures to comply with the DSB recommendations and rulings.

8.5 Specific circumstances of non-compliance may dictate that an Article 21.5 panel should make more exhaustive findings than the Original Panel so as to assist the party concerned. We recall in this respect the comment of the Appellate Body in *Australia – Salmon*:

¹⁵³ WT/DS245/11.

¹⁵⁴ See Appellate Body Report on *US – Wool Shirts and Blouses*, pp. 339-340.

"[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.

dissemination of the Operational Criteria were completed as late as 13 September 2004, the Operational Criteria should be considered as the embodiment and elaboration of the Detailed Rules, which were notified to WTO Members on 29 June 2004.

(iii) *Analysis of the Panel*

8.16 We note that the Operational Criteria provide for a number of procedures which are not otherwise specified in other parts of Japan's legislation:

- (a) The objectives of the border zones of around 10-meter width are two-fold. The first objective is to prevent branches of trees inside the "free area of fire blight" (as provided for by the Detailed Rules, hereinafter "orchard") from overlapping, or being in direct contact, with plants outside the orchard. The second objective is to delineate the boundary of the export orchard for which both authorities will ensure the absence of fire blight symptoms according to these criteria. The requirement will be automatically met when the orchard is surrounded by passageways, waterways or other equivalent zones of an around 10-meter width, as is normally the case. Consequently, if there are zones of the equivalent width inside one orchard at a certain location, each of the sections (blocks) surrounded by the zones will be considered an independent orchard.
- (b) No inspection of the border zone will be done as long as the border zone is not used as cultivating grounds of host plants of the disease. This requirement will also be met automatically when the orchard is surrounded by passageways or waterways.
- (c) The annual inspection by the US authorities (including confirmation by the US and Japanese authorities) will be done only *once*, visually, by officials driving through an orchard using a buggy car, inspecting the exterior of apple trees inside the orchard.
- (d) Inspection under (c) above is designed to detect only typical symptoms on large branch(es). Suspected symptoms will then be laboratory-tested before they are found positive.
- (e) When a heavily blighted tree is found, only the particular section (block) within the orchard will be disqualified, as long as the around 10-meter "border zone" (e.g., a passageway or a waterway) surrounds the section. The rest of the orchard will retain the status of a qualified export orchard and will be treated equally with other export orchards where no such tree was found.
- (f) As long as a particular growing lot is surrounded by a "border zone" of around 10 meters within an orchard, each such lot of any size will be considered an "independent orchard" or a "section" for the purpose of determination under (e) above, except for those varieties designated as "least resistant" to the fire blight disease by the USDA. Sections for these varieties must be surrounded by either a passageway, a waterway, a cliff or other natural barriers of around 10 meters in width.

8.17 As a preliminary remark, the Panel notes that the US request for a preliminary ruling was made after its first written submission, whereas paragraph 13 of the Panel working procedures provides that any such request should be filed at the time of the first written submission.¹⁵⁸ However, the United States claims that it became aware of the existence of the Operational Criteria only when

¹⁵⁸ See working procedures of the Panel, Annex I to 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*, para. 7.124.

¹⁶² See Appellate Body Report on *India – Patents (US)*, para. 65, quoting the judgement of the Permanent Court of International Justice in *Certain German Interests in Polish Upper Silesia*.

¹⁶³ Panel Report on *India – Autos*, paras. 8.27- 8.28.

¹⁶⁴ Panel Report on *Australia – Salmon (Article 21.5 – Canada)*, para. 7.10.

Agreement. We believe that if the guidelines referred to in *Japan – Agricultural Products II* were deemed to constitute "phytosanitary regulations" within the meaning of Annex B, paragraph 1, of the SPS Agreement, the Operational Criteria should *a fortiori* be considered to be "phytosanitary regulations" which have to be "published promptly in such a manner as to enable interested Members to become acquainted with them."

8.24 Japan did not provide any reason why the Operational Criteria could not be notified to the United States by the end of the reasonable period of time if they indeed, as Japan implies, had already been prepared, although apparently in a different form. We deduce from the obligation of Members to promptly publish their phytosanitary regulations pursuant to Article 7 and Annex B of the SPS Agreement that the United States was under no obligation to assume that Japan would adopt additional implementing instruments, nor that these instruments would take the form of Operational Criteria. Rather, it was for Japan to take appropriate steps to inform the United States.

8.25 However, totally disregarding the Operational Criteria in this case would go against the principle of prompt settlement of disputes contained in Article 3.3 of the DSU. The Operational Criteria obviously provide a statement of how Japan intends to implement the recommendations and rulings of the DSB at the time this Panel was called upon to review the "measures taken to comply" by Japan.

8.26 As a result, *the Panel will consider the Operational Criteria to the extent that they inform an objective assessment of the matter.*

8.27 However, the Panel regrets Japan's practice in this case. The communication of the Operational Criteria to the United States before the establishment of the Panel might well have assisted the United States in determining whether a recourse to Article 21.5 of the DSU would be fruitful. In particular, it would have allowed the United States to better assess the extent of Japan's compliance with the recommendations and rulings of the DSB and facilitated a prompt settlement of the dispute.

2. Scope of Japan's "measure(s) taken to comply"

(a) Whether the measure taken to comply should be treated as one measure composed of several requirements or as separate measures

8.28 We note that, on the one hand, the United States has requested that we treat each requirement imposed by Japan as a separate measure. On the other hand, Japan also requests us to make specific findings on each of the requirements that it maintains.

8.29 We recall that the Original Panel treated the requirements imposed by Japan as several elements of one single measure, essentially because all the requirements were presented as part of a systemic approach. The parties gave us no substantive reasons for us to treat the compliance measure any differently than the original measure. The approach of the Original Panel was not reversed by the Appellate Body and the same "systemic" approach as the one followed by Japan with respect to the original measure seems to have prevailed with the compliance measure. However, as highlighted above, the circumstances of this case may justify that we make specific findings on each of the elements of the compliance measure, without having to treat each element as a separate measure. As we will see below, many elements of the compliance measure are interrelated and justified on the basis of the same scientific evidence. Treating them as separate measures could give the impression that they can apply independently of each other, which may not always be the case.

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 'taken to comply with the recommendations and rulings' of the DSB will *not* be the same measure as the measure which was subject to the original dispute, so that, in principle, there would be two separate and distinct measures [footnote omitted]: the original measure which *gave rise* to the recommendations and rulings of the DSB, and the 'measures taken to comply' which are – or should be – adopted to *implement* those recommendations and rulings."¹⁶⁵

8.32 In its implementation process, Japan has made some changes to the original measure¹⁶⁶ and has produced new studies to support its view that (a) mature, symptomless apples can be "latently" infected and (b) infected apples could, once on the Japanese territory, contaminate host plants. On the basis of these studies, Japan has maintained many elements of the original measure in the measure taken to comply. For this reason, we consider that all the elements of the measure currently in place should be treated as the "measures taken to comply", even though many of those elements were already found in the original measure.

8.33 As a result, we conclude that the "measure taken to comply" which this Panel should review is composed of the following elements:

- (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;

¹⁶⁵ Appellate Body Report on *Canada – Aircraft (Article 21.5 – Brazil)*, para. 36.

¹⁶⁶ See paras. 4.14-4.20, above.

- (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. ARTICLE 2.2 OF THE SPS AGREEMENT

1. Approach of the Panel¹⁶⁷

8.34 Article 2.2 of the SPS Agreement reads as follows:

"Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5."

8.35 The United States claims that Japan has failed to comply with the recommendations and rulings of the Dispute Settlement Body and that Japan's compliance measure is not compatible with Article 2.2 of the SPS Agreement. In this regard, the United States only claims that the compliance measure is maintained without sufficient scientific evidence, within the meaning of Article 2.2.

8.36 Japan considers in substance that the new studies referred to in its submissions provide sufficient scientific evidence to justify all the elements of the compliance measure.

8.37 We recall that, in its report, the Original Panel proceeded in two steps. First, it assessed to what extent scientific evidence confirmed that apple fruit could be contaminated and, if exported to Japan, complete the pathway and contaminate host plants in Japan; secondly, it went on to assess to what extent the measure as a whole was maintained with sufficient scientific evidence, i.e. whether it bore any rational relationship with the scientific evidence. The Appellate Body did not contest the validity of this approach. We therefore consider that we can follow the same approach as the Original Panel, i.e.:

- (a) first, determine whether the scientific evidence in its present state confirms the possibility for apple fruits to serve as a pathway for the entry, establishment and spread of fire blight in Japan; and
- (b) second, determine whether the elements of the measure at issue are "not maintained without scientific evidence", i.e. whether a sufficient or adequate relationship exists between the scientific evidence and the elements of the compliance measure.

8.38 As an Article 21.5 compliance panel, we are required to look at the compliance measure as a new measure subject to new claims.¹⁶⁸ We note that the United States considers that the new studies submitted by Japan do not affect the body of scientific evidence relied upon by the Original Panel. Nor does Japan claim that the scientific evidence relied upon by the Original Panel is no longer valid. Rather, it claims that its new studies complement the existing scientific evidence. We therefore consider that the scientific evidence available to the Original Panel is still relevant to our examination

¹⁶⁷ A detailed account of the arguments of the parties can be found in paras. 4.21-4.130 of this Report.

¹⁶⁸ See, e.g., Appellate Body Report on *Canada – Aircraft (Article 21.5 – Brazil)*, paras. 40-42.

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 additional sequence of events which is deemed unlikely, and which has not even been experimentally established to date."¹⁶⁹

8.40 The Original Panel concluded that there was not sufficient scientific evidence that apple fruit are likely to serve as a pathway for the entry, establishment or spread of fire blight within Japan. The Panel nonetheless made a number of qualifications to this conclusion. It considered that the scientific evidence "does suggest that some slight risk of contamination cannot be excluded." It nonetheless stated that the experts all categorized this risk as 'negligible'¹⁷⁰ but could not agree with the United States that the scientific prudence displayed by the experts should be completely assimilated to a "theoretical risk".¹⁷¹

8.41 Japan claims that it has new scientific evidence of (i) possible infestation/infection of apple fruits through the pedicel which could lead to latent infection of otherwise mature and symptomless apples; and (ii) possible completion of the pathway through transmission of bacteria by flies from infected discarded apples to host plants in Japan.

8.42 The new studies relied upon by Japan are:

(a) Azegami, *et al.* (2005)¹⁷² which purports to show that maturing or mature apple fruit are not immune from infection by the bacteria.

¹⁶⁹ Panel Report on *Japan – Apples*, para. 8.171.

¹⁷⁰ Panel Report on *Japan – Apples*, para. 8.173.

¹⁷¹ Panel Report on *Japan – Apples*, para. 8.175.

¹⁷² Azegami *et al.*, "Invasion and colonization of mature apple fruit by *Erwinia amylovora* tagged with bioluminescent genes", *Journal of General Plant Pathology* 70(6) December 2004. In response to the US submission regarding a US study on the possibility that transpiration could explain bacterial movement into fruit (Exhibit USA-21), Japan also presented information on an additional study by Azegami (Azegami *et al.*, "Entry of *Erwinia amylovora* into apple fruit from fruit-bearing twig through abscission layer at the time of fruit maturation", Exhibit JPN-16) regarding the potential movement of bacteria through the abscission layer after it

- (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.* (2005b),¹⁷⁴ which purports to show completion of a pathway from infected (whether latently or not) apple fruit by common flies as a vector in an environment consistent with the Japanese fauna.
- (d) Kimura *et al.* (2005)¹⁷⁵ which discusses the probability of the infection of mature apples and completion of the pathway in a discussion of the risk of introduction and establishment of the disease in Japan.

8.43 The submission of these new studies by Japan in support of its compliance measure requires that we re-assess the scientific evidence so as to determine:

- (a) whether sufficient scientific evidence supports the assertion that mature and symptomless apples can nonetheless harbour endophytic bacteria; and
- (b) whether sufficient scientific evidence supports 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.

8.44 These are the two questions that we will successively address in this section.

8.45 Before proceeding with our review of those questions, we believe that we need to make the following clarification with respect to the notion of *sufficient* scientific evidence. This Panel is confronted with the situation where Japan claims that certain new pieces of scientific evidence specifically support its measure. Thus the question before us in this proceeding is not so much whether the evidence relied upon by Japan is "scientific"¹⁷⁶, but primarily whether it is "sufficient". In *Japan – Agricultural Products II*, the Appellate Body presented "sufficiency" as a relational concept between two elements: the scientific evidence and the measure at issue. The Original Panel stressed that the scientific evidence relates to a risk and is supposed to confirm the existence of a given risk.¹⁷⁷ We note that the measure is supposed to address that risk. In other words, in order for scientific evidence to support a measure sufficiently, it seems logical to us that such scientific evidence must also be sufficient to demonstrate the existence of the risk which the measure is supposed to address. As a result, it seems reasonable to consider the extent of the relationship between the scientific evidence and the risk which this evidence is claimed to establish.

8.46 We also note that Japan claims that the studies it commissioned do not contradict the evidence already available. Even if that were not the case, the fact that the studies relied upon by Japan may not correspond to the prevailing view representing the "mainstream" of international scientific opinion is

had been formed. This Azegami study was not referenced in Japan's 2004 risk assessment and had not been published at the time of the Panel proceeding. In addition, neither party directly discussed the information included in that study or otherwise indicated that it was essential to their arguments before the Panel.

¹⁷³ Tsukamoto *et al.*, "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).

¹⁷⁴ Tsukamoto *et al.*, "Transmission of *Erwinia amylovora* from blighted mature apple fruit to host plants via flies", Research Bulletin Plant Protection Service Japan (accepted for publication).

¹⁷⁵ Kimura *et al.*, "The probability of long-distance dissemination of bacterial disease via fruit", Journal of General Plant Pathology (submitted).

¹⁷⁶ We asked the experts whether the new studies presented by Japan met the criteria usually applicable in the field to be relevant scientific evidence. The replies of the experts are contained in paras. 6.8-6.18.

¹⁷⁷ Panel Report on *Japan – Apples*, para. 8.104.

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 Japan's new studies, support the assertion that mature and symptomless apples can nonetheless harbour endophytic bacteria?

(i) *Azegami et al. (2005)*¹⁷⁹

8.47 Japan essentially claims that *Azegami et al. (2005)* shows that bacteria passes through vascular tissues and that this potential infection route would remain active until the formation of the abscission layer.

8.48 The United States argues that *Azegami et al. (2005)* successfully introduced fire blight bacteria into apple fruit through the pedicel, only when the pedicel and its abscission layer were severed. The spread of bioluminescence into apple fruit was as likely a consequence of the cut-pedicel method and transpiration as a result of active colonization and invasion by bacteria.

8.49 Having considered the arguments of the parties and third parties on these two studies, we have reached the conclusion that, for the purposes of the Panel's assessment, the main issue concerning these studies was their relation to natural conditions in an orchard. We therefore sought the views of the scientific experts on this issue.

8.50 The experts consulted by the Panel generally consider that the conclusion of latent infection in *Azegami, et al. (2005)* did not provide any results on latent infection under natural conditions.¹⁸⁰ Dr Geider stated that, in late summer, the risk and occurrence of new fire blight incidence decline. Migration of *E. amylovora* from an infested branch into a disease-free branch and then into apple fruits seemed unrealistic from the known infection steps.¹⁸¹ Dr Hale noted that the results of *Azegami et al. (2005)* did not provide convincing evidence that mature fruit were likely to become infected under natural conditions in an orchard.¹⁸² Dr Smith stated that:

"The suggested scenario of Japan was that bacteria might enter mature fruits, from infections on twigs, through the pedicels, and be carried by the vascular system of the fruit to the cortex, where they might persist as a latent infection. There was no direct evidence that this happened under natural conditions. It seemed implausible that earlier studies on the isolation of bacteria from inside fruits, which included cortex, somehow had failed to detect these infections."¹⁸³

8.51 Dr Hayward was not persuaded by the *Azegami et al. (2005)* study.¹⁸⁴

8.52 In light of the opinion of the experts, we conclude that the *Azegami, et al. (2005)* study does not support the conclusion that apples would become mature and symptomless and yet be latently infected in the natural conditions of an orchard.

¹⁷⁸ See Appellate Body on *EC – Hormones*, paras. 193-194.

¹⁷⁹ For a description of the study, see paras. 4.38-4.44 above.

¹⁸⁰ Dr Smith, para. 6.32; Dr Hale, para. 6.27; Dr Hayward, para. 6.43.

¹⁸¹ Dr Geider, para. 6.25; Dr Hale, para. 6.30; Dr Hayward, para. 6.31.

¹⁸² Dr Hale, paras. 6.56-6.58.

¹⁸³ Dr Smith, para. 6.60.

¹⁸⁴ Dr Hayward, para. 6.59.

(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/consumption and of pear growth coincides. Finally, the level of

¹⁸⁵ For a description of the study, see paras. 4.44-4.47 above.

¹⁸⁶ Dr Hale, para. 6.93.

¹⁸⁷ Dr Hayward, para. 6.94.

¹⁸⁸ Dr Smith, para. 6.97.

¹⁸⁹ For a description of the study, see paras. 4.50-4.56 above.

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. Finally, the study also does not demonstrate that infection and disease development were a result of a natural interaction between the flies and the host material and were not dependent on artificial mechanical injury.

8.60 Having considered the arguments of the parties and third parties on these studies, the Panel sought the views of the scientific experts on three main issues:¹⁹⁰

- (a) whether the Tsukamoto *et al.* (2005b) study logically supported a risk of completion of the pathway;
- (b) whether the conditions the flies were subjected to in the Tsukamoto *et al.* (2005b) study related to "plausible ecological conditions"; and
- (c) to what extent flies could operate as possible vectors for the spread of fire blight.

8.61 Regarding the first question, Dr Geider stated that the chain of events required might not practically occur and was scientifically unlikely.¹⁹¹ Dr Hale had difficulties agreeing with Japan's argument that the logical conclusion from the results of that study, was that the combination of artificially infected apple fruit, flies, and suitable host plants poses a risk of completion of the disease pathway.¹⁹² Drs Hale and Hayward also noted that the experimental conditions imposed bore little resemblance to real world conditions. The Tsukamoto *et al.* (2005b) study eliminated all of the critical factors of the natural environment, such as desiccation, cyclical wetting/drying, UV irradiation and heat exposure, as well as biotic factors such as antagonism or predation of *E. amylovora* by other micro-organisms.¹⁹³ From the results of the study, 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 experiment. 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.¹⁹⁴ Dr Smith considered that the lack of investigation of direct infection by flies much weakened the claim that a pathway had been demonstrated.¹⁹⁵ Drs Geider, Hale and Hayward considered that insects were unlikely to visit both infected fruit and susceptible plant tissues such as blossoms.¹⁹⁶

¹⁹⁰ See questions 19, 20 and 21 of the Panel to the scientific experts, Section VI of this Report.

¹⁹¹ Dr Geider, para. 6.114.

¹⁹² Dr Hale, para. 6.115.

¹⁹³ Dr Hale, para. 6.116; Dr Hayward, para. 6.120.

¹⁹⁴ Dr Hale, para. 6.117.

¹⁹⁵ Dr Smith, para. 6.122.

¹⁹⁶ Dr Geider, para. 6.114; Dr Hale, para. 6.118; Dr Hayward, para. 6.120: "insect species had characteristic patterns of behaviour, substrate and host preference."

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) study did not provide convincing scientific evidence that the flies used in the experiments were vectors for the spread of fire blight. Drs Hale and Hayward referred to Taylor *et al.* (2003), which had documented the situation relating to the possible transmission of *E. amylovora* from discarded, infested, mature apple fruit to susceptible host tissues. Taylor *et al.* (2003) had been unable to recover the bacteria from insects trapped in the orchard or find any evidence of transmission from calyx-infested apples to susceptible hosts. Dr Hayward emphasized the importance of studies in orchard conditions and felt that more such studies should be carried out in these conditions.²⁰² For Dr Smith, it was simply not enough to work with any sort of fly. Other lines of studies could be envisaged, determining which insects in the field were attracted to rotten apples, or were found around pear or apple fruits. Dr Smith also recalled that the most significant result of Taylor *et al.* (2003) was that they were unable to recover the bacterium at all, from any insect tested.²⁰³

8.65 From the above, we conclude that the experts have confirmed the assertion of the United States that the Tsukamoto *et al.* (2005b) study does not establish that flies would serve as a vector which would complete the pathway. In particular, the conditions of the experiment are too removed from natural conditions. Comparatively, we note that the study by Taylor *et al.* (2003), carried out in natural conditions, did not recover bacterium from insects.

(ii) *Kimura et al.* (2005)²⁰⁴

8.66 Japan essentially claims that Kimura *et al.* (2005), using the results of Azegami *et al.* (2005) and Tsukamoto *et al.* (2005b) found that the quantitative risk of transmission of the disease by apple fruit was not insignificant. Kimura *et al.* (2005) also suggested an alternative explanation to the bacterial introduction to apple fruit. It could be through the pedicel, to the vascular tissue and the cortex (flesh), rather than through the calyx to the core. Japan also claims that Kimura *et al.* (2005) showed that the completion of the pathway by flies was not a theoretical risk but a real one.

8.67 The United States notes that Kimura *et al.* (2005) relied on Azegami and Tsukamoto's works. However, Kimura *et al.* (2005) misrepresented Azegami *et al.* (2005) by concluding that "even at a stage apple fruit gets ripe, it is likely enough that *E. amylovora* in fruit-bearing branches will infect the inside of apples." According to the United States, the Azegami *et al.* (2005) paper does not demonstrate that infection through the pedicel or abscission layer of a mature apple fruit is possible. Kimura *et al.* (2005) also 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,

¹⁹⁷ Dr Hale, para. 6.124.

¹⁹⁸ Dr Hayward, para. 6.125; Dr Smith, para. 6.126.

¹⁹⁹ Dr Smith, para. 6.126.

²⁰⁰ Dr Geider, para. 6.123.

²⁰¹ Dr Geider, para. 6.127.

²⁰² Dr Hayward, para. 6.131.

²⁰³ Dr Smith, para. 6.132.

²⁰⁴ For a description of the study, see paras. 4.57-4.67 above.

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.* (2005), Tsukamoto *et al.* (2005b) and Kimura *et al.* (2005).

8.68 Having reviewed the arguments of the parties and third parties, we consider that for the purposes of the Panel's assessment, the main issue relating to the Kimura *et al.* (2005) study is the reliance of this study on Azegami *et al.* (2005) and Tsukamoto *et al.* (2005b).

8.69 The experts consulted by the Panel considered that the Kimura *et al.* (2005) study depended heavily on the validity of the basic assumptions.²⁰⁵ Drs Hale and Hayward concurred in saying that the Kimura *et al.* (2005) study relied heavily on the infection study made by Azegami *et al.* (2005) and the pathway studies by Tsukamoto *et al.* (2005a, b)²⁰⁶, which did not provide any evidence that the pathway for disease, from infected fruit to susceptible host tissues, could be completed under natural ecological conditions. The fact that Kimura *et al.* (2005) assumed that the pathway could be completed by flies under natural ecological conditions was not supported by the published record.²⁰⁷

8.70 We conclude, in light of the arguments of the parties and the opinion of the experts that the Kimura *et al.* (2005) study does not provide sufficient scientific support for the quantification of the risk of completion of the pathway.

(d) Conclusion

8.71 From the above, we conclude that the new studies submitted by Japan do not provide sufficient scientific evidence to establish, in natural conditions, the risks which Japan tries to support with those studies that:

- (a) mature and symptomless apples can nonetheless harbour endophytic bacteria (latent infection); and that
- (b) the pathway would likely be completed between a discarded infested/infected apple and a host plant in Japan, so as to lead to the establishment and spread of fire blight in Japan.

8.72 Having reached that conclusion, we move to assess the existence of a *rational relationship* between the scientific evidence and each element of the compliance measure.

3. Review of each element of the compliance measure

(i) *Introductory remarks*

8.73 We note that both the scientific evidence available and the views of the experts consulted by the Panel support the assertion of the United States that mature, symptomless apples are unlikely to transmit fire blight to host plants in Japan. The scientific evidence available and the experts consulted

²⁰⁵ Dr Geider, para. 6.133.

²⁰⁶ Dr Hale, para. 6.134; Dr Hayward, para. 6.135. Dr Smith judged the probability estimates in Kimura *et al.* (2005) to be "debatable" (para. 6.137).

²⁰⁷ Dr Hale added that Taylor *et al.* (2003) had established that insects do not become contaminated with *E. amylovora* from infested fruit discarded in an orchard when susceptible host tissue was in abundance. Hale *et al.* (1996) had also reported that there was no detectable spread of *E. amylovora* from heavily infested calyxes and fruit surfaces to blossom clusters, immature or mature fruits. Taylor *et al.* (2003a) also found that the population levels of *E. amylovora* required for infection of susceptible host tissues under orchard conditions far exceeded the levels likely to be present in infected apple calyxes at harvest and after cold storage (para. 6.129).

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 evidence submitted before this Panel. Both the relevant scientific evidence and the opinions of the experts consulted by the Panel support the view that limiting exports of apples from the United States to mature, symptomless fruits would ensure that such shipments do not contaminate host plants in Japan.

8.75 We note that the United States proposes to export only mature, symptomless apples, and has also expressed its commitment, through its own legislation (the US Apple Export Act) to export only mature, symptomless apples. Since scientific meaning can be attached to the concepts of "mature" and "symptomless" apples, we consider such a commitment to be, in principle, an objective and verifiable one. We note that the experts stated that export quality controls have to be established and also verified.²¹⁰ We also note Japan's repeated concern that something other than mature, symptomless apples could be exported by mistake. We further recall that the concept of mature, symptomless apples is scientifically pertinent,²¹¹ and therefore a verifiable one. However, whether the controls currently in place to ensure that apples are mature and symptomless may be subject to discussion, as evidenced by Japan's arguments. This said, we assume that if the United States is ready to export only mature, symptomless apples and if, as evidenced by its position, the United States believes that "mature" and "symptomless" are objective concepts, then the United States should have no objection to measures necessary to control that shipments are actually composed only of mature, symptomless apples. We therefore consider that we should carry out our review of the elements of the compliance measure starting from the hypothesis that what is exported in principle is mature, symptomless apples.

8.76 In our examination of Japan's requirement, some elements of the measure will be reviewed together, because they relate to different aspects of the same concern.

(ii) *Requirement that: (a) fruit be produced in a designated fire blight-free orchard; (b) the export orchard be free of plants infected with fire blight; (c) the orchard and surrounding buffer zone be inspected once per year at early fruitlet stage; and (d) detection of a blighted tree in this area by inspection will disqualify the orchard*

Summary of the arguments of the parties²¹²

8.77 The United States argues that there is no scientific evidence that a fruit from a tree infected with fire blight poses a risk of transmission of fire blight if the fruit is mature and symptomless. Therefore, there is no rational relationship between the scientific evidence and Japan's requirement that apples be sourced from fire blight-free orchards.

²⁰⁸ Panel Report on *Japan – Apples*, para. 8.173.

²⁰⁹ Panel Report on *Japan – Apples*, paras. 8.115 and 8.118.

²¹⁰ Dr Hale, Transcript, Annex 3, para. 203; Dr Smith, para. 206.

²¹¹ See Panel Report on *Japan – Apples*, paras. 8.113 and 8.118.

²¹² A detailed account of the arguments of the parties can be found in paras. 4.70 to 4.114 of this Report.

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:

"There is some experience saying [apples from blighted orchards] are, in some cases, more infected in the calyx than apples from other orchards without fire blight. That would of course be very biased to have this precaution not to take the apples from the blighted orchards, but maybe this is the only reason I have. It is good commercial practice to obey limits of phytosanitary ordinance."

8.87 Dr Hale stated that "it would not be economic to even harvest [fruits from severely blighted orchards], never mind export them."²¹⁶ He added that, in the case of a neglected orchard, "it usually means that the treatment will be the use of the chainsaw."²¹⁷ Dr Hayward concluded that "If we accept all sides of the evidence about mature symptomless fruit it should still be possible to harvest fruit from a severely blighted orchard without risk",²¹⁸ and Dr Smith added, with respect to neglected orchards which had been found to be severely blighted, that "a neglected orchard is neglected not only with respect to fire blight, it is also neglected with respect to codling moth and everything else. So that fruits cannot be taken from some orchards. This is an academic argument."²¹⁹ Thus, the reason for not exporting from a blighted orchard is essentially one of good agricultural and commercial practice. A severely blighted orchard will produce only a few mature, symptomless apples, and those apples could also be infected by other pests or disease if, in addition, the orchard is neglected.

8.88 We conclude from the above that if a mature, symptomless apple is harvested from a blighted orchard, even a severely blighted one, the likelihood that it will be infected has not been established. Infestation is possible, though unlikely. Indeed, it was determined by the Original Panel and not contested in this proceeding, that any epiphytic *E. amylovora* that could be found on the surface of mature, symptomless apples are unlikely to have the capacity to contaminate host plants.²²⁰ If neither infection nor infestation by populations of *E. amylovora* is likely to be found in mature, symptomless apples harvested from severely blighted orchards, it is even less likely to be found in apples from lightly blighted orchards or non-blighted orchards where a fire blight-infected plant has been found.

8.89 We have determined that available scientific evidence does not support the view that mature symptomless apples harvested from blighted orchards, whether severely blighted or not, or from non-blighted orchards where other plants have been found to be infected, would harbour populations of *E. amylovora* capable of spreading fire blight disease. It follows from this determination that the requirements that apple fruit come from a designated orchard²²¹, that the orchard be free of apple trees or other plants infected with fire blight, that the orchard and surrounding buffer zone be inspected once per year at the early fruitlet stage, and that detection of a blighted tree in this area by inspection

²¹⁵ Dr Geider, Transcript, Annex 3, para. 187.

²¹⁶ Dr Hale, Transcript, Annex 3, para. 188.

²¹⁷ Dr Hale, Transcript, Annex 3, para. 193.

²¹⁸ Dr Hayward, Transcript, Annex 3, para. 190.

²¹⁹ Dr Smith, Transcript, Annex 3, para. 194.

²²⁰ Panel Report on *Japan – Apples*, paras. 8.134-8.136.

²²¹ We note that, for the time being, only orchards from the states of Washington or Oregon may be designated. We do not consider it necessary to make a finding on this issue essentially because Japan stated that the exclusion of states other than Washington and Oregon results from the failure of the United States to provide documentation regarding quarantine pests and diseases other than fire blight in relation to other states. We note 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 in this case.

will disqualify the orchard as a whole, cannot be considered to be supported by sufficient scientific evidence.

8.90 However, the Panel notes that orchard inspection may be part of good agricultural practices or even scientifically justified in relation to diseases other than fire blight.

(iii) *The fire blight-free orchard must be surrounded by a ten-meter buffer zone (or border zone) free of fire blight*

8.91 The United States claims that the requirement of a buffer zone is not scientifically justified. This is further demonstrated by considering that a fire blight-free requirement in a buffer zone means that trees tens, hundreds, or thousands of meters away from a potential source of inoculum will be disqualified for export to Japan.

8.92 Japan argues that the buffer zone is necessary to (i) clearly delineate and define an "export orchard," separate from the rest of the grounds and subject to phytosanitary requirements, and to (ii) prevent branches of trees inside the orchard from overlapping, or being in direct contact, with plants outside the orchard.

8.93 It has been established before the Original Panel that no buffer zone or border zone of any size was justified by the existing scientific data, as fruit harvested from blighted trees or adjacent to blighted trees had not harboured *E. amylovora*.²²² Experts before this Panel have confirmed the absence of scientific justification for imposing buffer zones or border zones. Referring to Roberts *et al.* (2002), both Dr Hale and Dr Hayward confirmed 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*.²²³ This conclusion equally applied to resistant or least resistant varieties of apples.²²⁴

8.94 As mentioned above, our analysis is based on the premise that the product to be exported by the United States to Japan will be mature, symptomless apple fruit. If this is the case, i.e. apples are not infected and do not harbour viable epiphytic populations of *E. amylovora*, irrespective of whether they were harvested from a blighted tree or not, the requirement of a 10-meter border zone, to the extent that it is supposed to avoid the spreading of fire blight to non infected apple trees, is not supported by sufficient scientific evidence.

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

8.95 We note that Japan has asserted that the washing of apple fruit was part of the normal commercial treatment of US apples and hence caused no additional burden on US exporters. The United States argues that it applies surface disinfection as a result of Japan's requirement, as evidenced by its phytosanitary certificate form for exports to Japan.

8.96 The experts have expressed the view that surface disinfection is not regularly accepted commercial practice.²²⁵ It may even be harmful to human health.²²⁶ Moreover, Dr Hayward stated:

²²² Panel Report on *Japan – Apples*, para. 8.189.

²²³ Dr Hale, paras. 6.68-6.69; Dr Hayward, para. 6.71.

²²⁴ Dr Hale, para. 6.69; Dr Hayward, para. 6.71.

²²⁵ Dr Smith, Transcript, Annex 3, para. 172; Dr Hale, para. 175.

²²⁶ Dr Geider, Transcript, Annex 3, para. 178.

"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*

8.103 The United States argues that there is no scientific justification for the requirement that apple fruit destined for export to Japan be kept physically separate from other apple fruit.

²²⁷ Dr Hayward, Transcript, Annex 3, para. 174.

²²⁸ Dr Smith, Transcript, Annex 3, para. 172; Dr Hayward, para. 174; Dr Hale, para. 175.

²²⁹ Dr Hale, Transcript, para. 175, regarding New Zealand.

²³⁰ See in this respect our conclusion regarding Tsukamoto *et al.* (2005a), para. 8.57 above.

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 that separation of fruit destined for Japan would not be difficult given that many fruit exporters already have the capacity to separate fruit destined for different markets all over the world.

8.105 Like the preceding elements of Japan's compliance measure, this requirement seems to derive from the perceived risk that apples destined for Japan could be contaminated by other apples. We consider that, if it were to occur, such contamination would only affect the surface of the fruit and the bacteria would be unlikely to survive commercial handling, storage and transportation in sufficient number to contaminate host plants in Japan. The experts consulted by the Panel have generally considered that preserving the integrity and security of consignments may be necessary in relation to pests or diseases other than fire blight.²³² However, there was no evidence that an apple fruit could become *infected* by *E. amylovora* as a result of a contact with infected fruit.²³³

8.106 The same considerations that lead us to conclude that the requirement of chlorine disinfection of packing facilities was not scientifically supported would lead us to conclude that this requirement also is not justified by sufficient scientific evidence. Indeed, since scientific evidence and the experts have confirmed that mature, symptomless apples are unlikely to harbour viable populations of epiphytic *E. amylovora*, we conclude that the requirement of separation of fruit destined for Japan is not supported by sufficient scientific evidence.

(vii) *US plant protection officials must certify that fruits are free from fire blight and have been treated post-harvest with chlorine*

8.107 Japan argues that the issuance of phytosanitary certificates is standard regulatory practice and does not result in any burden to US exporters. As a phytosanitary measure, the requirement is necessarily procedural. The United States argues that Japan maintains its post-harvest measures without sufficient scientific evidence.

8.108 This requirement relates to certification by US authorities. However, it relates to two separate aspects (a) certification that fruits destined for Japan are free from fire blight and (b) certification that the fruits destined for Japan have been treated post-harvest with chlorine. Accordingly, we will first address the question of certification in general. Thereafter, we will determine whether these two certification requirements in the present case are justified by sufficient scientific evidence.

8.109 We recall that the United States informed us that it had no fixed, required form for a phytosanitary certificate and that certificates were adjusted to the requirements of the importing countries. The United States provided us with copies of phytosanitary certificates which confirmed that certain treatments had been performed for codling moth (methyl bromide and cold storage) and *E. amylovora* (chlorine disinfection). We also recall that export certificates submitted by the United States certified that exported apples complied with the US Apple Export Act.

8.110 We first note that phytosanitary certificates are common procedural requirements. We agree with Japan that the issuance of phytosanitary certificates is standard regulatory practice.²³⁴ Second, whether a certification will be justified by scientific evidence will, in our opinion, generally depend

²³¹ Dr Hale, Transcript, Annex 3, para. 175, regarding New Zealand.

²³² Dr Smith, Transcript, Annex 3, para. 155; Dr Hale, Transcript, Annex 3, para. 157; Dr Smith, Transcript, para. 158.

²³³ Dr Smith, Transcript, paras. 163 and 170; Dr Hayward, Transcript, para. 165; Dr Hale, Transcript, para. 167; Dr Geider, Transcript, para. 169.

²³⁴ Moreover, they may be required in order to certify the performance of quality controls, including those aimed at ascertaining that exported apples are mature and symptomless.

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 scientifically justified in requesting certification that apples exported to its territory be free from that disease.²³⁵

- *Certification that exported apples have been treated post-harvest with chlorine*

8.112 As far as certification of chlorine treatment is concerned, we recall our findings regarding the scientific justification for chlorine treatment as such:²³⁶ that this requirement is not scientifically justified with respect to fire blight. In application of our reasoning in paragraph 8.110 above, we conclude that a certification requirement relating to a requirement which is itself not scientifically justified cannot be scientifically justified either.

(viii) *Japanese officials must confirm the US officials' certifications and inspect packing facilities*

8.113 We note that Japan argues that inspection at export/import stages would offer security for the risk of accidental shipment of observably infected apple fruit and inspection upon importation would be beneficial for determining symptoms which may have developed during shipping. The United States claims that inspection is a costly process borne by US exporters.

8.114 We first note that this requirement contains two distinct aspects: (a) confirmation of US official certifications by Japanese officials; and (b) inspection of packing facilities by Japanese officials. We further recall that confirmation under item (a) applies to two elements: (i) certification that exported apples are free from fire blight and (ii) certification that chlorine treatment has been applied to exported apples. We will address each of these elements individually hereafter.

8.115 We are of the view that, as for certification, whether confirmation or inspection in relation to a particular measure, treatment or action will be scientifically justified largely depends on whether such measure, treatment or action is itself scientifically justified. In other words, Japan is entitled to apply confirmation procedures in relation to requirements that Japan is scientifically justified to apply. Confirmation and inspection procedures can be legitimate phytosanitary instruments if they support measures necessary to address legitimate phytosanitary risks.

- *Confirmation by Japanese officials of certification by US officials*

Freedom from fire blight

8.116 Regarding the confirmation of the certification by US officials that exported apples are free from fire blight, we believe that the same reasoning should apply as for the certification requirement. We therefore conclude that Japan is entitled to have its officials confirm US official certifications that

²³⁵ We note in this respect that the United States already applies the requirement that export apples be fire blight-free under its domestic legislation. We recall that the requirement under US law is for exported apples to comply with the US Apple Export Act No. 1 Grade standard. The US Apple Export Act requires that exported apples be mature and symptomless, *and free of disease*.

²³⁶ See paras. 8.95-8.97 above.

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 Although the United States referred to paragraphs 1, 2, 3, 5 and 6 of Article 5 of the SPS Agreement in its request for establishment of a panel²⁴⁰ it has, in the course of these proceedings, only raised claims in relation to paragraphs 1 and 6 of Article 5. The US claims under Article 5.6 are

²³⁷ See paras. 8.95-8.97 above.

²³⁸ See paras. 8.95-8.106 above.

²³⁹ Dr Hale, Transcript, Annex 3, para. 203; Dr Smith, para. 206.

²⁴⁰ WT/DS245/11.

addressed in the following section. In this section, we will address the US allegation exclusively in relation to a violation of Article 5.1.

8.123 Article 5.1 reads as follows:

"Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risk to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."

8.124 We recall that, in our review of the measure at issue under Article 5.1, we need to take into account the context of this provision, which includes Article 5.2.²⁴¹ We are also mindful of the Appellate Body's observation that Article 2.2 informs Article 5.1 and that they should "constantly be read together".²⁴²

8.125 We also recall that the notion of risk assessment is defined in paragraph 4 of Annex A of the SPS Agreement. Paragraph 4 of Annex A of the SPS Agreement reads as follows:

"4. *Risk assessment* - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs."

8.126 As has been noted by previous panels, the general obligation reflected in Article 5.1 contains two elements:

- (a) an assessment of risk; and
- (b) that Members must ensure that their SPS measures are *based on* such an assessment.

8.127 We note that the United States claims that Japan's September 2004 risk assessment (hereafter the "2004 PRA") 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 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 did not demonstrate that such a commodity could exist in the real world.

8.128 Japan argues that new evidence shows 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. The 2004 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.

8.129 The Panel notes that the practice in previous disputes, and indeed that which was followed by the Original Panel, was to consider first whether there existed an assessment, as appropriate to the circumstances, of the risk to plant health and, secondly, whether there was a rational relationship

²⁴¹ Article 5.2 provided, *inter alia*, that "In the assessment of risks, Members shall take into account available scientific evidence".

²⁴² Appellate Body Report on *EC – Hormones*, para. 180. The text of Article 2.2 of the SPS Agreement is found in para. 8.34 above.

between the measure and the risk assessment. The consideration of whether there exists a risk assessment appropriate to the circumstances is not limited to a procedural review as to whether the risk assessment followed a certain form, *in casu* the IPPC Standards.²⁴³ More importantly, the substance of the PRA, that is the scientific evidence which is being evaluated, must support the conclusions of the PRA. This is particularly relevant in this case, given our analysis under Article 2.2 and our remark above on the Appellate Body's observation that Article 2.2 informs Article 5.1.

8.130 In light of the above, we will first examine the substantive validity of the 2004 PRA and, as appropriate, whether the PRA complies with certain procedural requirements attached to risk assessments. Second, we will determine whether the measure at issue is based on a valid risk assessment, in the sense of whether there is a rational relationship between the measure and the risk assessment.²⁴⁴

2. Existence of an assessment, as appropriate to the circumstances, of the risk to plant life or health

(a) Summary of the arguments of the parties²⁴⁵

8.131 Japan claims that the revised 2004 PRA considered all of the issues raised by Dr Hale at the Original Panel meeting with experts. In the 2004 PRA, Japan identified "US apple fruit" as a possible pathway for introduction of fire blight. The revised PRA then examined the probability of infection of US apple fruit, the survivability of *E. amylovora* during handling, storage and shipment and finally the completion of the pathway. The revised PRA also reviewed and assessed the necessity of individual elements of Japan's Systemic Approach.

8.132 The United States considers that, like the 1999 PRA, the 2004 PRA fails to address the commodity actually exported by the United States – mature, symptomless apple fruit – and instead relies on the existence of a commodity that does not exist in nature: mature, symptomless, yet latently infected apple fruit. In the absence of any scientific evidence of a fire blight-risk posed by mature, symptomless apple fruit, any risk analysis which concludes otherwise would not "take into account available scientific evidence," and would not meet the requirements for a risk assessment under Article 5.1.

8.133 Japan argues that the 2004 PRA meets the requirement of specificity of the risk assessment. The 2004 PRA took into account that apple fruit under the current US export practice might or might not be actually "mature" in the horticultural sense or "healthy" in the pathological sense, and addressed these risks accordingly.

8.134 The United States argues that Japan's 2004 PRA ignored US pre-harvest and post-harvest procedures for quality control. By failing to address actual US practices and disputing the effectiveness of those practices, Japan failed to take into account ISPM 11.

(b) Analysis of the Panel

8.135 We note that, in section 2-5, the 2004 PRA reaches the following conclusions:

²⁴³ See para. 2.23, Appellate Body Report on *Australia – Salmon*, para. 121; Appellate Body Report on *Japan – Agricultural Products II*, para. 112.

²⁴⁴ Appellate Body Report on *EC – Hormones*, paras. 193-194.

²⁴⁵ A more detailed account of the arguments of the parties can be found in paras. 4.140-4.142 and 4.160 of this Report.

"[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 mindful that we are not supposed to conduct our own risk assessment or to impose any scientific opinion on Japan. Like the panels in *Australia – Salmon* and *Japan – Agricultural Products II*, we will only examine and evaluate the evidence, including the information we received from the experts advising the Panel, and the arguments put before us in light of the relevant WTO provisions.

8.138 We note that neither the United States nor the experts consulted by the Panel contest the conclusion in the 2004 PRA that immature apple fruit can be infected with *E. amylovora* and that wounded/decayed apple fruit can be infected with *E. amylovora*. This is not contested either in the relevant literature. The parts of the 2004 PRA conclusions contested by the United States are:

- (a) that apples exported from a severely blighted orchard could be mature but nonetheless internally affected with *E. amylovora*; and
- (b) that once the bacteria enters Japan in significant populations, the bacteria will likely establish and spread in Japan (completion of the pathway).

8.139 We note that Japan relies in the 2004 PRA on the very studies we reviewed under Article 2.2. We therefore need to determine whether the conclusions of the 2004 PRA are actually supported by the scientific evidence already addressed in the context of Article 2.2. The fact that we have found that the measure at issue was maintained without sufficient scientific evidence does not, in our view, enable us to dispense with making findings on Article 5.1. It remains for us to ascertain to what extent Japan actually relied, in the 2004 PRA, on the studies we considered in our review of the measure at issue in the context of Article 2.2.

8.140 We have already found, in the context of our examination of Japan's compliance measure under Article 2.2 of the SPS Agreement, that the studies relied upon by Japan do not support Japan's allegation that mature, symptomless apples can be latently infected. As confirmed by the experts, the studies relied upon by Japan do not demonstrate that such latent infection could occur in real orchard conditions. Likewise, we have also found that the studies relied upon by Japan do not support the view that apple fruit would be likely to complete the pathway and contaminate host plants in Japan under non-laboratory conditions. We stress the importance of our reference to "real orchard conditions" and "non-laboratory conditions". Indeed, as recalled by the experts, laboratory experiments may not reflect natural conditions, whereas production and trade in apples take place in

²⁴⁶ See para. 8.124, above.

²⁴⁷ See Panel Report on *Australia – Salmon*, para. 8.57.

the real world. Even if the studies relied upon by Japan actually confirmed latent infection and completion of the pathway, their relevance for the 2004 PRA could still be questioned, to the extent that the assessment must be appropriate to the circumstances. In this case, this implies that the assessment reflect the real production and trade conditions.

8.141 In Section 2-3-1-1(2)(A) of the 2004 PRA, Japan acknowledges the existence of a consensus among foreign fire blight experts that mature, symptomless apples are unlikely to be infected by the disease. However, Japan relies on Azegami *et al.* (2005) as conclusive demonstration that mature apple fruit are not immune or resistant to infection by *E. amylovora* in a laboratory study.

8.142 The conclusions drawn from Azegami *et al.* (2005) have been considered by the experts as not reflecting orchard conditions.²⁴⁸

8.143 The 2004 PRA also relies on Tsukamoto *et al.* (2005a) to establish the probability that *E. amylovora* will survive during transportation and storage (2004 PRA, section 2-3-1-2). The United States has argued and the experts have confirmed that the experimental conditions in Tsukamoto *et al.* (2005a) did not reflect commercial practice.

8.144 On the probability of *E. amylovora* transferring to and infecting suitable host plants (2004 PRA, section 2-3-1-4), Japan relies on Tsukamoto *et al.* (2005b). The United States has argued and the experts have confirmed that Tsukamoto *et al.* (2005b) did not reflect natural conditions.²⁴⁹

8.145 On the basis of the evidence before us, including the comments of the scientific experts consulted by the Panel²⁵⁰, we conclude that the new studies relied upon by Japan do not support the 2004 PRA conclusions that mature apples could be latently infected, nor the conclusion in the 2004 PRA that the pathway would likely be completed. Since the scientific evidence relied upon by Japan does not support the conclusions reached by Japan in its 2004 PRA, we conclude that the 2004 PRA is not an assessment, as appropriate to the circumstances, of the risks to plant life or health, within the meaning of Article 5.1 of the SPS Agreement.

8.146 Our approach is consistent with the view of the Appellate Body in *EC – Hormones*, whereby a WTO Member may choose to rely on a minority scientific opinion. The scientific studies relied upon by Japan cannot be assimilated to a minority opinion. As confirmed by the experts, these studies can be deemed to be scientific in nature. However, they do not objectively support what Japan would like to demonstrate, i.e. that mature apples could be latently infected and that the pathway would likely be completed in real conditions.

8.147 With respect to procedural requirements, we note the views expressed by the experts that the 2004 PRA formally followed most of the steps in ISPM 11.²⁵¹ However, having concluded that the 2004 PRA does not amount to a risk assessment because the scientific evidence relied upon does not support the conclusions drawn by Japan in the PRA, we see no need to make findings as to whether the 2004 PRA followed the procedural requirements applicable under the circumstances.

²⁴⁸ See paras. 8.47-8.52 above.

²⁴⁹ See para. 8.65 above.

²⁵⁰ See paras. 6.148-6.158; Dr Hale, Transcript, Annex 3, para. 35.

²⁵¹ See Dr Hale, para. 6.147; Dr Hayward, para. 6.150: "The format of the revised PRA followed that of ISPM 11 closely"; Dr Smith, para. 6.151.

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 The United States claims that Japan failed to validate its revised measures through the production of the new PRA. 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 do not rationally relate to a risk assessment that failed to identify any scientific evidence supporting these premises.

8.151 According to Japan, its 2004 PRA shows that there is a rational relationship between the evidence and the measure, consistent with Article 2.2. Potential/actual infection of apple fruit poses a risk of introduction of the disease.

(b) Analysis of the Panel

8.152 We first address the argument of the United States that the measure at issue is not based on the 2004 PRA because the 2004 PRA is dated September 2004 whereas the measure at issue itself dates back to 30 June 2004.

8.153 We note the argument of Japan that the 2004 PRA was actually completed by mid-June and that the only difference between the June version and the September version of the PRA was the reference to the status of the studies which were finalized after June 2004.

8.154 We recall that the Panel in *Australia – Salmon (Article 21.5 – Canada)* rejected an argument similar to that of the United States. In that case, the new measures had been published on 19 July 1999, whereas the Australian risk assessment for these amended measures was only published in its final form on 12 November 1999. The Panel noted in that case that the amendments made in the final version of the risk assessment did not alter the substance or the conclusions of the report as announced on 19 July 1999.²⁵³

8.155 In the present case, Japan produced two versions of its PRA, one in June 2004²⁵⁴ and one in September 2004.²⁵⁵ A review of the two documents shows no substantive difference between the two texts. As stated by Japan, the differences are of an editorial nature. The fact that the final version of the 2004 PRA is subsequent to the adoption of the measure at issue does not preclude the measure from being based on the 2004 PRA. All substantive elements and conclusions of the PRA were already included in the June version of the 2004 PRA. Japan states that this version was completed in mid-June, i.e. before the adoption of the new measures. Even though the PRA was not published, we have no reason to question Japan's statement.

²⁵² A more detailed account of the arguments of the parties can be found in paras. 4.158 to 4.161 of this Report.

²⁵³ Panel Report on *Australia – Salmon (Article 21.5 – Canada)*, paras. 7.76-7.77.

²⁵⁴ Exhibit JPN-17.

²⁵⁵ Exhibit JPN-3.

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 phytosanitary protection, taking into account technical and economic feasibility."
[Footnote 3]

8.159 Footnote 3 to Article 5.6 reads as follows:

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

8.160 We recall that the Original Panel exercised judicial economy with respect to the US claim of violation of Article 5.6 of the SPS Agreement.²⁵⁶

8.161 In these proceedings, we need to take into account the request of the parties for specific findings²⁵⁷ as well as the fact that we are at the compliance stage. Moreover, as mentioned above, we have decided to assess the legality of each element of the measure. A finding under Article 5.6 becomes useful to assess the extent to which Japan may still need to modify its legislation in order to comply with the recommendations and rulings of the DSB.²⁵⁸

8.162 In doing this, we shall apply the three-pronged test confirmed by the Appellate Body in *Australia – Salmon*, i.e. determine whether there is an alternative SPS measure which:

- (a) is reasonably available taking into account technical and economic feasibility;
- (b) achieves the Member's appropriate level of sanitary or phytosanitary protection; and
- (c) is significantly less restrictive to trade than the SPS measure contested.

²⁵⁶ Panel Report on *Japan – Apples*, para. 8.303.

²⁵⁷ United States, para. 4.115; Japan, para. 4.69.

²⁵⁸ See Appellate Body Report on *Australia – Salmon*, para. 223.

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.

(b) Analysis of the Panel

8.169 We understand that the alternative measure proposed by the United States would consist of requiring that only mature, symptomless apples be exported to Japan.²⁶⁰ Such a requirement is undeniably "reasonably available taking into account technical and economic feasibility" since this is the requirement already applied by the United States under the US Apple Export Act for all exports abroad.

8.170 We note Japan's argument that the requirement that apples be mature and symptomless is only a quality standard and the result of "current commercial practices". We first note that this is not completely correct since the standards are specified in legislation and subject to control by duly licensed government inspectors. We also note that, as currently applied, the alternative measure proposed by the United States appears to be a combination of public and private interventions. We see no reason to reject *a priori* the alternative measure proposed by the United States simply because it is the result of commercial practices rather than of administrative requirements or because it involves private operators and not exclusively public authorities. However, in any case, sufficient guarantees must be in place to provide adequate assurances that such practices or requirements, whether public or private, will be adhered to.

8.171 We are of the view that, when considering whether an alternative measure is reasonably available taking into account technical and economic feasibility, we should determine whether the alternative measure would constitute an option reasonably available taking into account technical and economic feasibility in the real world. In our opinion, the risk of incorrect enforcement is part of the technical feasibility of a measure.

8.172 We are mindful of Japan's argument according to which the requirement that apples be mature and symptomless is simply a "product specification" and not a phytosanitary measure because it provides for no test methods for verification or ways to achieve the specification.

8.173 We agree that the requirement that apples be mature and symptomless could appear not to constitute a phytosanitary measure at a first sight. However, the United States has provided scientific evidence, and the experts have confirmed that, mature, symptomless apples do not harbour endophytic or epiphytic populations of *E. amylovora* (i.e. a quantity of bacteria capable of transmitting fire blight). As a result, requiring that apples be mature and symptomless is a phytosanitary measure to the extent that such requirement is based on the scientific evidence that mature, symptomless apples will not contaminate host plants.

8.174 With regard to Japan's argument that the United States does not provide for any specifications in relation to mature, symptomless apples, and that no test method is provided, we first note that the United States has informed us of the requirement of the US Apple Export Act for "US No. 1 Grade", according to which the apple must be:

"[m]ature but not overripe, carefully handpicked, clean, fairly-well formed; free from decay, internal browning, internal breakdown, bitter pit, Jonathan spot, scald, freezing injury [...] and broken skin or bruises except those which are incident to proper handling and packaging [;] free from damage caused by sunburn or sprayburn, limb rubs, hail, drought spots, scars, stem or calyx cracks, disease, insects, [or] damage by other means."²⁶¹

²⁶⁰ See para. 8.174 below description of apples meeting US "No. 1 Grade", United States Standards for Grades of Apples, 7 C.F.R., §§ 51.301, and 51.302.

²⁶¹ United States Standards for Grades of Apples, 7 C.F.R. §§ 51.301, and 51.302.

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 technical and economic feasibility.

²⁶² 7 C.F.R. § 51.312.

²⁶³ See para. 4.81 and footnote 51 above.

²⁶⁴ Appellate Body Report on *Japan – Apples*, footnote 289.

²⁶⁵ Dr Hale, para. 6.160; Dr Hayward, para. 6.161; Dr Smith, para. 6.162.

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 "relatively objective concept," it never found that what the US apple industry ships would be "mature, symptomless" apple fruit. The issue of how to ensure that quality, or the relevant specifications and test methods, is therefore an entirely open issue in this proceeding.

8.185 Japan stresses that "mature, symptomless apple fruit" is a "product specification." These types of specifications typically describe (i) required qualities/parameters and (ii) test methods to ensure the qualities together with acceptable allowances. The United States has not provided the "mature, symptomless" specifications. Instead, it describes the "multiple processes" to ensure the quality of apple fruit shipped by US growers and equates these processes with the specifications. The United States calls the apples produced through a process compliant with these specifications as "mature, symptomless," without regard to their true quality. As such, the "mature, symptomless" apples as defined by the United States might or might not match the definition of mature, symptomless apple fruit.

(b) Analysis of the Panel

8.186 We note that the United States not only states that the requirement to export only "mature, symptomless apples" would be significantly less trade restrictive, it also suggests to apply this requirement in lieu of the measure at issue. We can infer from this that the measure would actually be "significantly less trade restrictive", or at least that it would satisfy the United States as being significantly less trade restrictive. We note that Japan does not contest this. Actually, Japan criticizes the US proposal by stating that it would be allowing the United States to export whatever it wants. The United States has also asserted that the current measure entailed costs for apple growers and exporters.

8.187 We note that a requirement that the United States do what it claims to be already doing under its national legislation would certainly be significantly less trade restrictive than a combination of requirements which undeniably impose constraints on US exporters, as evidenced by the fact that, in

²⁶⁶ A more detailed account of the arguments of the parties can be found in paras. 4.183-4.190 of this Report.

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 and symptomless theoretically meets Japan's ALOP. We note that Japan insists in its argumentation on the risk attached to inspection error or non-compliance with the US prescription that exported apples be mature and symptomless. We have mentioned above that Japan had failed to demonstrate that such error had occurred. Japan also failed to demonstrate before the Original Panel that apples, even if they were not mature or symptomless, would be likely to complete the pathway. We do not

²⁶⁷ A more detailed account of the arguments of the parties can be found in paras. 4.174-4.182 of this Report.

believe that the United States requests Japan to accept whatever it exports. The United States not only claims to export mature, symptomless apples, it applies standards and tests to ensure that only mature, symptomless apples are exported. Japan is free to establish mechanisms, as appropriate to the circumstances and compatible with the SPS Agreement, to ensure that apples imported from the United States are mature and symptomless.

8.194 With respect to the effectiveness of a requirement that export be limited to mature, symptomless apples, we recall that the experts have confirmed their previous conclusions that mature, symptomless apples are unlikely to complete the pathway and contaminate a host plant in Japan.²⁶⁸ In other words, we agree with the United States, on the basis of the scientific evidence available and having regard to the opinions of the experts, that restricting imports exclusively to mature, symptomless apples could meet Japan's ALOP.

8.195 With respect to the implementation of the measure, we agree with Japan that its ALOP may not be met by the US requirement if sufficient guarantees are not obtained in terms of implementation. However, this has nothing to do with the requirement that apples be mature and symptomless, but with the controls necessary to enforce the requirement.

8.196 We therefore conclude that the United States has demonstrated that the requirement that apples imported into Japan be mature and symptomless is an alternative measure that could meet Japan's ALOP.

5. Conclusion on Article 5.6 of the SPS Agreement

8.197 We note that Japan is concerned about the importation of other apples than mature, symptomless apples. We note that the United States does not claim that it wants to export anything other than mature, symptomless apples. Thus, what we are looking at is a measure consisting of exporting mature, symptomless apples. If the United States only exports mature, symptomless apples, the alternative measure proposed by the United States meets the requirements of Article 5.6 as a substitute to Japan's current measure.

8.198 We therefore conclude that the United States has made a prima facie case that the measure at issue does not comply with the requirement of Article 5.6. Japan has not rebutted this prima facie case.

8.199 Finally, the Panel would like to clarify that even though it chose to examine the measure proposed by the United States as an alternative that would be reasonably available, meet Japan's appropriate level of phytosanitary protection and would be significantly less trade restrictive, this does not mean that this measure is necessarily the only one meeting the requirements of Article 5.6 and available to Japan. However, it is an indication of a solution which could be available, provided appropriate means of control are put in place to give adequate assurances that apples exported from the United States are mature and symptomless.

F. ARTICLE XI OF GATT 1994

1. Summary of the arguments of the parties²⁶⁹

8.200 The United States claims that, since Japan's measures are not legitimate SPS measures, they are non-tariff trade barriers breaching Article XI of GATT 1994. According to the United States,

²⁶⁸ Dr Geider para. 6.142, Dr Hale para. 6.143, Dr Hayward para. 6.144 and Dr Smith para. 6.145.

²⁶⁹ A more detailed account of the arguments of the parties can be found in paras. 4.191-4.192 of this Report.

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 and rulings of the DSB violates Article 2.2, 5.1 and 5.6 of the SPS Agreement. We recall that the Original Panel exercised judicial economy with respect to the United States claims relating to Article XI of GATT 1994, in line with other panel's exercise of judicial economy in similar situations of violation of the SPS Agreement. We note that none of the parties contested the decision of the Original Panel before the Appellate Body in this respect and see no reason why we should follow a different approach under Article 21.5 of the DSU. We therefore exercise judicial economy with respect to the United States claim regarding Article XI of GATT 1994.

8.203 Since we have found that the phytosanitary measure at issue is inconsistent with the requirements of the SPS Agreement, we see no need to further examine whether this measure is also inconsistent with Article XI of GATT 1994.

G. ARTICLE 4.2 OF THE AGREEMENT ON AGRICULTURE

1. Summary of the arguments of the parties²⁷⁰

8.204 The United States claims that Japan's measures are also non-tariff barriers in breach of Article 4.2 of the Agreement on Agriculture. There was no dispute that Japan's measures fall within the scope of footnote 1 to Article 4 of the Agreement on Agriculture, that they are restrictions on imports of apples and that these restrictions have not been tariffed.

8.205 Japan argues that the new measure is consistent with Article 4.2 of the Agreement on Agriculture, as it is a phytosanitary measure fully consistent with the SPS Agreement and thus is 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 Article 4.2.

2. Analysis of the Panel

8.206 We have found above that the measure taken by Japan to comply with the recommendations and rulings of the DSB violates Article 2.2, 5.1 and 5.6 of the SPS Agreement. We recall that the Original Panel exercised judicial economy with respect to the US claims relating to Article 4.2 of the Agreement on Agriculture. We note that none of the parties contested the decision of the Original Panel before the Appellate Body in this respect and see no reason why we should follow a different approach under Article 21.5 of the DSU. We therefore exercise judicial economy with respect to the US claim regarding Article 4.2 of the Agreement on Agriculture.

8.207 Since we have found that the phytosanitary measure at issue is inconsistent with the requirements of the SPS Agreement, we see no need to further examine whether this measure is also inconsistent with Article 4.2 of the Agreement on Agriculture.

²⁷⁰ A more detailed account of the arguments of the parties can be found in paras. 4.193-4.194 of this Report.

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 relied upon by Japan is maintaining a phytosanitary measure that is not based on an assessment, as appropriate to the circumstances, of the risk to plant life or health, contrary to Article 5.1 of the SPS Agreement.
- (c) Japan breaches Article 5.6 of the SPS Agreement, to the extent that the measure at issue is more trade-restrictive than required to achieve Japan's appropriate level of phytosanitary protection, taking into account technical and economic feasibility.

9.2 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement [including the SPS Agreement], the action is considered prima facie to constitute a case of nullification or impairment". We note that Japan failed to rebut this presumption. We conclude that, to the extent Japan has acted inconsistently with the SPS Agreement, it has nullified or impaired the benefits accruing to the United States under the SPS Agreement.

9.3 We recommend that the Dispute Settlement Body request Japan to bring the phytosanitary measure in dispute into conformity with its obligations under the SPS Agreement.