

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

Report of the Panel

The report of the Panel on Japan – Measures Affecting the Importation of Apples is being circulated to all Members, pursuant to the DSU. The report is being circulated as an unrestricted document from 15 July 2003 pursuant to the Procedures for the Circulation and Derestriction of WTO Documents (WT/L/452). Members are reminded that in accordance with the DSU only parties to the dispute may appeal a panel report. An appeal shall be limited to issues of law covered in the Panel report and legal interpretations developed by the Panel. There shall be no *ex parte* communications with the Panel or Appellate Body concerning matters under consideration by the Panel or Appellate Body.

Note by the Secretariat: This Panel Report shall be adopted by the Dispute Settlement Body (DSB) within 60 days after the date of its circulation unless a party to the dispute decides to appeal or the DSB decides by consensus not to adopt the report. If the Panel Report is appealed to the Appellate Body, it shall not be considered for adoption by the DSB until after the completion of the appeal. Information on the current status of the Panel Report is available from the WTO Secretariat.

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. FACTUAL ASPECTS	2
A. THE DISEASE AT ISSUE.....	2
1. Fire blight (<i>Erwinia amylovora</i>)	2
2. Host plants	3
3. Geographical distribution of fire blight	3
4. Relevant technical and scientific terms.....	3
B. JAPAN'S FIRE BLIGHT MEASURES	4
C. INTERNATIONAL STANDARDS, GUIDELINES AND RECOMMENDATIONS	6
1. The IPPC	6
2. International standards for phytosanitary measures (ISPMs)	7
III. CLAIMS OF THE PARTIES	9
IV. ARGUMENTS OF THE PARTIES	11
A. THE SCOPE OF THE DISPUTE.....	11
1. Relevant provisions.....	11
2. Objection to submitted evidence.....	12
B. THE MEASURE (OR MEASURES) AT ISSUE	14
1. Fire blight status of Japan.....	16
2. History of the dispute.....	16
C. APPLICATION OF THE <i>SPS AGREEMENT</i>	19
D. BURDEN OF PROOF.....	19
E. ARTICLE 2.2	22
1. General.....	22
2. Nature of the scientific evidence	24
3. Transmission of the disease.....	27
4. Pathway for transmission of the disease	32
5. Endophytic (internal) bacteria and mature apple fruit.....	34
6. Epiphytic bacteria and mature apple fruit.....	39
7. Scientific evidence and the steps in Japan's systems approach	41
(i) <i>Prohibition of imported apples from orchards in which any fire blight is detected</i>	<i>41</i>
(ii) <i>Prohibition of imported apples from any orchard should fire blight be detected within a 500-meter buffer zone surrounding the orchard.....</i>	<i>42</i>
(iii) <i>Inspection of orchards three times yearly</i>	<i>44</i>
(iv) <i>Prohibition of imported apples unless treated with chlorine.....</i>	<i>45</i>
(v) <i>Prohibition of imported apples from US states other than Washington or Oregon</i>	<i>45</i>

(vi)	<i>Prohibition of imported apples unless other production, harvesting, and importation requirements are met</i>	46
F.	ARTICLE 5.1	47
1.	General	47
2.	Evaluation of the likelihood of entry, establishment or spread	47
3.	Evaluation of risk according to the measure which might be applied	53
4.	Measures based on an assessment of the risks	54
G.	ARTICLE 5.2	56
H.	ARTICLE 5.6	58
I.	ARTICLE 5.7	63
J.	ARTICLE 7 (ANNEX B)	68
K.	ARTICLE XI OF GATT	69
L.	ARTICLE 4.2 OF THE AGREEMENT ON AGRICULTURE	69
V.	SUMMARY OF THIRD PARTY SUBMISSIONS	69
A.	AUSTRALIA	69
1.	Burden of proof	70
2.	Standard for developing a prima facie presumption	70
3.	Conflicting scientific evidence and opinion	70
4.	The product at issue	73
B.	BRAZIL.....	74
1.	Issues in relation to the SPS Agreement	74
2.	Brazilian phytosanitary measures on US apples	75
C.	EUROPEAN COMMUNITIES	76
1.	Procedural issues	76
2.	Legal arguments on Articles 2.2, 5.1 and 5.7	78
D.	NEW ZEALAND.....	81
1.	Scientific evidence relating to fire blight	81
2.	Inconsistency of Japan's fire blight measures with the SPS Agreement	83
3.	Chronology of bilateral discussion between New Zealand and Japan	84
4.	Apple maturity and trade	84
E.	SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU	85
1.	Chinese Taipei's measures on US apples	86
VI.	PANEL'S CONSULTATION WITH SCIENTIFIC EXPERTS	87
A.	PANEL'S PROCEDURES	87
B.	SUMMARY OF THE WRITTEN RESPONSES BY THE EXPERTS TO THE PANEL'S QUESTIONS	89
VII.	INTERIM REVIEW	131
A.	INTRODUCTION	131

B.	COMMENTS BY JAPAN.....	131
1.	Burden of proof.....	131
2.	Article 2.2 of the SPS Agreement	132
3.	Article 5.7 of the SPS Agreement	132
4.	Article 5.1 of the SPS Agreement	133
5.	Article 7 of the SPS Agreement	135
C.	COMMENTS BY THE UNITED STATES	135
1.	Requests for additional findings.....	135
2.	Comments on specific paragraphs of the Report.....	136
VIII.	FINDINGS	139
A.	APPROACH FOLLOWED BY THE PANEL.....	139
B.	THE MEASURE AT ISSUE AND THE PRODUCT SUBJECT TO THIS MEASURE.....	141
1.	The measure at issue.....	141
(a)	Summary of the arguments of the parties	141
(b)	Analysis of the Panel	143
(i)	<i>One or more measures?.....</i>	<i>143</i>
(ii)	<i>Elements constituting the phytosanitary measure at issue.....</i>	<i>145</i>
2.	The product subject to the phytosanitary measure at issue.....	147
(a)	Summary of the arguments of the parties	147
(b)	Analysis of the Panel	147
C.	PROCEDURAL ISSUES.....	149
1.	Introduction.....	149
2.	Burden of proof.....	150
3.	Japan's requests for preliminary rulings.....	152
(a)	Introduction.....	152
(b)	Japan's request that we "remove" certain pieces of evidence from the proceedings.....	153
(c)	Japan's request regarding some claims not developed by the United States in its first submission	153
(i)	<i>Summary of the arguments of the parties.....</i>	<i>153</i>
(ii)	<i>Analysis of the Panel.....</i>	<i>154</i>
-	Request (a).....	154
-	Request (b)	154
D.	ARTICLE 2.2 OF THE SPS AGREEMENT.....	155
1.	Summary of the arguments of the parties	155
(a)	United States	155
(b)	Japan	156
2.	Approach of the Panel with respect to the review of the phytosanitary measure at issue under Article 2.2 of the SPS Agreement.....	157

(a)	Preliminary remarks: limitation of findings to whether the measure is maintained "without sufficient scientific evidence"	157
(b)	Determining whether the measure at issue is (or not) "maintained without sufficient scientific evidence"	157
(i)	<i>Introduction</i>	157
(ii)	<i>What needs to be demonstrated in substance?</i>	158
(iii)	<i>How to demonstrate the existence or absence of sufficient scientific evidence?</i>	160
-	"Scientific evidence"	160
-	"Sufficient" scientific evidence	162
3.	Preliminary question: the relevance and consequences of the notion of "mature, symptomless" apple fruit in the assessment of the phytosanitary measure at issue under Article 2.2.....	164
(a)	Summary of the arguments of the parties	164
(b)	Analysis of the Panel	164
(i)	<i>Introduction</i>	164
(ii)	<i>Mature, symptomless apples v. other apples</i>	165
(iii)	<i>Relevance of addressing the risks related to both mature, symptomless apples and other apples</i>	166
4.	Infestation and infection of mature, symptomless apple fruit	168
(a)	Infestation	168
(i)	<i>Endophytic bacteria</i>	168
(ii)	<i>Epiphytic bacteria</i>	169
(b)	Infection	170
5.	Risk of entry, establishment or spread of fire blight within Japan by imported US apple fruit (apple fruit as a pathway)	170
(a)	Introduction.....	170
(b)	Mature, symptomless apple fruit.....	171
(c)	Apples other than "mature, symptomless apple fruit"	173
(i)	<i>Capacity of infected apple fruit to serve as pathway</i>	173
(ii)	<i>Error of handling and illegal action</i>	174
(d)	Risk of completion of the pathway	175
6.	Intermediate conclusion	176
7.	Conformity of the phytosanitary measure at issue with Article 2.2 of the SPS Agreement	178
(a)	Absence of a "rational relationship" between the scientific evidence available and the measure at issue	178
(i)	<i>The prohibition of imported apples from any orchard (whether or not it is free of fire blight) should fire blight be detected within a 500-meter buffer zone surrounding such orchard</i>	179

(ii)	<i>The requirement that export orchards be inspected at least three times yearly (at blossom, fruitlet, and harvest stages) for the presence of fire blight</i>	181
(b)	Conclusion	182
8.	Provisional conclusion on Article 2.2 of the SPS Agreement	182
E.	ARTICLE 5.7 OF THE SPS AGREEMENT	182
1.	Summary of the arguments of the parties	182
2.	Analysis of the Panel	183
3.	Final conclusion on Article 2.2 of the SPS Agreement	186
F.	ARTICLES 5.1 AND 5.2 OF THE SPS AGREEMENT	186
1.	Introduction	186
2.	Japan's risk assessment	187
(a)	Requirements of a risk assessment under Article 5.1	187
(b)	A risk assessment "as appropriate to the circumstances"	188
(c)	International risk assessment techniques developed by relevant international organizations.....	188
(d)	Japan's risk assessment in light of the requirements under Annex A, paragraph 4 of the SPS Agreement	189
(i)	<i>Introduction</i>	189
(ii)	<i>The disease at issue and the potential biological and economic consequences associated with its entry, establishment or spread</i>	191
(iii)	<i>The likelihood of entry, establishment or spread of the disease</i>	191
-	Japan's 1999 PRA.....	192
-	Assessment of Japan's risk assessment.....	193
(iv)	<i>According to the SPS measures which might be applied</i>	197
3.	Is the measure "based on" a risk assessment?	199
4.	Conclusion	199
G.	ARTICLE 5.6 OF THE SPS AGREEMENT.....	199
1.	Summary of the arguments of the parties	199
2.	Analysis of the Panel	200
H.	ARTICLE 7 AND ANNEX B OF THE SPS AGREEMENT	202
1.	Summary of the arguments of the parties	202
2.	Assessment by the Panel	202
I.	ARTICLE XI OF GATT 1994	206
J.	OTHER CLAIMS INCLUDED IN THE REQUEST FOR ESTABLISHMENT OF THE PANEL.....	206
IX.	CONCLUSIONS	207
	ANNEX 1	207
	ANNEX 2	210
	ANNEX 3	212

I. INTRODUCTION

1.1 In a communication dated 1 March 2002, the United States requested consultations with Japan pursuant to Articles 1 and 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU"), Article XXIII of the General Agreement on Tariffs and Trade 1994 ("GATT 1994"), Article 11 of the Agreement on the Application of Sanitary and Phytosanitary Measures ("*SPS Agreement*") and Article 19 of the Agreement on Agriculture, with respect to restrictions imposed by Japan on imports of apples from the United States.¹

1.2 The United States stated that since 1994, Japan had applied quarantine restrictions on US apples imported into Japan to protect against the introduction of fire blight (*Erwinia amylovora*). These restrictions included, *inter alia*, the prohibition of imported apples from orchards in which any fire blight is detected, the requirement that export orchards be inspected three times yearly for the presence of fire blight, the disqualification of any orchard from exporting to Japan should fire blight be detected within a 500-metre buffer zone surrounding such orchard, and a post-harvest treatment of exported apples with chlorine. The United States alleged that Japan's measures were inconsistent with Article XI of GATT 1994; Articles 2.2, 2.3, 5.1, 5.2, 5.3, 5.6, 6.1, 6.2 and 7 and Annex B of the *SPS Agreement*; and Article 14 of the Agreement on Agriculture. Consultations were held on 18 April 2002, but failed to settle the dispute.

1.3 In a communication dated 7 May 2002, the United States requested the Dispute Settlement Body ("DSB") to establish a panel pursuant to Article 6 of the DSU, with standard terms of reference as set out in Article 7.1 of the DSU.² The US claims of inconsistency in their Request for the Establishment of a Panel were identical to those set out in their request for consultations, except for additional claims of inconsistency under Article 5.5 of the *SPS Agreement* and Article 4.2 of the Agreement on Agriculture, and omission of the previous claim under Article 14 of the Agreement on Agriculture.

1.4 On 3 June 2002, the DSB established a panel in accordance with Article 6 of the DSU.³ In accordance with Article 7.1 of the DSU, the terms of reference of the Panel were:

"To examine, in the light of the relevant provisions of the covered agreements cited by the United States in document WT/DS245/2, 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."

1.5 On 16 July 2002, the Director-General determined the composition of the Panel as follows:

Chairman: Mr Michael Cartland

Panelists: Mr Christian Häberli
Ms Kathy-Ann Brown

1.6 Australia, Brazil, the European Communities, New Zealand and the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu reserved their right to participate in the Panel proceedings as third parties.

1.7 The Panel met with the parties on 21 and 22 October 2002. It met with third parties on 22 October 2002. The Panel consulted scientific and technical experts and met with them on 13 and 14 January 2003. The Panel held a second meeting with the parties on 16 January 2003.

¹ WT/DS245/1.

² WT/DS245/2.

³ WT/DS245/3.

1.8 On 17 January 2003, the Chairman of the Panel informed the DSB that the Panel had not been able to issue its report within six months. The reasons for that delay were given in document WT/DS245/4.

1.9 The Panel issued its interim report on 20 March 2003. The Final Report was circulated to the parties on 25 June 2003. The report was circulated to Members in all three languages 15 July 2003.

II. FACTUAL ASPECTS

A. THE DISEASE AT ISSUE

1. Fire blight (*Erwinia amylovora*)⁴

2.1 *Erwinia amylovora* (*E. amylovora*), the scientific name for the fire blight bacterium, was first reported in the Hudson River Valley of New York State in the United States in 1793. Symptoms of infection of host plants with fire blight depend on the parts infected. Infected flowers droop, wither, and die, becoming dry and darkened in color. Infected shoots and twigs wither, darken, and die; as shoots and twigs wither, they bend downwards resembling a shepherd's crook. Infected leaves take on a curled, scorched appearance.⁵ Infected fruit fail to 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 overwinter exclusively in infected host plants. In the presence of warm, wet conditions in spring, the disease cycle commences when cankers on infected hosts exude a bacterial-laden ooze or inoculum. This inoculum is transmitted primarily through wind and/or rain and by insects or birds to open flowers on the same or new host plants. *E. amylovora* bacteria multiply externally on the stigmas of these open flowers and enter the plant through stomata (openings through which the plant breathes), nectaries (plant glands that secrete nectar), or wounds. The bacteria may spread within the host plant, causing disease in blossoms and fruiting spurs, twigs, branches, or leaves. New cankers (sunken areas surrounded by cracked bark) can be formed on infected branches or twigs. When bacteria form a canker on the branches, this canker remains as an over-wintering lesion until the next year. Cankers generally cease ooze production during the hot summer months and remain inactive until the following spring when they may reactivate and begin the disease cycle anew.

2.3 Secondary infection can occur during the growing season. The source of the secondary inoculum is bacterial ooze exuding from lesions on shoots, leaves, fruits or branches and which is carried by wind and/or rain, insects or birds.

2.4 Immature apples can be infected with *E. amylovora* through natural openings in the skin (i.e. lenticels) or by diseased branches. The infection of fruit commonly occurs after hail storms in the summer months. Infected fruit exude bacterial ooze, become dry, mummify and remain on the branches.

⁴ Description compiled from "Report on Pest Risk Analysis concerning Fire Blight Pathogen (*Erwinia amylovora*): Fresh apples produced in the United States of America", Ministry of Agriculture, Forestry and Fisheries, Japan, August 1999 (the "1999 PRA") (Exhibit USA-3 and Exhibit JPN-34) and US First Submission.

⁵ The name "fire blight" was apparently coined in 1817 to describe the sudden browning of leaves associated with *E. amylovora* "as if they had passed through a hot flame and causing a morbid matter to exude from the pores of the bark", Coxe. W. *A View of the Cultivation of Fruit Trees, and the Management of Orchards and Cider*, Pears, M. Carey and Son, Philadelphia, 1817.

2. Host plants

2.5 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.⁶

3. Geographical distribution of fire blight

2.6 It is believed that the fire blight bacterium (*E. amylovora*) is native to North America. By the early 1900s, fire blight had been reported in Canada from Ontario to British Columbia, in northern Mexico, and in the United States from the East Coast to California and the Pacific Northwest. Fire blight was reported in New Zealand in 1919, Great Britain in 1957, and Egypt in 1964. The disease has spread across northern and western Europe, although Portugal and Finland remain fire blight-free, and it remains localized in France and Switzerland and restricted to certain spots in Spain, Italy, and Austria. Norway has reported eradication of the disease.⁷ Fire blight has spread across the Mediterranean region, including Greece, Turkey, Israel, Lebanon, Iran, and several Central European countries.⁸ Latin America and substantial parts of Africa and Asia apparently remain fire blight-free. In 1997, Australia reported the presence of fire blight in the Adelaide and Melbourne Botanical Gardens, but eradication efforts were successful and no further outbreaks have been reported.

4. Relevant technical and scientific terms

Buffer zone

2.7 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

2.8 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.

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. With respect to *E. amylovora*, the term

⁶ European and Mediterranean Plant Protection Organization (EPPO), "Data Sheet on Quarantine Pests: *Erwinia amylovora*", Quarantine for Europe, 1997, p. 1-2 (Exhibit USA-5).

⁷ At the Panel meeting with the experts on 14 January 2003, Dr Geider noted that there had been a recent report of an outbreak of fire blight in Norway.

⁸ Commonwealth Agriculture Bureau International (CABI), Crop Protection Compendium: Data Sheet on *Erwinia amylovora* (2002) "Notes on Distribution" (Exhibit USA-6).

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.⁹

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.

Vector

2.16 An organism able to transport and transmit a pathogen.

B. JAPAN'S FIRE BLIGHT MEASURES

2.17 The legislation of Japan relevant to this dispute is:

- 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

⁹ The Panel has followed the scientific definition of bacterial infestation offered by the experts consulted by the Panel. See Anne 3, para. 67. A general definition of infestation is to be found in *International Standards for Phytosanitary Measures No.5: Glossary of Phytosanitary Terms*, FAO, Rome 2002. "Presence in a commodity of a living pest of the plant or plant product concerned. Infestation included infection."

- MAFF "Detailed Rules for Plant Quarantine Enforcement Regulation Concerning Fresh Fruit of Apple Produced in the United States of America " dated 1 April 1997.

2.18 Under the Plant Protection Law and the Enforcement Regulations, importation of host plants of 15 quarantine pests, including fire blight bacteria and pests of rice plant not found in Japan, is prohibited.¹⁰ The legislation, however, permits Japan to decide, on a case-by-case basis, to lift the import prohibition with respect to plants and products according to certain criteria that have been established by past practice. These criteria are:

- Lifting is subject to a proposal of an alternative measure by a foreign government;
- the level of protection required of the proposed measure is that equivalent to import prohibition; and
- the exporting government bears the burden of proving that the proposed measure achieves the required level of protection.

2.19 Paragraph 25 of the Annexed List to Table 2 of the Plant Protection Law Enforcement Regulations sets out conditions under which US apples may be imported into Japan: "Fresh fruit of apple which are shipped from the United States of America directly to Japan without calling at any port and which conform to the standards established by the Ministry of Agriculture, Forestry and Fisheries".¹¹ The relevant standards are currently set by MAFF Notification No. 354¹² and the related Detailed Rules.¹³ These are:

- (i) 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. Any detection of a blighted tree in this area by inspection will disqualify the orchard. Currently, the designation is made for orchards in the States of Washington and Oregon;¹⁴
- (ii) the export orchard must be free of plants infected with fire blight and free of host plants of fire blight (other than apples), whether or not infected;

¹⁰ Article 7, paragraph 1, item 1 of the Law (Exhibits JPN-20 and USA-8) and Article 9, item 1 and Annexed Table 2 of the Enforcement Regulation (Exhibits JPN-21 and USA-9).

¹¹ Ministerial Ordinance No. 73: Plant Protection Law Enforcement Regulations, Annexed List, para. 25 (Exhibit JPN-21 and Exhibit USA-9). The United States contends that paragraph 25 of the Annexed List to Table 2 of the Plant Protection Law Enforcement Regulations limits the importation of fresh fruit of apple from the United States to Golden Delicious and Red Delicious apple varieties. The Panel, however, notes that there is disagreement between the parties as to the English translation of the aforementioned paragraph 25. The English translation of paragraph 25 provided by Japan makes no mention of the Golden Delicious and Red Delicious variety requirement.

¹² MAFF Notification No. 354, 10 March 1997, (Exhibit USA-10 and Exhibit JPN-22). Notification No. 354 replaced an earlier Notification No. 1184, which first put into place the Japanese fire blight restrictions. See MAFF Notification No. 1184, 22 August 1994, (Exhibit USA-11).

¹³ MAFF Detailed Rules for US Apples, 1 April 1997, (US translation, Exhibit USA-12 and Exhibit JPN-23). The 1997 Detailed Rules amended but did not replace in full the 22 August 1994 Detailed Rules, which implemented MAFF Notification No. 1184. It is therefore necessary to read the 1994 Detailed Rules in conjunction with the 1997 Detailed Rules in order to understand the full scope of the Japanese fire blight measures. See MAFF Detailed Rules for US Apples, 22 August 1994, (US translation, Exhibit USA-13).

¹⁴ Japan argues that the current phytosanitary requirements against fire blight can be applicable to apple fruit produced in other states, but that United States has not submitted documentation on the status of other quarantine pests for states other than Washington and Oregon. As such, Japan argues that this is a procedural matter. Japan, Response to Questions from the Panel, 13 November, 2002, Question 47.

- (iii) the fire blight-free orchard must be surrounded by a 500-meter buffer zone. Detection of a blighted tree or plant in this zone will disqualify the export orchard;
- (iv) the fire blight-free orchard and surrounding buffer zone must be inspected at least three times annually. US officials will visually inspect twice, at the blossom and the fruitlet stages, the export area and the buffer zone for any symptom of fire blight. Japanese and US officials will jointly conduct visual inspection of these sites at harvest time. Additional inspections are required following any strong storm (such as a hail storm);
- (v) harvested apples must be treated with surface disinfection by soaking in sodium hypochlorite solution (100 ppm or more effective chlorine concentration) for one minute or longer;
- (vi) containers for harvesting must be disinfected by a chlorine treatment;
- (vii) the interior of the packing facility must be disinfected by a chlorine treatment;
- (viii) fruit destined for Japan must be kept separated post-harvest from other fruit;
- (ix) US plant protection officials must certify or declare that fruit are free of quarantine pests, "are not infested/infected with . . . fire blight", and were treated with chlorine; and
- (x) Japanese officials must confirm that the US official has made the necessary certification and that the chlorine treatment and orchard designations were properly made. Japanese officials must also inspect both the disinfestation and packing facilities.

C. INTERNATIONAL STANDARDS, GUIDELINES AND RECOMMENDATIONS

2.20 In their submissions, the parties considered certain international standards developed by the Interim Commission on Phytosanitary Measures of the International Plant Protection Convention ("IPPC") as relevant to the dispute. The *SPS Agreement* makes reference, in a number of provisions, to "relevant international standards, guidelines and recommendations". Annex A:3(c) of the *SPS Agreement* states that the international standards, guidelines and recommendations relevant for plant health are those developed under the auspices of the IPPC in cooperation with regional organizations operating within the framework of the IPPC.

1. The IPPC

2.21 The IPPC is an international treaty deposited and administered by the Food and Agriculture Organization of the United Nations (FAO) but implemented through the cooperation of member governments and regional plant protection organizations. The IPPC currently has 120 contracting parties.

2.22 The first text of the IPPC was drafted in 1929 and came into force in 1952, adopted by the FAO Conference one year prior to that. Amendments were adopted by the FAO in 1979 and the revised text came into force in 1991. In response to the role of the IPPC in the context of the Uruguay Round and the negotiation of the *SPS Agreement*, the FAO established a Secretariat for the IPPC in 1992, followed by the formation of the Committee of Experts on Phytosanitary Measures (CEPM) in 1993. Negotiations for amendments to the IPPC, in order to reflect contemporary changes, particularly in light of the *SPS Agreement*, started in 1995 and were finalized in 1997 when the FAO Conference adopted the New Revised Text of the IPPC. The New Revised Text makes provision for

the formation of a Commission on Phytosanitary Measures. The amended IPPC will come into force upon ratification by two thirds of its contracting parties.

2.23 The purpose of the IPPC is to secure common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control. An important role of the IPPC is that of developing International Standards for Phytosanitary Measures (ISPM). National plant protection organizations or regional plant protection organizations may submit draft standards to the Secretariat of the IPPC. These drafts are reviewed, edited, and referred by the Secretariat to the CEPM. Alternatively, the IPPC Secretariat may form an international working group or enlist experts to help draft a standard. The CEPM considers the proposals and recommends action. ISPMs are adopted by the Interim Commission on Phytosanitary Measures following a procedure that includes country consultation.

2. International standards for phytosanitary measures (ISPMs)

2.24 Two ISPMs that have been referred to in this dispute are ISPM 2 on Guidelines for Pest Risk Analysis, adopted in 1996, and ISPM 11 on Pest Risk Analysis for Quarantine Pests, adopted in 2001.¹⁵

2.25 ISPM 2 provides general guidelines for pest risk analysis (PRA) whereas ISPM 11 establishes guidelines for conducting a risk analysis for *quarantine* pests.¹⁶ The former does not replace the latter, therefore they have been designated by the IPPC as *different* international standards. However, the two standards are related and present the same general framework for conducting a pest risk assessment, although ISPM 11 outlines the analytical items in greater detail than ISPM 2.

2.26 Both ISPM 2 and ISPM 11 describe 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 both PRA Guidelines as: "initiating the process for analysing risk", "assessing pest risk" and "managing pest risk", respectively.

2.27 In ISPM 2, the process for pest risk assessment is broadly divided into five interrelated steps: consideration of geographical and regulatory criteria; economic importance criteria; spread potential after establishment; potential economic importance; and introduction potential. The 1996 guidelines provide a partial checklist of factors that might affect entry and establishment of a pest.

2.28 In ISPM 11, the process for pest risk assessment is set out in more detail. The PRA process can be broadly divided into three interrelated steps: pest categorization, assessment of the probability of introduction and spread, and an assessment of potential economic consequences (including environmental impacts). Pest introduction is comprised of both entry and establishment. Assessing the probability of introduction requires an analysis of each of the pathways with which a pest may be associated from its origin to its establishment in the PRA area. The 2001 guidelines identify the

¹⁵ *International Standard for Phytosanitary Measures No.2: Guidelines for Pest Risk Analysis*, FAO, Rome 1996 (Exhibit JPN-30), and *International Standard for Phytosanitary Measures No.11: Pest Risk Analysis for Quarantine Pests*, FAO, Rome 2001 (Exhibit USA-15).

¹⁶ The IPPC defines a quarantine pest as: a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled. *International Standards for Phytosanitary Measures No.5: Glossary of Phytosanitary Terms*, p.14, FAO, Rome 2002.

following broad issues which should be considered and provides detailed guidance under each heading:

- (a) Probability of the pest being associated with the pathway at origin;
- (b) probability of survival during transport or storage;
- (c) probability of pest surviving existing pest management procedures;
- (d) probability of transfer to a suitable host;
- (e) probability of establishment;
- (f) availability of suitable hosts, alternate hosts and vectors in the PRA area;
- (g) suitability of environment;
- (h) cultural practices and control measures;
- (i) other characteristics of the pest affecting the probability of establishment; and
- (j) probability of spread after establishment.

2.29 ISPM 2 states that pest risk management should be proportional to the risk identified in the assessment of risk. Pest risk management options identified in the 1996 guidelines are:

- (a) Inclusion in list of prohibited pests;
- (b) phytosanitary inspection and certification prior to export;
- (c) definition of requirements to be satisfied before export (e.g. treatment, origin from pest-free area, growing season inspection, certification scheme);
- (d) inspection at entry;
- (e) treatment at point of entry, inspection station or, if appropriate, at place of destination;
- (f) detention in post-entry quarantine;
- (g) post-entry measures (restrictions on use of product, control measures); and
- (h) prohibition of entry of specific products from specific origins.

2.30 Pest risk management options may also concern ways of reducing risk of damage. ISPM 2 states that the efficacy and impact of the various options in reducing risk to an acceptable level should be evaluated in terms of the following factors:

- (a) Biological effectiveness;
- (b) cost/benefit of implementation;
- (c) impact on existing regulations;
- (d) commercial impact;

- (e) social impact;
- (f) phytosanitary policy considerations;
- (g) time to implement a new regulation;
- (h) efficacy of option against other quarantine pests; and
- (i) environmental impact.

2.31 ISPM 11 identifies risk management options in more detail. The 2001 guidelines specifically state that zero-risk is not a reasonable option, and that the guiding principle for risk management should be to manage risk to achieve the required degree of safety that can be justified and is feasible within the limits of available options and resources. As such, pest risk management (in the analytical sense) is the process of identifying ways to react to a perceived risk, evaluating the efficacy of these actions, and identifying the most appropriate options. The uncertainties noted in the assessments of economic consequences and probability of introduction should also be considered and included in the selection of a pest management option.¹⁷ The ISPM lists examples of measures classified into broad categories that relate to the pest status of the pathway in the country of origin. These include measures:

- (a) Applied to the consignment;
- (b) applied to prevent or reduce original infestation in the crop;
- (c) to ensure the area or place or site of production or crop is free from the pest;
- (d) for other types of pathways (such as to curb natural spread);
- (e) within the importing country;
- (f) concerning the prohibition of commodities; and
- (g) phytosanitary certificates and other compliance measures.

2.32 Another ISPM referred to by Japan in this dispute was ISPM 10 on Requirements for the Establishment of Pest Free Places of Production and Pest Free Production Sites.¹⁸

III. CLAIMS OF THE PARTIES

3.1 The **United States** claimed that Japan prohibited the importation of apple fruit unless such apples were produced, treated, and imported in accordance with Japan's highly-restrictive fire blight measures. The United States did not question that fire blight was a plant disease of serious biological and economic consequences nor Japan's right to enact measures to protect against the risks arising from transmission of fire blight disease within its territory. However, the United States claimed that Japan's measures on the importation of apple fruit were not consistent with Japan's obligations under the *SPS Agreement* in that:

- ***Japan had failed to ensure that its fire blight measures were not maintained without sufficient scientific evidence and these measures were therefore inconsistent with Article 2.2 of the SPS Agreement;***

¹⁷ Op. cit., ISPM 11, para 3.

¹⁸ *International Standard for Phytosanitary Measures No.10: Requirements for the Establishment of Pest Free Places of Production and Pest Free Production Sites*, FAO, Rome 1999 (Exhibit JPN-24).

- *Japan had failed to ensure that its fire blight measures were based on an assessment of the risks to plant life or health and therefore these measures were inconsistent with Article 5.1 of the SPS Agreement;*
- *In its assessment of risks, Japan had failed to take into account available scientific evidence, relevant ecological and environmental conditions, and quarantine or other treatment and therefore had acted inconsistently with Article 5.2 of the SPS Agreement;*
- *Japan had failed to ensure that its fire blight measures were not more trade-restrictive than required to achieve its appropriate level of phytosanitary protection, taking into account technical and economic feasibility, and these measures were therefore inconsistent with Article 5.6 of the SPS Agreement;*
- *Japan had failed to notify changes in and information on its fire blight measures and therefore had acted inconsistently with Article 7 and Annex B of the SPS Agreement.*

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

3.2 **Japan** argued that the United States had not established a prima facie case in respect of the claims it had made. Japan claimed its measure was fully consistent with Articles 2.2, 5.1, 5.2, 5.6, 7, and Annex B of the *SPS Agreement*, Article XI of GATT of 1994, and Article 4.2 of the Agreement on Agriculture. Alternatively, Japan claimed that the measure was a provisional measure in conformity with Article 5.7 of the *SPS Agreement* and was otherwise consistent with Articles 5.1, 5.2, 5.6, 7, and Annex B of the *SPS Agreement*, Article XI of GATT of 1994, and Article 4.2 of the Agreement on Agriculture.

[Sections IV through VI and Annexes deleted from this version.]

VII. INTERIM REVIEW

A. INTRODUCTION

7.1 The Panel issued the draft descriptive sections of its report (factual and arguments) to the parties on 6 February 2003, in accordance with Article 15.1 of the DSU. Both parties offered written comments on the draft descriptive sections on 24 February 2003. The Panel noted all these comments and amended the draft descriptive part where appropriate. The Panel issued its interim report to the parties on 20 March 2003, in accordance with Article 15.2 of the DSU. In communications dated 3 April 2003, both Japan and the United States requested that the Panel review precise aspects of the interim report. Neither of the parties requested an interim review meeting. On 11 April 2003, Japan and the United States provided written comments on each other's comments on the interim report, as permitted by the Panel's working procedures. The Panel carefully reviewed the arguments made. They are discussed in this section and, to the extent necessary, are reflected in the findings section below, in accordance with Article 15.3 of the DSU.¹⁸⁰

B. COMMENTS BY JAPAN¹⁸¹

1. Burden of proof

7.2 Japan's first comment relates to our statement in paragraph 8.44 according to which:

"We do not see the greater expertise of the exporting country as a factor which should automatically justify a different allocation of the burden of proof."

7.3 Japan requests that we review that conclusion because of the difficulties it faces in conducting field experiments on its territory and because of the problems occurring when cooperation from exporting country governments is required. We have explained, in paragraphs 8.45-8.46 below, why we believe that such an argument is not compelling under the circumstances of this case. We would like to add that the United States is not the only country where fire blight is present and where scientific experiments could be performed.

7.4 Japan's argument would imply in practice either that a more demanding standard of proof to establish a prima facie case be imposed on the United States, or that Japan either be granted a different standard of proof when rebutting the US arguments or be relieved of rebutting the US claim. Neither of these suggestions is supported by the approach on burden of proof defined by the Appellate Body in *EC – Hormones* and recalled in paragraph 8.42 below. Moreover, nowhere does the *SPS Agreement* provide for a specific standard of proof in relation to dispute settlement.

7.5 We also consider that our statement in paragraph 8.44 does not imply that an exporting country will be "allowed to prevail by merely contradicting the evidence the importing country has".¹⁸² We applied the principle of allocation of burden of proof as identified by the Appellate Body in *United States - Shirts and Blouses* and recalled, as mentioned in paragraph 8.42 below, in

¹⁸⁰ Section VII of this Report entitled "Interim Review" therefore forms part of the findings of the final panel report, in accordance with Article 15.3 of the DSU.

¹⁸¹ This section is divided according to the sections of the findings on which comments have been made.

¹⁸² Japan's comments, 3 April 2003, para. 3.

the context of the *SPS Agreement* in the Appellate Body Report on *EC – Hormones*. The requirement that the complainant make a prima facie case is the same in a dispute relating to the *SPS Agreement* as under any other WTO agreement. In *EC - Hormones*, the Appellate Body described the establishment of a prima facie case as follows:

"In accordance with our ruling in *United States – Wool Shirts and Blouses*¹⁸³, the Panel should have begun the analysis of each legal provision by examining whether the United States and Canada had presented evidence and legal arguments sufficient to demonstrate that the EC measures were inconsistent with the obligations assumed by the European Communities under each Article of the *SPS Agreement* addressed by the Panel, i.e., Articles 3.1, 3.3, 5.1 and 5.5. Only after such a prima facie determination had been made by the Panel may the onus be shifted to the European Communities to bring forward evidence and arguments to disprove the complaining party's claim."¹⁸⁴

This is exactly what we requested from the parties in this case.

2. Article 2.2 of the *SPS Agreement*

7.6 Japan requests us to review our assessment of the 1990 article of van der Zwet *et al.* in paragraphs 8.127-8.128 below. We did not find Japan's arguments in support of its request sufficiently convincing. In particular, Japan's allegation that Professor van der Zwet admitted in Roberts *et al.* (1998) that the tested apple fruit in van der Zwet *et al.* (1990) were mature and symptomless is not supported by the information contained in that very article. On the basis of the nature of the information reported in the articles, the experts' views and the comments of Professor van der Zwet himself in his statement of 16 July 2002, Exhibit USA-18, we see no reason to change our assessment of van der Zwet *et al.* (1990) and of Roberts *et al.* (1998).

7.7 In response to comments from both parties, we revised our findings in section D.

3. Article 5.7 of the *SPS Agreement*

7.8 In its comments of 3 April 2003, Japan contests our reasoning under Article 5.7 of the *SPS Agreement*. Japan first claims that it should be possible to invoke Article 5.7, for example, in situations where the process of scientific discovery is at work and thus available scientific evidence is not conclusive, even though the quantity of the evidence is more than little.

7.9 We have no reason of principle to reject the hypothesis suggested by Japan, although we note that the process of scientific discovery is by its nature an ongoing process. It is possible that, in a given situation, a lot of scientific research may have been carried out on a particular issue without yielding sufficiently "relevant" – within the meaning of Article 5.7 - or reliable evidence. In such a case, however, there is little or no reliable evidence on the subject matter at issue. This is not the case here. There is a great deal of "relevant" scientific material available. What Japan addresses in its comment on paragraph 8.219 is, in fact, a question of weighing the evidence before the Panel. We have carefully reviewed the material submitted in this case and found that

¹⁸³Adopted 23 May 1997, WT/DS33/AB/R, pp. 14-16.

¹⁸⁴ (*original footnote*) Our finding that the Panel erred in allocating the burden of proof generally to the Member imposing the measure, however, does not deal with the quite separate issue of whether the United States and Canada actually made a prima facie case of violation of each of the following Articles of the *SPS Agreement*: 3.1, 3.3, 5.1 and 5.5. See in this respect, footnote 180 of this Report.

the present situation was one where a lot of "relevant scientific evidence" had already been accumulated. Our assessment was not simply quantitative; it was also qualitative, as demonstrated by the position we have taken on van der Zwet *et al.* (1990) on the basis, *inter alia*, of the opinion of the experts consulted by the Panel.¹⁸⁵

7.10 Japan also argues that we should not include, in our assessment under Article 5.7, scientific evidence which has become available after the date of entry into force of the *SPS Agreement* in 1995. We do not see in the text of Article 5.7, or of Article 2.2 for that matter, any reason to limit our assessment of the "relevant scientific evidence" to evidence available before 1995. On the contrary, since Article 5.7 provides for an exception to Article 2.2, and an assessment of the compatibility of a measure with Article 2.2 is made at the time the matter is reviewed by the Panel, there is no justification for assessing any alleged provisional measure at a different date. If we were to agree with Japan, a measure could be indefinitely maintained on a provisional basis under Article 5.7, and the requirement that Members seek to obtain the additional information for a more objective assessment of risks and review the phytosanitary measure accordingly within a reasonable period of time would become ineffective. Such a selective interpretation of Article 5.7 is not acceptable.

4. Article 5.1 of the *SPS Agreement*

7.11 Japan argues that, contrary to what is mentioned in paragraph 8.247 below, the conformity of a PRA under Article 5.1 should be assessed in light of information available at the time when the PRA was conducted, and no later evidence should be considered.

7.12 We corrected paragraph 8.247 as far as the representation of Japan's arguments is concerned. However, we do not agree with Japan's position that no information subsequent to the completion of a PRA should be taken into consideration by a Panel, particularly if, as in the present case, that PRA is already almost four years old at the time it is reviewed. Some assessment of the subsequent evolution of the scientific evidence is not only acceptable, it is also necessary, if only to monitor the development of any new evidence which might require a revision of the risk assessment. One must not lose sight of the purpose of a risk assessment, which is to serve as a basis for regulatory actions. If the scientific evidence evolves, this may be an indication that the risk assessment should be reviewed or a new assessment undertaken. It would be also legally inconsistent to require, on the one hand, that phytosanitary measures not be maintained without sufficient scientific evidence pursuant to Article 2.2¹⁸⁶ while, on the other hand, accepting that risk assessments not be renewed in the face of new scientific evidence.¹⁸⁷ Even though new evidence may not always justify a new risk assessment, it would be contrary to the purpose of risk assessments under the *SPS Agreement* to follow the approach advocated by Japan.

7.13 In relation to our findings on Article 5.1, Japan further argues that the Panel was wrong in stating in paragraph 8.271 that "the 1999 PRA is not sufficiently specific to the matter at issue [apple fruit] to constitute a proper risk assessment under Article 5.1 of the *SPS Agreement*".

¹⁸⁵ See para. 8.127, below.

¹⁸⁶ We note in this respect that "in connection with Article 2.2, Japan believes that the provision requires a measure to be based on sufficient scientific evidence available at the time of the finding of the Panel." (Japan's reply to question 4 of the Additional Questions from the Panel, 28 January 2003).

¹⁸⁷ We note in this respect that the Appellate Body in *EC – Hormones*, recalled that "Article 2.2 and 5.1 should constantly be read together. Article 2.2 informs Article 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1." (Appellate Body Report, para. 180)

According to Japan, the 1996 and 2001 IPPC Guidelines admit the initiation of a PRA by the identification of a pest, as well as the identification of a pathway. These Guidelines do not limit the scope of the PRA to a particular host of bacteria, but rather allow for assessing a variety of hosts.

7.14 We agree with Japan that the 1996 and 2001 IPPC Guidelines for PRAs do not limit consideration to just one particular host of a kind of bacteria. However, they do require that the risk relating to the particular commodity to be imported be evaluated. In its 1999 PRA, Japan evaluated the risks associated with all possible hosts taken together, not sufficiently considering the risks specifically associated with the commodity at issue: US apple fruit exported to Japan. We therefore see no reason to change our findings in this respect.

7.15 Moreover, Japan contests our finding in paragraph 8.280 that "Japan's PRA does not evaluate the likelihood of entry or spread of fire blight through the importation of apple fruits" because Japan's 1999 PRA does not suggest any precise evaluation of the degree of potentiality or probability for the occurrence of the event and fails to provide more than an indication of a potential for entry or spread, or does not assess the probability of such events occurring. Japan argues that, even though the 1999 PRA's use of the terms "suggest" or "can" to describe probability might have been misleading, Japan stated in its first written submission to the Panel that the 1999 PRA addressed not a theoretical possibility but the likelihood of the introduction and spread of fire blight through apple fruit.

7.16 We consider that the fact that Japan further elaborated before the Panel on the meaning of the terms it used in its 1999 PRA cannot correct the fact that the 1999 PRA itself did not use the terms used by Japan before the Panel and actually did not sufficiently evaluate the likelihood of entry, establishment or spread of fire blight, as well as the associated potential biological and economic consequences, within the meaning of Article 5.1 and Annex A, paragraph 4 of the *SPS Agreement*. It is not merely the use of some terms that is at issue here, it is the whole approach followed by Japan in undertaking the 1999 PRA. We recall that, in *Australia – Salmon*, the Appellate Body insisted that a conclusion of mere possibility of entry, establishment or spread of a disease was not sufficient to meet the requirements of Article 5.1¹⁸⁸, just as *some* evaluation of the likelihood of entry, establishment or spread was not sufficient either.¹⁸⁹ Likewise, the Appellate Body recalled that the existence of unknown or uncertain elements did not justify a departure from the requirements of, *inter alia*, Article 5.1.¹⁹⁰ In the light of the relatively strict standard applied by the Appellate Body in *Australia – Salmon*, we see no reason to reconsider our findings.

7.17 Japan further contests our reasoning and conclusions in paragraph 8.285 below. Japan claims that in 1999, it considered the US proposal to narrow the width of the buffer zone and to reduce the number of field inspection routines. However, such consideration is not apparent in the 1999 PRA.

7.18 In essence, Japan considers that, once a measure is in place, the analysis and evaluation will inevitably focus on the existing measure, in the absence of alternative proposals. Japan seems to suggest that it was up to the United States to bring to the attention of Japan the existence of alternative measures or options. We cannot agree with either of these points. Regarding the

¹⁸⁸ Appellate Body Report, para. 123.

¹⁸⁹ Ibid, para. 124.

¹⁹⁰ Appellate Body Report, paras. 129-130.

first one, there is no technical reason why, once a measure is in place, it would not be possible to consider alternatives. Japan argues as much, by stating that the analysis "will inevitably focus" on the existing measure. Yet, information on alternative options does not become less available because one measure has been put in place by a Member. Likewise, nothing in the text of Article 5.1 and Annex A, paragraph 4, suggests that alternative options have to be proposed by the exporting Member. On the contrary, given the importance of the PRA to support the imposition of a measure, it is in the interest of the importing Member to consider alternatives on its own initiative.

7.19 We do not consider either that a requirement to consider alternative options would create a situation where a Member could not be confident, at any time, of the consistency of its PRAs with Article 5.1 of the *SPS Agreement*. First, this requirement does not result from the reasoning of the Panel, but from the terms of Article 5.1 and Annex A, paragraph 4 of the *SPS Agreement*, which refer to "the SPS measures which might be applied", thus making it clear that a Member has an obligation to consider other measures than those it actually applies. Whether such a requirement could actually create a problem of legal certainty for a Member performing risk assessments is not an issue before us. Indeed, since Japan did not appear to have considered measures other than those it applies¹⁹¹, it clearly did not meet its obligation and it is not necessary to determine how far it should have gone in identifying "SPS measures that might be applied" to comply with Article 5.1 and Annex A, paragraph 4 of the *SPS Agreement*.

5. Article 7 of the *SPS Agreement*

7.20 Finally, we took note of the factual information provided by Japan regarding Article 7 and Annex B to the *SPS Agreement*, as well as the additional comments of the United States. As a result we revised our findings on this claim.

C. COMMENTS BY THE UNITED STATES¹⁹²

1. Requests for additional findings

7.21 The United States requests the Panel to make a number of additional findings, most of which are essentially factual. As a general remark, we believe that panels are bound by their terms of reference, but they need only make the findings which they deem necessary for the resolution of the case. As a result, while we agreed with some of the US requests, we did not find it necessary to make all the additional findings that the United States requested in its comments.¹⁹³ We do not, for example, consider it necessary to make a finding that the United States has raised a presumption that there is no scientific evidence that mature apples have ever been the means of introduction of fire blight into a previously fire blight-free area, and Japan has failed to rebut that presumption. While we have some reliable indication that this statement by the United States might well be correct, we see no need to make a specific finding on this question. Rather, we will use the information available in support of our finding as to whether apples exported from the United States into Japan could serve as a pathway for the entry, establishment or spread of fire blight within Japan.

¹⁹¹ See para. 8.285, below.

¹⁹² This section is divided according to the sections of the findings on which comments have been made.

¹⁹³ In addition to the discussion in this paragraph, see para. 7.25 below.

2. Comments on specific paragraphs of the Report

7.22 The United States also made a number of specific comments on paragraphs of the findings. In this respect, we clarified or corrected, as necessary a number of paragraphs. This was the case with paragraph 2.1. Regarding paragraph 2.22, we have recognized the definition contained in *International Standards for Phytosanitary Measures No.5: Glossary of Phytosanitary Terms*, FAO, Rome 2002. However, we have clarified that, for the purposes of this case, we have relied on an alternative definition given during the Panel meeting with the experts which differentiates between infection and infestation.¹⁹⁴

7.23 The first specific comments of the United States on the findings relate to our identification of the elements composing the phytosanitary measure at issue (paragraphs 8.22 to 8.25). We originally were of the view that the two elements which the United States wants us to include in the measure¹⁹⁵ were not worth considering in an assessment of the measure *as a whole*, since their economic impact was very limited and these types of measures are commonly used by Members. However, we agree with the United States that, even though they are part of a broader measure, they are phytosanitary measures within the meaning of Annex A, paragraph 1 of the *SPS Agreement*. Since they also were identified by the United States in its request for establishment of a panel, they ought to be listed among the elements composing the phytosanitary measure at issue. We accordingly modified paragraphs 8.24 and 8.25.

7.24 The United States makes a second comment in relation to paragraph 8.25 and requests that we make a finding that the prohibition of imports of US apples from states other than Washington or Oregon is not rationally related to any scientific evidence of a risk of introduction of fire blight via imported apples. The United States argues that the failure of the United States to provide documentation relating to other quarantine pests cannot justify the maintenance of a fire blight restriction limiting importation from the states of Oregon and Washington exclusively.

7.25 We understand the position of Japan to be that what prevents the importation of apples from states other than Oregon and Washington is not their fire blight status, but the status of other quarantine pests. Japan argues that if proper documentation were submitted by the United States with respect to those other pests, shipments of apples from states other than Oregon and Washington could be exported to Japan under the same conditions which apply to apples from Oregon and Washington.¹⁹⁶ We agree that failure to provide documentation on other quarantine pests than fire blight cannot justify the imposition of restrictions based on fire blight, but if a product cannot be exported for other phytosanitary reasons, the fact that it could be free of fire blight will not make it exportable. The United States did not demonstrate that Japan was imposing measures relating to fire blight in relation to other quarantine pests. We therefore see no reason to make the ruling requested by the United States.

7.26 We also clarified paragraphs 8.84 and 8.88 to reflect what the United States had to demonstrate under Article 2.2 of the *SPS Agreement* in this particular case. Paragraph 8.90 was also modified to reflect more accurately the position of the United States. However, we did not

¹⁹⁴ Annex 3, para. 67.

¹⁹⁵ The two elements are: (1) the certification by US plant protection officials that fruits are free of fire blight and have been treated post harvest with chlorine; and (2) the confirmation by Japanese officials of the US officials' certification and inspection by Japanese officials of disinfection and packaging facilities.

¹⁹⁶ See para. 4.132, above.

find it necessary to modify paragraph 8.106 on burden of proof. Likewise, we find it relevant to state in paragraph 8.212, that Japan, as the party invoking Article 5.7 of the *SPS Agreement*, bears the burden to make a prima facie case. The fact that the issue of burden of proof was not addressed by the parties or that Japan clearly did not meet the four cumulative requirements in order for the measure at issue to qualify for the exemption under Article 5.7 does not relieve the Panel from applying the standards recalled by the Appellate Body in *United States – Wool Shirts and Blouses*. Each party has to prove its allegations. This principle applies whether the provision invoked is or is not an exception. In this case, Japan invoked Article 5.7; it had the burden to establish its claim prima facie and failed to do so.

7.27 We also did not find it appropriate to amend the last sentence of paragraph 8.196. Indeed we consider that the two propositions of this sentence are logically connected. If surface *E. amylovora* is found rarely on apples coming from severely infected orchards, the risk of entry, establishment or spread of fire blight within Japan through apples coming from severely blighted orchards can only be very low (assuming, as we did, that endophytic bacteria would not be found in mature, symptomless apples).

7.28 The United States also claims that, even though its request for establishment of a panel referred to "US apples" in general, it advanced arguments only relating to mature, symptomless apples. The United States considers as a result that we need not address the issue of other apple fruit with respect to which the United States presented no evidence. The United States requests that we remove our finding in paragraph 8.161.

7.29 As mentioned in paragraph 8.33, we consider that the US claims are based on two assumptions: (a) that mature, symptomless apples are not a pathway for fire blight; and (b) shipments from the United States to Japan only contain mature, symptomless apples. These assumptions were largely confirmed in our findings.

7.30 This said, the position defended by the United States in its request for review seems in this respect to be contradictory. On the one hand, it claims that requiring the importation of mature, symptomless apples should be sufficient to meet the level of protection sought by Japan in light of the established risk, thus assuming that only mature, symptomless apples will ever be exported. On the other hand, it claims that it did not address the issue relating to non mature or damaged apples. In our opinion, these issues are two sides of the same coin, and the United States actually had to address the issue of control to support the assumption that it exports only mature, symptomless apples.¹⁹⁷ Indeed, the United States provided considerable information regarding its control procedures.¹⁹⁸ As a result, we do not believe that we go beyond our terms of reference by considering the risk that apple fruit other than mature, symptomless apples could be exported to Japan.

7.31 Moreover, even if we were to agree with the United States that the matter before us is limited to mature, symptomless apples, we do believe that we are entitled to address Japan's position that a risk of entry, establishment or spread could result from a malfunction in the sorting of apples or of an illegal action in the country of exportation. We cannot agree that we should concentrate our findings exclusively on that very product simply because the United States apparently limits its claims, arguments and evidence to it. The purpose of phytosanitary measures is to prevent the introduction of diseases into the territory of the Member imposing them. As

¹⁹⁷ See, e.g., paras. 4.188-4.190.

¹⁹⁸ See, eg., paras. 4.182, 4.187-4.189, and the footnotes relating to these paragraphs.

recalled by the Appellate Body in *Australia – Salmon* with respect to Article 5.6 of the *SPS Agreement*,

"The determination of the appropriate level of protection, a notion defined in paragraph 5 of Annex A, as 'the level of protection deemed appropriate by the Member establishing a sanitary ... measure', is a *prerogative* of the Member concerned and not of the panel or of the Appellate Body."¹⁹⁹

7.32 If we were to restrict our findings to "mature, symptomless apples", we would disregard the position of Japan that the protection to be achieved by the measure should be equivalent to that of an import prohibition. It seems to us legitimate to consider all the aspects referred to by Japan in relation to the importation of apples from the United States. This issue is addressed in our discussion of Article 2.2, paragraphs 8.119-8.122.

7.33 We agree with the United States that our remarks regarding developmental or technical circumstances prevailing in the importing Member in paragraph 8.239²⁰⁰ were more an *obiter dictum* than a consideration necessary for the resolution of this case. In paragraphs 8.45 and 8.46 we already considered that Japan was not put at a disadvantage in terms of submission of evidence by the fact that its territory was free from fire blight. We therefore adjusted paragraphs 8.239-8.240.

7.34 We also clarified the US position as presented in paragraphs 8.265 and 8.284, even though it seemed quite obvious from the context that the statements concerned originated in Japan's 1999 PRA.

7.35 Finally, we clarified the arguments of the United States in paragraph 8.295.

¹⁹⁹ Appellate Body Report on *Australia – Salmon*, para. 199.

²⁰⁰ This paragraph and the following paragraph previously read:

"It might be observed, in this context, that the requirement that the risk assessment be 'appropriate to the circumstances' has been considered to leave some flexibility for an assessment of risk 'on a case by case basis, in terms of product, origin and destination, in particular country-specific destinations'. The Panel is of the view that 'appropriate to the circumstances' might also be with regard to the developmental or technical circumstances prevailing in the importing Member. For example, what might be expected in terms of a risk assessment put forward by a developing country with limited plant protection services and trained professional staff may not be 'appropriate' with respect to an importing country with sophisticated plant protection services and highly trained professional staff. Furthermore, the access the importing country has to relevant data and scientific information might be relevant in consideration of whether a risk assessment is 'appropriate to the circumstances'.

"In this dispute, the Panel notes that both parties are developed countries with highly sophisticated plant protection services and skilled professional staff. Furthermore, the Panel has already found no evidence that Japan did not have ready access to the relevant scientific evidence necessary to conduct an appropriate risk assessment."

VIII. FINDINGS

A. APPROACH FOLLOWED BY THE PANEL

8.1 The United States raises the following claims:

- (a) Japan's measures on US apples are inconsistent with Article 2.2 of the *SPS Agreement* because they are "maintained without sufficient scientific evidence";
- (b) Japan's measures on US apples are inconsistent with Article 5.1 of the *SPS Agreement* because they are not based on a risk assessment;
- (c) by failing to take into account certain information in its assessment of risks, Japan has acted inconsistently with Article 5.2 of the *SPS Agreement*;
- (d) Japan's measures are inconsistent with Article 5.6 of the *SPS Agreement* because they are more trade-restrictive than required to achieve Japan's appropriate level of protection;
- (e) Japan has failed to notify changes to its fire blight measures and to provide information as required by Article 7 and Annex B of the *SPS Agreement*;
- (f) in addition, the United States developed, at the first and second substantive meetings with the Panel, two of the claims against Japan that it had listed in its request for establishment of a panel but not developed in its first written submission: the violation of Article XI of GATT 1994 and of Article 4.2 of the Agreement on Agriculture.

8.2 Japan makes the following main arguments in response:

- (a) Japan requests that the claims contained in the request for establishment of a panel but not raised in consultations and/or not developed in the first written submission of the United States be "removed" from the proceedings of the Panel;
- (b) Japan's measure is not "maintained without sufficient scientific evidence" and is consistent with Article 2.2 of the *SPS Agreement*. Alternatively, Japan's measure is justifiable as a provisional phytosanitary measure under Article 5.7 of the *SPS Agreement*;
- (c) Japan has conducted a risk assessment ("Pest Risk Analysis" – "PRA") compliant with Article 5.1 of the *SPS Agreement*;
- (d) Japan's PRA is consistent with the requirements of Article 5.2;
- (e) Japan's measure is consistent with Article 5.6 of the *SPS Agreement*;
- (f) Japan acted in compliance with Article 7 and Annex B of the *SPS Agreement* regarding transparency.

8.3 Having regard to the arguments of the parties, we will first define what we consider to be the phytosanitary measure at issue and the product subject to this measure. We will then address

the procedural issues raised by the parties, in particular the treatment of the burden of proof and the preliminary rulings requested by Japan.

8.4 Thereafter, giving due consideration to the order in which the parties have argued the case and consistent with the opinions of the Appellate Body in *EC – Hormones* and in *Australia – Salmon*²⁰¹, we will address the issues before us in the following order:

- (a) We will first address the application of Article 2.2 of the *SPS Agreement* to the phytosanitary measure at issue. However, we note that Japan presented an alternative defence under Article 5.7 of the *SPS Agreement*, in the event that the United States should successfully establish violation of Article 2.2. We recall that, in *Japan – Agricultural Products II*, the panel faced a comparable situation where Japan had presented a defence under both Article 2.2 and Article 5.7. In that case, the panel refrained from making a final finding of violation of Article 2.2 until it had reached a conclusion on the application of Article 5.7. It recalled that Article 2.2 of the *SPS Agreement* provides that Members shall ensure that any phytosanitary measure "is not maintained without sufficient scientific evidence, *except as provided for in paragraph 7 of Article 5*" and concluded that it had to examine whether the measure at issue was a measure meeting the requirements in Article 5.7. If the measure at issue met these requirements, it would not find a violation of Article 2.2.²⁰² We believe it appropriate to follow, in this case too, the approach of the panel in *Japan – Agricultural Products II*. There is only one situation where it may not be necessary to address Article 5.7. This is if we find that the measure or measures as a whole is/are "not maintained without sufficient scientific evidence" within the meaning of Article 2.2. If we were to find, however, that part or all of the measure or measures at issue is/are maintained without sufficient scientific evidence, we would suspend our final conclusion on the consistency of the measure(s) at issue with that provision until we have completed our examination under Article 5.7 of the *SPS Agreement*.
- (b) In that context, our analysis of the conformity of part or all of the phytosanitary measure(s) at issue with Article 5.7 will immediately follow our analysis of the US claim under Article 2.2.
- (c) At that juncture, should we find the measure or measures at issue to be inconsistent with both Article 2.2 and Article 5.7, we could legitimately abstain from making any findings on the other claims of the United States. However, we

²⁰¹ Appellate Body Report in *EC – Hormones*, para. 250, where the Appellate Body expressed its surprise at the fact that the panel began its analysis of the whole case with Articles 3 and 5, and not by focussing on Article 2 that is captioned "Basic Rights and Obligations", an approach that, to the Appellate Body, appeared "logically attractive".

In *Australia – Salmon* case, at para. 138 of its report, the Appellate Body considered that:

"by maintaining an import prohibition on fresh, chilled or frozen ocean-caught Pacific salmon, in violation of Article 5.1, Australia has, by implication, also acted inconsistently with Article 2.2 of the *SPS Agreement*."

However, we do not read this finding as implying that we *should* address the US claim of violation of Article 5.1 before its claims on Article 2.2.

²⁰² *Japan – Agricultural Products II*, para. 8.41, emphasis in the original.

are of the view that findings regarding, more particularly, the claims raised with respect to Japan's obligations in terms of risk assessment may assist the Dispute Settlement Body (DSB) in making sufficiently precise recommendations and rulings so as to allow for prompt compliance, in order to ensure effective resolution of the dispute.²⁰³ This is why we will also address the claims relating to those obligations, beginning with Article 5.1 (risk assessment).

- (d) We will then continue our assessment of the matter with the examination of the claims regarding Article 7 and Annex B to the *SPS Agreement*. For reasons explained in Section G below, we will not review the US claims under Article 5.6.
- (e) Finally, for the reasons explained in Sections I and J, we do not intend to make findings with respect to the US claims on Articles XI of the GATT 1994, Article 4.2 of the Agreement on Agriculture and the other claims not developed by the United States in its submissions before the Panel.

B. THE MEASURE AT ISSUE AND THE PRODUCT SUBJECT TO THIS MEASURE

1. The measure at issue

- (a) Summary of the arguments of the parties²⁰⁴

8.5 According to the United States, Japan maintains measures restricting the importation of US apples in connection with fire blight or the fire blight disease-causing organism, *Erwinia amylovora* (hereafter *E. amylovora*). The United States has identified nine specific prohibitions or requirements imposed by Japan:²⁰⁵

- (a) The prohibition of imported apples from US states other than apples produced in designated areas in the states of Oregon or Washington²⁰⁶;
- (b) the prohibition of imported apples from orchards in which any fire blight is detected on plants or in which host plants of fire blight (other than apple trees) are found, whether or not infected;
- (c) the prohibition of imported apples from any orchard (whether or not it is free of fire blight) should fire blight be detected within a 500-meter buffer zone surrounding such orchard;

²⁰³ See Appellate Body Report in *Australia – Salmon*, para. 223.

²⁰⁴ A detailed account of Japan's measures and of the arguments of the parties can be found in paras. 2.17-2.19, and paras. 4.17-4.33, respectively.

²⁰⁵ US Request for Establishment of a Panel, WT/DS245/2; US First Submission, para. 19; US Answers to Additional Questions from the Panel, 28 January 2003, para. 2.

²⁰⁶ The United States contends that paragraph 25 of the Annexed List to Table 2 of the Plant Protection Law Enforcement Regulations limits the importation of fresh fruit of apple from the United States to Golden Delicious and Red Delicious apple varieties. The Panel, however, notes that there is disagreement between the parties as to the English translation of the aforementioned paragraph 25. The English translation of paragraph 25 provided by Japan makes no mention of the Golden Delicious and Red Delicious variety requirement. Ministerial Ordinance No. 73: Plant Protection Law Enforcement Regulations, Annexed List, para. 25 (Exhibit JPN-21 and Exhibit USA-9).

- (d) the requirement that export orchards be inspected three times yearly (at blossom, fruitlet, and harvest stages) for the presence of fire blight for purposes of applying the above-mentioned prohibitions;
- (e) a post-harvest surface treatment of apples for export with chlorine;
- (f) production requirements, such as chlorine treatment of containers for harvesting and chlorine treatment of the packing facility;
- (g) post-harvest separation of apples for export to Japan from fruits destined to other markets;
- (h) certification by US plant protection officials that fruits are free of fire blight and have been treated post harvest with chlorine; and
- (i) confirmation by Japanese officials of the US officials' certification and inspection by Japanese officials of disinfection and packaging facilities.

8.6 Japan does not dispute the description of the requirements at issue made by the United States. Japan recalls, however, that points (h) and (i) above are not included in its description of its fire blight requirements since "certification or declaration by officials of the exporting country" and "confirmation by Japanese officials" are mere procedural steps to ensure compliance with the substantive requirements and are common for all phytosanitary measures. On the other hand, Japan describes the disinfection of the harvest containers and the disinfection of the packing facilities (item(f)) as two separate elements of its requirements.

8.7 The United States considers that the means through which Japan maintains these restrictions and requirements consist of: (i) the Plant Protection Law (Law No. 151; enacted 4 May 1950), as amended; (ii) the Plant Protection Regulations (Ministry of Agriculture, Forestry, and Fisheries Ordinance No. 73, enacted 30 June 1950), as amended; (iii) Ministry of Agriculture, Forestry and Fisheries Notification No. 354 (dated 10 March 1997); and (iv) related detailed rules and regulations, including Ministry of Agriculture, Forestry, and Fisheries Circular 8103.

8.8 The United States argues that Japan prohibits the importation of apples from the United States unless all of the requirements referred to above are satisfied. While this cumulative requirement is, in its view, contrary to the *SPS Agreement*, the United States also contends that each of the nine specific requirements listed above could be considered as a separate phytosanitary measure and that each of them is inconsistent with Japan's obligations under Article 2.2 of the *SPS Agreement* because they are maintained without sufficient scientific evidence.

8.9 Japan does not dispute that the measure is covered by the *SPS Agreement*. However, Japan argues that its requirements constitute a "systemic approach".²⁰⁷ The systems approach consists of approving only those apples produced in environmental conditions that will not allow

²⁰⁷ Hereafter "systems approach". ("The integration of different pest risk management measures, at least two of which act independently, and which cumulatively achieve the appropriate level of phytosanitary protection". *International Standard for Phytosanitary Measures No.5: Glossary of Phytosanitary Terms*, FAO, Rome, 2002).

the presence of fire blight bacteria, both outside and inside of apple fruit, at various stages from blossom to growth, harvest and shipment. Japan therefore disputes the allegation of the United States that each aspect of the measure could be addressed in isolation. Even though each requirement is technically independent, some of the components are interrelated. As a whole they are, in Japan's view, cumulative, inseparable and integral parts of a single measure.²⁰⁸

(b) Analysis of the Panel

8.10 Before going any further, we need first to clarify the relevance, in our assessment, of treating the Japanese requirements and restrictions at issue as one single measure or as a combination of several individual measures. As stated by the Appellate Body in *Australia – Salmon*²⁰⁹, our findings must assist the DSB in making sufficiently precise recommendations and rulings so as to allow for prompt compliance, in order to ensure effective resolution of the dispute. In that context, given the number of requirements identified by the United States, it may be relevant to address each of them as a separate "measure". However, we note that Japan insisted on the fact that those requirements are part of one single systems approach. Furthermore, some of the requirements are clearly interrelated. For example, the requirement of a buffer zone is directly related to the requirement that the export orchard be disease-free.

(i) *One or more measures?*

8.11 We recall that the concept of "measure" is not defined in the DSU, even though the term "measures at issue" is found in Article 6.2 regarding the establishment of a panel. The use of the term "measures at issue" in plural suggests that a matter brought before the DSB may refer to several "measures". This said, Article 19.1 refers to "a measure" that is found to be inconsistent. The definition of the concept is the result of the practice of panels and the Appellate Body under the GATT and the WTO. "Measure", for the purpose of dispute resolution under GATT and the WTO, has generally been understood to refer to an action in which there was "sufficient government involvement".²¹⁰

8.12 We note that Annex A, paragraph 1, of the *SPS Agreement* provides a definition of "phytosanitary measure". In *Australia – Salmon*, the Appellate Body, by referring to the "sanitary measure at issue in this dispute", seems to have implied that a "measure" in a phytosanitary case should be defined with reference to the definition of "phytosanitary measure" in the *SPS Agreement*.²¹¹

8.13 Paragraph 1 of Annex A of the *SPS Agreement* defines as a phytosanitary measure "all measures applied to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms". However, this definition provides little direct guidance in determining whether we should treat the several requirements identified by the United States together as one measure or separately as individual measures.

²⁰⁸ Japan, Response to Additional Questions from the Panel, 28 January 2003, Question 1.

²⁰⁹ Appellate Body Report, para. 223.

²¹⁰ Panel Report in *Japan - Film*, paras. 10.55-10.56, referring to GATT panel reports *Japan – Semiconductors*, para. 102 and *EC – Restrictions on Imports of Dessert Apples* (Complaint by Chile), para.126.

²¹¹ We also note that in *Japan – Agricultural products II*, the Appellate Body characterised varietal testing as a regulation, within the meaning of paragraph 1 of Annex B, implicitly identifying it as a "measure" under paragraph 1 of Annex A.

8.14 We recall, however, that panels and the Appellate Body have in the past considered as one single "measure" legal requirements comprised of several obligations, some simply prohibiting importation, some allowing importation under certain conditions. In *Australia – Salmon*, the Appellate Body considered that the measure at issue was a text called QP86A, as confirmed by an Australian decision of 1996. As mentioned by the Appellate Body, QP86A "impose[d] an import prohibition, [but also] delegate[d] authority to the Director of Quarantine to allow imports that have been subject to such treatment as is likely, in his opinion, to prevent the introduction of any disease".²¹² The Appellate Body nonetheless described the measure as a whole as an "import prohibition".²¹³

8.15 We note that in this instance, on the one hand, the United States does not suggest that it would be inappropriate for us to treat the nine "requirements" it identified as one single measure. Indeed, it considers that none of those requirements is justified, as long as the exported product is mature, symptomless apples. On the other hand, Japan objects to our reviewing each of these requirements separately, as it considers them to be the necessary elements of a systems approach.

8.16 We further note that these requirements cumulatively constitute the measures *actually applied* by Japan to the importation of US apple fruit to protect itself against the entry, establishment or spread of fire blight within its territory. As noted above, they are interrelated, and it is this entire set of requirements that must be met in order for US apples to be exported to Japan. We recall in this respect the Appellate Body's statement, in *Australia – Salmon*, that "the SPS measure at issue can *only* be the measure which is *actually* applied to the product at issue".²¹⁴

8.17 In the light of the above, we consider that there is no legal, logical or factual obstacle to treating the requirements identified by the United States as one single phytosanitary measure within the meaning of the *SPS Agreement*. There are, on the contrary, good reasons to do so, in particular the fact that both parties themselves have argued the case as an "all or nothing" exercise. We note in this regard that the United States did not argue that part or all of the requirements it identified were not "necessary" within the meaning of Article 2.2 of the *SPS Agreement*. Rather, the United States argues that there was not sufficient scientific evidence to support any of those requirements. Treating the requirements at issue as one measure is,

²¹² Appellate Body Report in *Australia - Salmon*, para. 98.

²¹³ The Appellate Body rejected the description of the measure by the panel as two sides of the same coin because part of the measure (the heat treatment requirement) did not actually apply to fresh salmon (see paras. 103-104). On the treatment of a legislation with several requirements as one measure, see also Appellate Body Report in *EC – Asbestos*, para. 64 :

"In our view, the proper legal character of the measure at issue cannot be determined unless the measure is examined as a whole. Article 1 of the Decree contains broad, general prohibitions on asbestos and products containing asbestos. However, the scope and generality of those prohibitions can only be understood in light of the exceptions to it which, albeit for a limited period, *permit, inter alia*, the use of certain products containing asbestos and, principally, products containing chrysotile asbestos fibres. The measure is, therefore, *not a total* prohibition on asbestos fibres, because it also includes provisions that *permit*, for a limited duration, the use of asbestos in certain situations. Thus, to characterize the measure simply as a general prohibition, and to examine it as such, overlooks the complexities of the measure, which include both prohibitive and permissive elements. In addition, we observe that the exceptions in the measure would have no autonomous legal significance in the absence of the prohibitions. We, therefore, conclude that the measure at issue is to be examined as an integrated whole, taking into account, as appropriate, the prohibitive and the permissive elements that are part of it."

²¹⁴ Appellate Body Report in *Australia - Salmon*, para. 103 (emphasis in the original).

therefore, appropriate, especially in the context of Article 2.2 of the *SPS Agreement*, provided that we determine that the measure as a whole is – or is not – compatible with the *SPS Agreement*.

8.18 However, we do not exclude that, as we carry out our analysis, especially under Article 2.2 of the *SPS Agreement*, we may be apprised of scientific evidence to support certain aspects of the measure and not others. In this regard, the Panel is guided by the opinions of the experts which it appointed to serve as scientific and technical advisers.²¹⁵ While this may, in principle, justify specific findings on those aspects of the measure, we recall that neither the United States nor Japan have taken the view that the phytosanitary measure at issue could be partly justified under the *SPS Agreement*. The United States' position is that none of the aspects of the measure is justified with respect to the importation of mature, symptomless apple fruit. Japan argues, on the contrary, that each of the components of the measure is inseparably part of a systems approach.

8.19 We may of course conclude that one aspect of a measure is illegal and not others, even when the complainant argues that the measure as a whole is illegal. Indeed, since the *SPS Agreement* establishes different rights and obligations, it may be also appropriate, depending on the provision at issue, to consider the specific requirements individually. However, to assume such a subdivision would disregard the way in which those requirements are presented by the parties and applied, i.e., as one single measure.

8.20 For these reasons, we find that we should consider together the requirements identified by the United States as the phytosanitary measure at issue in this dispute.

(ii) *Elements constituting the phytosanitary measure at issue*

8.21 We note that the parties disagree as to the actual number of requirements imposed by Japan with respect to the importation of US apples. We recall that the United States listed nine requirements and that although Japan lists the requirements differently, Japan does not dispute the description made by the United States, except with regard to two items.

8.22 Concerning the first one (certification by US plant protection officials that fruits are free of fire blight and have been treated post harvest with chlorine), we agree with Japan that it is essentially a procedural requirement and that phytosanitary certificates are common practice in international trade. Indeed, we note that the relevant international standards setting body in this respect, the Interim Commission on Phytosanitary Measures, has adopted standards for such certificates.²¹⁶ Furthermore, we note that the US Apple Export Act provides for the issuance of phytosanitary certificates for apples exported from the United States that are of a certain grade

²¹⁵ Noting that this Panel involved scientific or technical issues, and noting that both parties acknowledged that the Panel may need to consult with scientific and technical experts, we decided, pursuant to Article 13.1 of the DSU and Article 11.2 of the *SPS Agreement*, to select and appoint specialists in the field of plant pathology and pathogenic bacteria. The procedure followed for the selection and consultation of the experts is described in paras. 6.1-6.4 above. The experts appointed by the Panel were: Dr Klaus Geider, Professor of Molecular Genetics and Phytopathology, Max-Planck-Institut für Zellbiologie, University of Heidelberg, Ladenburg, Germany; Dr Chris Hale, Science Capability Leader, Insect Group (Plant Health and Fire Blight) HortResearch, Auckland, New Zealand; Dr Chris Hayward, Consultant on Bacterial Plant Diseases, Indooroopilly, Queensland, Australia; and Dr Ian Smith, Director-General, European Plant Protection Organization, Paris, France. Consistent with the principles recalled by the Appellate Body regarding burden of proof, the opinions of the experts were used by the Panel to assess the factual allegations raised by the parties in support of their claims.

²¹⁶ Op. cit., ISPM 12.

and quality. In this respect, our opinion is without prejudice as to what exactly should be certified.

8.23 Regarding the second item (i.e., the confirmation by Japanese officials of the US officials' certification and inspection by Japanese officials of disinfection and packaging facilities), it appears that they do not entail significant additional obligations for the United States compared with the other requirements identified.

8.24 However, we note that both requirements fall within the definition of phytosanitary measures contained in Annex A, paragraph 1, of the *SPS Agreement*, which includes "inspection, certification and approval procedures". We also note that the definition in Annex A, paragraph 1, does not consider the trade effect of a given measure as a factor to determine whether such a measure is or is not a phytosanitary measure. While such requirements are common practices and, on their own, may not have justified the initiation of this case by the United States, we note that they are part of the measure as a whole and that, in combination with other elements of that measure, they may contribute to the restrictive effect of the measure at issue.

8.25 For these reasons, we conclude that the measure at issue 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. Any detection of a blighted tree in this area by inspection will disqualify the orchard. For the time being, the designation is accepted only for orchards in the states of Washington and Oregon²¹⁷;**
- (b) the export orchard must be free of plants infected with fire blight and free of host plants of fire blight (other than apples), whether or not infected;**
- (c) the fire blight-free orchard must be surrounded by a 500-meter buffer zone. Detection of a blighted tree or plant in this zone will disqualify the export orchard;**
- (d) the fire blight-free orchard and surrounding buffer zone must be inspected at least three times annually. US officials will visually inspect twice, at the blossom and the fruitlet stages, the export area and the buffer zone for any symptom of fire blight. Japanese and US officials will jointly conduct visual**

²¹⁷ Japan argues that the current phytosanitary requirements against fire blight can be applicable to apple fruit produced in other States, but that the United States has not submitted documentation on the status of other quarantine pests for states other than Washington and Oregon. As such, Japan argues that this is a procedural matter. (Japan, Response to Questions from the Panel, 13 November 2002, Question 47) The United States argues that Japan prohibits the importation of US fruit other than fruit produced in designated export orchards within either of the two states of Washington or Oregon. The United States has in the past requested that Japan expand the list of states eligible to export apple fruit to Japan, to no avail. While there is scientific evidence that fire blight bacteria are not associated internally or externally with mature, symptomless apple fruit from the state of Washington, there is not a rational or objective relationship between the scientific evidence and Japan's prohibition of apples other than those harvested in the states of Washington or Oregon (US First Submission, para. 58).

inspection of these sites at harvest time. Additional inspections are required following any strong storm (such as a hail storm);

- (e) harvested apples must be treated with surface disinfection by soaking in sodium hypochlorite solution;**
- (f) containers for harvesting must be disinfected by a chlorine treatment;**
- (g) the interior of the packing facility must be disinfected by a chlorine treatment;**
- (h) fruit destined for Japan must be kept separated post-harvest from other fruit;**
- (i) US plant protection officials must certify that fruits are free from fire blight and have been treated post harvest with chlorine; and**
- (j) Japanese officials must confirm the US officials' certification and Japanese officials must inspect packaging facilities.**

2. The product subject to the phytosanitary measure at issue

- (a) Summary of the arguments of the parties²¹⁸

8.26 The United States argues that the commodity subject to the measure at issue is the product it allegedly exports, i.e., "mature, symptomless apples". Japan contests the notions of "mature" and "symptomless" as subjective. The United States replies that these notions are scientifically supported.

- (b) Analysis of the Panel

8.27 On the basis of the information before us, we understand that Japan's concern is that fire blight could be introduced into its territory through apples imported from the United States and their containers (e.g., crates).

8.28 Japan argues that:

- (a) fire blight bacteria are capable of long-term survival inside or on the surface of "mature, symptomless" apples, such that the apple fruit could develop fire blight symptoms sometime after their selection and packing for export. Hence, apple fruit could be contaminated and yet be found fit for exportation. Once introduced into Japan, fire blight would have ample potential for growth and infection with major negative, irreversible consequences²¹⁹; and that
- (b) there is a very real risk of accidental contamination or erroneous grading, which could lead to the introduction of infected or infested apples in a shipment of

²¹⁸ For a more detailed account of the arguments of the parties see, *inter alia*, paras. 4.51, 4.63-4.64 and 4.99.

²¹⁹ Para. 4.50.

otherwise mature, symptomless apple fruit bound for Japan, or to the contamination of crates.²²⁰

Hence, in the absence of an appropriate quarantine inspection method or internal apple disinfection treatment technique, Japan considers that a systems approach is the only viable alternative (short of import prohibition) to ensure that there is no presence of fire blight bacteria either inside or outside of apple fruit shipped to Japan.²²¹

8.29 We recall the argument of the United States that it exports only mature, symptomless apples, which it claims have been proven not to be a pathway for fire blight (i.e., they are not capable of transmitting fire blight to other hosts). We understand the US position to be that, in that context, none of the requirements contained in the measure at issue is compatible with the *SPS Agreement*.

8.30 In light of the claims and arguments of the parties, we consider it essential to identify precisely the "product" subject to the measure at issue.²²² Indeed, if we consider that "product" to be limited to "mature, symptomless apple fruit", as claimed by the United States, many aspects of the measure at issue might, *ipso facto*, lose their *raison d'être* and may become incompatible with the *SPS Agreement*. This could be the case for most of the requirements, which under the measure currently applied by Japan, take place before harvesting. If, on the contrary, we conclude that the product at issue is "any apple to be shipped to Japan from the United States", then we actually need to address the justification of the requirements imposed by Japan as a whole.

8.31 We note that some requirements may appear to relate to the apples that *cannot* be exported (prohibitions), whereas some others apply only to those that *can* be exported. If we follow the US definition of the product at issue, we run the risk of reviewing only the requirements applying to mature, symptomless apples, which would be illogical.

8.32 We also note that the request for establishment of a panel submitted by the United States only refers to "US apples", which is less specific than "mature, symptomless apples".²²³ The request for establishment of a panel is the document that defines our mandate. It is not exclusively a limitation to our jurisdiction, it defines it positively too. The fact that the United States intended to address "only" mature, symptomless apples in its submission does not affect our mandate.²²⁴ We also recall the arguments of the parties and the experts regarding the notion of "mature" and "symptomless" apple fruit, and the fact that the susceptibility of apples to infestation or infection by *E. amylovora* is related to the maturity of apples. In this respect, the experts were able to provide definitions of, and to distinguish between, "physiological" and

²²⁰ Para. 4.190.

²²¹ Paras. 4.19-4.20.

²²² We note in this respect that an approach aiming at identifying precisely the product subject to the measure was confirmed by the Appellate Body in *Australia – Salmon*, paras. 94-95.

²²³ See WT/DS245/2: "Japan currently maintains measures restricting the importation of US apples in connection with fire blight or the fire blight disease-causing organism, *Erwinia amylovora*" (underlining added).

²²⁴ We note in this respect that Japan claims that it was made aware of the concept of "mature, symptomless apples" during the consultations. This suggests that, by the time the United States requested the establishment of this Panel, it could have referred specifically to "mature, symptomless apples".

"commercial" maturity. Furthermore, the experts confirmed that there were widely used and accepted objective methods for determining the maturity of apples.²²⁵

8.33 Without prejudice to our discussion of the merits of this case, we feel bound at this early stage of our reasoning not to prejudge our conclusions by unduly restricting the scope of our findings to mature, symptomless apple fruit. Indeed, we believe that the US claim that the product at issue is "mature, symptomless apples" is based essentially on two assumptions: (a) mature, symptomless apple fruit are not a pathway for fire blight and (b) shipments from the United States to Japan only contain mature, symptomless apples. In our opinion, these assumptions can only be verified through a review of the merits of the case, in particular the central question of whether, and under which conditions, apples may or may not act as a pathway for fire blight.

8.34 We therefore conclude that we should consider the measure at issue as applicable to apple fruit produced in the United States for exportation to Japan.

C. PROCEDURAL ISSUES

1. Introduction

8.35 In its first submission, Japan requested the Panel to address three "procedural issues".²²⁶

8.36 Japan requested that we exercise our authority under paragraph 9 of our Working Procedures²²⁷ to seek clarification from the United States of the time as of which it considers that the Japanese measure at issue was no longer supported by sufficient scientific evidence. The United States subsequently stated in reply to a question from the Panel that it considered that the measure had never been compatible with the *SPS Agreement*.²²⁸ As a result, we find that it is no longer necessary to address this request by Japan.

8.37 Japan also requested in its first written submission that we "remove", in accordance with paragraph 10 of our Working Procedures, two documents submitted by the United States as evidence in its first submission.

8.38 Moreover, Japan requested that, in accordance with paragraph 10 of our Working Procedures, we "remove" from the "scope of our proceedings" all the provisions that the United States did not address in its first submission.

8.39 In addition, while it seems undisputed by the parties that the United States bears the burden of presenting a prima facie case for each of its claims, Japan has, on several occasions²²⁹, raised questions relating in particular to the administration of evidence, including the accessibility of the information, the fact that scientific evidence should not be limited to "direct evidence" and the standard of proof to be applied by the Panel. Since these questions are primarily of a procedural nature, we consider it appropriate to address them at this stage.

²²⁵ Dr Hale, para. 6.5.

²²⁶ Japan first submission, paras. 17-34.

²²⁷ The Working Procedures for the Panel are reproduced in Annex 1 and the Working Procedures for the consultation of experts are contained in para. 6.2 of the Report..

²²⁸ US Response to Questions from the Panel, 13 November 2002, para.87.

²²⁹ Japan first submission, paras. 17-34, 47-50, 129-141, Japan Second Submission, paras. 1, 38-47.

8.40 As a result, in this section we will:

- (a) Under a heading regarding burden of proof, recall the general obligations of the parties in terms of burden of proof, including with respect to the question of the general access of Japan to scientific information;
- (b) Under a heading relating to Japan's requests made under paragraph 10 of our Working Procedures, recall our decision regarding the treatment of the two communications the admissibility of which is contested by Japan and address Japan's request on the scope of our mandate in relation to the US claims not developed in the first submission of the United States.

2. Burden of proof

8.41 At the outset, we find it important to clarify that, as recalled by the Appellate Body in *EC – Hormones*, there is not any necessary connection between "the undertaking of Members to ensure, for example, that SPS measures are 'applied only to the extent necessary to protect human, animal or plant life or health ...' and the allocation of burden of proof in a dispute settlement proceeding. Article 5.8 of the *SPS Agreement* does not purport to address burden of proof problems; it does not deal with a dispute settlement situation".²³⁰ A distinction must therefore be made between the obligations of Members in adopting and maintaining the measures concerned and the separate issue of burden of proof in dispute proceedings.

8.42 As a result, we shall apply the principles of allocation of the burden of proof as identified by the Appellate Body in *EC – Hormones*:

"The initial burden lies on the complaining party, which must establish a prima facie case of inconsistency with a particular provision of the *SPS Agreement* on the part of the defending party, or more precisely, of its SPS measure or measures complained about. When that prima facie case is made, the burden of proof moves to the defending party, which must in turn counter or refute the claimed inconsistency."²³¹

8.43 We nonetheless note that Japan raised some specific questions regarding the burden of proof in general and the nature of admissible evidence.

8.44 Japan argues that the United States, as the exporting country affected by the disease, would "naturally" have more information on the *E. amylovora* bacteria. We do not see the greater expertise of the exporting country as a factor that should automatically justify a different allocation of the burden of proof or the imposition of a heavier burden of proof on one party.

8.45 We do not disagree that specific pieces of scientific evidence may be more readily available in some countries than others, and in the case of a disease-free country, that evidence relating to the spread of that disease may naturally be less extensively developed within that territory than in a country with direct exposure to the disease. However, this should not mean

²³⁰ Appellate Body Report in *EC – Hormones*, para. 102.

²³¹ Appellate Body Report in *EC – Hormones*, para. 98. See also the Panel Report in *Australia – Salmon - Article 21.5 (Canada)*, para. 7.37 and the Panel Report in *Japan – Agricultural Products II*, para. 8.13.

that a Member should be exempted from an obligation to provide evidence of its allegations simply because its territory is free from a particular disease, or that a heavier burden of proof should be imposed *ipso facto* on a Member simply because its territory is not disease-free. Indeed, a number of developing countries affected by a pest or disease may not have the resources to gather information on that pest and may need to rely on information gathered in other countries.

8.46 We note, moreover, that Japan could have sought to perform or commission research on *E. amylovora* in third countries. Japan has in the past undertaken studies in relation to fire blight-like diseases of pears, and in 2002 regarding fire blight in apples. Furthermore, Japan proposed and engaged in joint field experiments with the United States regarding fire blight in US apples.²³²

8.47 In addition, Japan has been arguing that evidence should be limited to public information. In the case of scientific evidence, it should have been peer reviewed by other scientists. We note that virtually all of the evidence presented in this case, with the exception of the most recent research undertaken by both countries²³³ and the clarifications sought by the United States²³⁴, is publicly available.

8.48 As a result, we do not consider that Japan should be exempted from its obligation to sufficiently support its allegations or that a heavier burden of proof should be imposed on the United States for the reasons alleged by Japan above. In drawing this conclusion, however, we bear in mind the duty of all parties in a dispute to cooperate in the proceedings, including, as necessary, in the gathering of information relevant to the Panel's assessment of the matter.

8.49 A related question is whether the Panel should consider evidence that became available only after the establishment of the Panel. Our approach in this respect should be pragmatic. Besides the situation contemplated in paragraph 11 of our Working Procedures, we decided not to reject evidence submitted by a party on which the other party had had an opportunity to comment, whether it took advantage of such an opportunity or not. This is without prejudice to the admissibility of such evidence on other grounds or the weight that we might eventually give to such evidence.

8.50 However, our discussion above does not dispose of the question of the actual standard or level of proof that must be satisfied for each claim to succeed. As recalled by the Appellate Body in *US – Wool Shirts and Blouses*:

"In the context of the GATT 1994 and the *WTO Agreement*, precisely how much and precisely what kind of evidence will be required to establish [a prima facie case] will necessarily vary from measure to measure, provision to provision, and case to case."²³⁵

8.51 We are therefore of the view that this aspect will be more appropriately addressed in the sections regarding each claim.²³⁶

²³² See discussion in paras. 4.174-4.178.

²³³ Exhibits JPN-33, JPN-39, JPN-42, USA-32 to USA-39.

²³⁴ Exhibits USA-18 and USA-19.

²³⁵ Appellate Body Report in *US – Wool Shirts and Blouses*, p. 335.

²³⁶ This is without prejudice to the standard of review for fact-finding to be applied in this case. As recalled by the Appellate Body in *EC – Hormones*:

3. Japan's requests for preliminary rulings

(a) Introduction

8.52 As mentioned above, Japan requested that we issue a preliminary ruling on two issues, in accordance with paragraph 10 of our Working Procedures. First, Japan requested that we "remove" two documents submitted by the United States as evidence²³⁷ essentially:

- (a) because these documents were submitted in such a way that Japan was prevented from discussing them during consultations, with the consequence that it was denied an opportunity to settle the matter in good faith through bilateral consultations; and
- (b) because the probative value of those communications is questionable, given the conditions in which they were obtained.²³⁸

Indeed, Japan contends that the declarations at issue were pre-worded by the United States to suit its position.²³⁹

8.53 Second, Japan requests that we "remove" from the "scope of our proceedings" all the provisions that the United States did not address in its first submission.

8.54 At our request, the United States submitted written comments before our first substantive meeting.²⁴⁰ The issues were further addressed by the parties at our first meeting and subsequently

"The standard of review appropriately applicable in proceedings under the *SPS Agreement*, of course, must reflect the balance established in that Agreement between the jurisdictional competences conceded by the Members to the WTO and the jurisdictional competences retained by the Members for themselves. To adopt a standard of review not clearly rooted in the text of the *SPS Agreement* itself, may well amount to changing that finely drawn balance; and neither a panel nor the Appellate Body is authorized to do that.

... In our view, Article 11 of the DSU bears directly on this matter and, in effect, articulates with great succinctness but with sufficient clarity the appropriate standard of review for panels in respect of both the ascertainment of facts and the legal characterization of such facts under the relevant agreements.

So far as fact-finding by panels is concerned, their activities are always constrained by the mandate of Article 11 of the DSU: the applicable standard is neither *de novo* review as such, nor 'total deference', but rather the 'objective assessment of the facts'. Many panels have in the past refused to undertake *de novo* review, wisely, since under current practice and systems, they are in any case poorly suited to engage in such a review. On the other hand, 'total deference to the findings of the national authorities', it has been well said, 'could not ensure an 'objective assessment' as foreseen by Article 11 of the DSU'" (paras. 115-117).

²³⁷ These documents are (a) a declaration by Dr Tom van der Zwet (Exhibit USA-18) and a letter by Professor Sherman Thomson (Exhibit USA-19).

²³⁸ A detailed account of the arguments of the parties can be found in paras. 4.6-4.16.

²³⁹ Comments of Japan on Experts' Responses, 23 December 2002, paras. 13 and 17.

by Japan in its second written submission and during our second substantive meeting with the parties.

(b) Japan's request that we "remove" certain pieces of evidence from the proceedings

8.55 With regard to Japan's first request, in a letter dated 15 January 2003, we informed the parties of the following:

"The Panel refers to Japan's request for a preliminary ruling concerning the admissibility of two exhibits submitted by the United States with its first written submission, namely the declaration from T. van der Zwet (USA – 18) and the letter from S. V. Thomson (USA – 19).

The Panel notes that, as a matter of principle, the parties are entitled to submit evidence in support of their arguments. Having considered the arguments of the parties, the Panel is not convinced that, in this particular instance, it should exclude the aforementioned exhibits from the proceedings *a priori*. This decision is without prejudice to the weight, if any, that the Panel may ultimately ascribe to these documents, including in light of Japan's comments.

Japan may, if it deems necessary, make further representations or ask additional questions regarding the contents of these documents in the course of the second substantive meeting."

8.56 We confirm our decision not to reject the two pieces of evidence submitted by the United States as Exhibits USA-18 and USA-19. We are of the view that our obligation, pursuant to Article 11 of the DSU, to make an objective assessment of the matter before us, including an objective assessment of the facts of the case, imposes on us an obligation not to exclude *a priori* any evidence submitted in due time by any party. However, the fact that we accepted the evidence at issue as a matter of principle is, as stated in the letter above, without prejudice to the weight that we will ultimately give to these exhibits in our discussion of the substance of this case. We also note that, consistent with the practice of panels, we provided Japan with the opportunity to comment on the substance of these documents.

(c) Japan's request regarding some claims not developed by the United States in its first submission

(i) *Summary of the arguments of the parties*²⁴¹

8.57 Japan requests that we "remove" from the scope of our proceedings a number of claims contained in the request of the United States for the establishment of the Panel. With respect to Article 4.2 of the Agreement on Agriculture and Article 5.5 of the *SPS Agreement*, Japan argues that no bilateral consultations were held. Regarding Article XI GATT 1994, Article 4.2 of the Agreement on Agriculture and Articles 2.3, 5.3, 5.5, 6.1 and 6.2 of the *SPS Agreement*, Japan argues that the United States should not be entitled to develop those claims during these proceedings since it did not address them in its first submission.

²⁴⁰ Reply of the United States to the Request by Japan for Preliminary Rulings, 16 October 2002. See paras. 4.7, 4.8, 4.10, 4.12, 4.13.

²⁴¹ A detailed account of the arguments of the parties can be found in paras. 4.1-4.5 of this Report.

8.58 The United States argues that there is no basis for the Panel to remove claims that are within the Panel's terms of reference as established by the DSB. There is, in its view, no obligation under the DSU to consult on a particular claim in order to include that claim in the Panel's terms of reference. The purpose of consultations is to provide a better understanding of the facts and circumstances of a dispute. Logically, then, a party may identify new claims in the course of consultations and include them in the request for establishment of a panel.

(ii) *Analysis of the Panel*

8.59 We understand that Japan wants us to declare that the claims at issue are either not properly before the Panel or should otherwise not be addressed by the Panel. In other words, Japan wants us to interpret our terms of reference, as defined by Article 7 of the DSU and the US request for establishment of a panel. Japan's request seems to be based on two reasons:

- (a) Some of those claims (those regarding Article 4.2 of the Agreement on Agriculture and Article 5.5 of the *SPS Agreement*) were not found in the initial request for consultations contained in document WT/DS245/1 (hereafter "Request (a)"); and
- (b) Some of those claims (those regarding Article XI GATT 1994, Article 4.2 of the Agreement on Agriculture and Articles 2.3, 5.3, 5.5, 6.1 and 6.2 of the *SPS Agreement*) were not developed in the US first written submission (hereafter "Request (b)").

- Request (a)

8.60 Concerning the claims referred to under (a) above, we first recall that, even though the United States included Article 5.5 in its request for establishment of a panel, it did not submit any argument or evidence in support of that claim. As a result, it is not necessary for the Panel to issue any ruling on the admissibility of a claim that was not addressed by the complaining party.

8.61 Regarding the claim of the United States under Article 4.2 of the Agreement on Agriculture, we consider that, in the light of our findings on the merits of this case²⁴², it is not necessary to decide on the admissibility of that claim.

8.62 For these reasons, we refrain from making any finding on Japan's request that those claims be "removed" from these proceedings by the Panel because they were not found in the initial request for consultations.

- Request (b)

8.63 As regards the claims referred to under (b) above, we first note that we are bound by our terms of reference.²⁴³ We also note that the Appellate Body in *EC – Bananas* stated that:

"There is no requirement in the DSU or in GATT practice for arguments on all claims relating to the matter referred to the DSB to be set out in a complaining party's first submission to the panel. It is the panel's terms of reference,

²⁴² See para. 8.336 below. See also paras. 8.63-8.66.

²⁴³ Appellate Body Report in *India – Patents (US)*, paras. 92-93.

governed by Article 7 of the DSU, which set out the claims of the complaining parties relating to the matter referred to the DSB."²⁴⁴

8.64 Therefore, it is well established that a complainant is not prevented, as a matter of principle, from developing in its second submission arguments relating to a claim that is within the terms of reference of the panel, even if it did not do so in its first written submission.

8.65 In the present case, the United States made arguments in relation to its claims under Article XI GATT 1994 and Article 4.2 of the Agreement on Agriculture only during our two substantive hearings with the parties. Such a tactic may seem questionable since nothing prevented the United States from presenting arguments on these claims in its first submission, and such an approach may significantly limit the possibility for the defending party to argue in response, depending on the circumstances of the case, or at least could unduly delay the proceedings.

8.66 Taking into account the established practice on issues such as this, and having given due consideration to Japan's request, we decided that the most appropriate way to deal with this issue was to give Japan sufficient opportunity to reply. We declined to rule on this issue at the first substantive meeting and made the following statement at our second meeting with the parties:

"Referring to the letter we sent yesterday [reproduced in paragraph 8.55 above], we addressed only one of the issues on which a preliminary ruling had been sought by Japan. We did not address the other point as we intend to address that in the findings. Since one party referred to this other issue this morning, the Panel notes that it is still open to the parties to make further comment on it at this meeting or within the deadlines for comment on matters arising from this meeting by close of business Tuesday 28 January"²⁴⁵.

The US claims under Article XI GATT 1994 and Article 4.2 of the Agreement on Agriculture are discussed in Sections I and J below.

D. ARTICLE 2.2 OF THE *SPS AGREEMENT*

1. Summary of the arguments of the parties²⁴⁶

(a) United States

8.67 The United States argues that Japan's fire blight measure is inconsistent with Article 2.2 of the *SPS Agreement* because it is maintained without sufficient scientific evidence, contrary to the last requirement of that Article.

8.68 The United States argues that in *Japan – Agricultural Products II*, the Appellate Body interpreted the relevant part of Article 2.2 in light of the ordinary meaning of the word "sufficient" ("of a quantity, extent, or scope adequate to a certain purpose or object") and in the

²⁴⁴ Appellate Body Report in *EC – Bananas*, para. 145. This position has been reaffirmed recently in the Report of the Appellate Body in *EC – Sardines*, para. 280 and in the Report of the Appellate Body in *Chile – Price Band System*, para. 158.

²⁴⁵ Statement by the Chairman of the Panel, Mr Michael Cartland, at the Panel meeting with the parties on 16 January 2003.

²⁴⁶ A detailed account of the arguments of the parties can be found in paras. 4.48-4.137 of this Report.

context of Articles 5.1, 3.3 and 5.7. The Appellate Body affirmed the conclusion of the panel that the obligation in Article 2.2 not to maintain an SPS measure "without sufficient scientific evidence" requires that "there be a rational or objective relationship between the SPS measure and the scientific evidence" which is to be determined on a case-by-case basis and will depend on the particular circumstances of the case, "including the characteristics of the measure at issue and the quality and quantity of the scientific evidence".²⁴⁷

8.69 The United States argues that there is no evidence that the apple fruit sought to be exported from the United States, i.e. mature, symptomless apples, have ever transmitted and or would transmit fire blight disease to Japan.²⁴⁸ All of the scientific evidence shows that mature, symptomless apples are not a pathway for the disease.

8.70 The United States adds that scientific evidence is borne out by real world experience. Over the past 35 years, there has not been a single reported instance of fire blight spread through export of US apples. Thus, there is no rational or objective relationship between the scientific evidence and the Japanese fire blight measures.

8.71 The United States further argues that mature, symptomless apples do not serve as a "pathway" for fire blight disease. The International Plant Protection Convention defines a pathway as "[a]ny means that allows the entry, establishment or spread of a pest". Phytosanitary measures under the *SPS Agreement* must, by their nature, address a risk that arises due to an identifiable pathway.

(b) Japan

8.72 Japan argues that each of the current requirements on the importation of US apples to prevent the entry of fire blight is reasonably supported by scientific evidence, similar measures taken by other countries and international standards. As such, Japan contends that there is a "rational or objective relationship" between the measure and the evidence.

8.73 Japan argues that a variety of published literature on the ecology, properties and survivability of *E. amylovora* establish that the bacteria is evidently capable of long-term survival inside or on the surface of what the United States termed "mature, symptomless" apple fruit. The fact that bacteria could exist and survive inside mature, symptomless apple fruit means that the fruit could cause fire blight symptoms later on. As such, apple fruit could be contaminated and yet be found fit for exportation. Once introduced into Japan, fire blight would have ample potential for growth and infection and lead to major negative, irreversible consequences. Previous instances of trans-oceanic dissemination of fire blight showed the survivability of bacterium and no ecological study had pin-pointed the exact pathway for transmission of the diseases in those cases. As such, apple fruit could not be ruled out as a vector for the transmission of fire blight.

8.74 Japan also contends that the United States places too much weight on "direct evidence" in assessing the risk of introducing fire blight with apple fruit. If one considers also the "indirect" scientific evidence, then Japan argues that there is evidence that contaminated apple fruit can go through each of the steps necessary for it to eventually cause fire blight in the importing country.

²⁴⁷ US first submission, para. 22.

²⁴⁸ US first submission, para. 23-24.

8.75 Japan further argues that the US criteria of mature, symptomless apple fruit is ambiguous. "Immature" and "mature" apples are not two clearly separate phenomena. Japan contends that maturation is a "continuous process". Such an ambiguous concept is therefore, in the view of Japan, unworkable.

8.76 Apple export data supplied by the United States are misleading, according to Japan. Japan notes that the top ten markets for US apples have very different climatic conditions from Japan (eight being found in the tropical region and the other two in desert climates). As such, none has favourable conditions for the establishment of fire blight, unlike Japan.

2. Approach of the Panel with respect to the review of the phytosanitary measure at issue under Article 2.2 of the SPS Agreement

(a) Preliminary remarks: limitation of findings to whether the measure is maintained "without sufficient scientific evidence"

8.77 Having reviewed the arguments of the parties, we note that the US claim regarding the violation by Japan of Article 2.2 of the *SPS Agreement* is limited to the allegation that the measure at issue is maintained "without sufficient scientific evidence". We are therefore not requested to identify a violation, or the absence thereof, of any other requirement of Article 2.2 of the *SPS Agreement*, such as whether the phytosanitary measure is based on scientific principles, even though these other requirements may be useful in understanding the extent of Japan's obligations under that Article. This said, it is essential to recall, as a first step of our analysis, what the parties must demonstrate in relation to this very specific aspect of Article 2.2.

8.78 In this respect, we should also be careful not to confuse the requirement that a measure is not maintained without sufficient scientific evidence with the requirement of Article 5.6 of the *SPS Agreement* that the measure is "not more trade-restrictive than required to achieve [Japan's] appropriate level of ... phytosanitary protection". In other words, while we might find that some specific requirements of the measure at issue are not supported by sufficient scientific evidence, our findings should be limited to Article 2.2.

(b) Determining whether the measure at issue is (or not) "maintained without sufficient scientific evidence"

(i) *Introduction*

8.79 The relevant part of Article 2.2 of the *SPS Agreement* reads as follows:

"Members shall ensure that any sanitary or phytosanitary measure ... is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5."

8.80 First, we recall that, as mentioned above, Japan has argued that the measure would still be justified under Article 5.7 of the *SPS Agreement*, even if it were found to be maintained without sufficient scientific evidence. We have already discussed the interrelation between Article 2.2 and Article 5.7 in the section regarding our general approach to this case. The arguments of Japan regarding Article 5.7 will be addressed immediately after this section. At this stage, we will address the claim made by the United States specifically under Article 2.2 of the *SPS Agreement*, i.e., that Japan maintains the measure at issue without sufficient scientific evidence, and Japan's arguments relating specifically to that provision.

8.81 Second, it is clear that we must determine in general whether the phytosanitary measure at issue is maintained without sufficient scientific evidence. However, before we can address the evidence submitted by each party, it is necessary to identify *what*, in substance, needs to be demonstrated.

8.82 Third, we will need to determine *how* parties can demonstrate their respective views. We note that the parties have extensively discussed the question of the evidence that may be submitted in these proceedings. In this respect, we note that the term "sufficient scientific evidence" contains a number of elements that need to be taken into consideration:

- (a) First, the very notion of "scientific evidence" seems to exclude elements of information that cannot be considered as "evidence". The same notion also seems to exclude any evidence that is not "scientific".
- (b) Second, the term "sufficient" seems to address not only the quantity and quality of the evidence as such, but also the "causal link" between the phytosanitary measure at issue and the scientific evidence establishing a phytosanitary risk and justifying the measure.

8.83 We will therefore need to address the question of (a) the nature of the evidence that may be accepted and (b) the quality of the evidence to be accepted.

(ii) *What needs to be demonstrated in substance?*

8.84 We note that the approach followed by the United States in order to demonstrate that the phytosanitary measure at issue is maintained without sufficient scientific evidence consists, in substance, of trying to establish that there is no evidence that "mature, symptomless apples" have introduced or could serve as a pathway for the entry, establishment or spread of fire blight by alleging that:

- (a) There is no evidence that mature, symptomless apple fruit can be infected by *E. amylovora*;
- (b) there is no scientific evidence that mature, symptomless apples can be endophytically²⁴⁹ infested by the bacteria;
- (c) scientific evidence shows that presence of epiphytic²⁵⁰ bacteria is rare and limited to apples harvested on or very close to blighted trees; and
- (d) there is no evidence that apples, even on those rare occasions that epiphytic bacteria is present, can act as a pathway for the dissemination of fire blight. Indeed, such bacteria are unlikely to survive normal commercial handling, storage and transport of fruit. In addition, even if the infested apple is placed near a suitable host that is receptive to an infection, there is no dispersal mechanism or vector to allow movement of such bacteria from the fruit to that host.

²⁴⁹ See definition of endophytic and epiphytic, para. 2.10.

²⁵⁰ *Idem*.

8.85 Japan, on the contrary, argues that:

- (a) Fire blight can be harboured in or on mature, symptomless apple fruit;
- (b) apple fruit is a possible pathway for the transmission of the disease;
- (c) trans-oceanic dissemination of the disease has previously occurred; and
- (d) it must also protect itself against failures in the control systems of exporting countries which could lead to the introduction of contaminated apples.

In the absence of any reliable quarantine inspection methods to detect fire blight in or on mature, symptomless apples, Japan views a systems approach as necessary.

8.86 A first issue to consider is, therefore, whether there is sufficient scientific evidence, within the meaning of Article 2.2 of the *SPS Agreement*, to support the view that "mature, symptomless apple fruit" can harbour the bacteria causing fire blight. If the United States were to demonstrate that this is not the case, most of the restrictions imposed by Japan would not be justified.

8.87 However, even if it were the case that mature, symptomless apples cannot be infected and do not harbour endophytic or epiphytic populations of bacteria susceptible of transmitting fire blight to a host plant in Japan, this may not exclude the possibility that fire blight-free apples become contaminated after they are harvested, nor does it exclude a risk of failure in the control procedures which normally lead to the exportation of only "mature, symptomless apples". This consideration implies that we have previously established that apples other than "mature, symptomless apples" could pose a higher risk and, thus, that we do not limit our analysis to mature, symptomless apple fruit.

8.88 Conversely, even if the United States were to fail to demonstrate that there is not sufficient evidence supporting the view that mature, symptomless apples have introduced fireblight or could serve as a pathway for the entry, establishment or spread of fire blight, this would not, *ipso facto*, imply that the Japanese measure *as a whole* is maintained with sufficient scientific evidence. We recall that this measure is composed of a number of elements all of which Japan presents as indispensable in the framework of a systems approach. If we were to find that some of these elements are redundant, i.e., that their imposition in the context of the phytosanitary measure at issue is not justified as such in response to a scientifically established risk, or that other elements of the measure already serve the same purpose, we may find that these elements are maintained without sufficient scientific evidence. Under such circumstances, the measure as a whole, at least to the extent it includes those "redundant" requirements, would be deemed to be imposed without sufficient scientific evidence.

8.89 In order to address this question, we will assess the following five elements:

- (a) As a preliminary matter, whether the notion of mature, symptomless apple fruit is scientifically supported and whether it is appropriate to restrict our examination of the measure at issue to its application to mature, symptomless apples;
- (b) whether mature apple fruit can be infected;
- (c) whether endophytic bacteria may be found in mature apple fruit;

- (d) whether mature apple fruit may harbour epiphytic bacteria;
 - (e) whether infested or infected apple fruit harbouring endophytic or epiphytic bacteria can complete the fire blight transmission pathway, i.e. whether the bacteria can survive commercial handling, storage and transportation and whether, once it has entered Japan, it can transmit the bacteria to host plants at a receptive stage (apple as a pathway).
- (iii) *How to demonstrate the existence or absence of sufficient scientific evidence?*
- "Scientific evidence"

8.90 We note that previous cases have essentially dealt with the question of *sufficient* scientific evidence. In this case, however, both parties have addressed the question of the *nature* of the evidence that should be considered. The United States argues that evidence under Article 2.2 must be scientific, i.e. valid according to the objective principles of the scientific method. Circumstantial evidence should, in its view, be rejected. Japan argues that the US approach to "evidence", limited to "direct" evidence, is inappropriate. In Japan's view, "indirect" evidence should also be taken into account. Japan defines "direct" evidence as "conclusive scientific discovery", whereas "indirect" evidence would be, for instance, evidence that would show the ability of contaminated apple fruit to go through each step of the pathway that could eventually cause fire blight in the importing country.

8.91 Starting with the notion of "scientific" evidence, we do not see the positions of the United States and Japan as fundamentally incompatible. It seems to us that Japan refers to scientific evidence when it points to both "direct" and "indirect" evidence. The only difference between "direct" and "indirect" evidence if we follow Japan's view is, in a sense, the degree of relationship of the evidence with the facts that Japan wishes to demonstrate with this evidence. In any event, indirect evidence may be scientific, even if it does not directly prove the facts.

8.92 We consider that, in accordance with the general principles of interpretation of public international law, we must give full meaning to the term "scientific" and conclude that, in the context of Article 2.2, the evidence to be considered should be evidence gathered through scientific methods, excluding by the same token information not acquired through a scientific method. We further note that scientific evidence may include evidence that a particular risk may occur (e.g., the entry, establishment or spread of the bacteria that causes fire blight disease) as well as evidence that a particular requirement may reduce or eliminate that risk (e.g., the effectiveness of chlorine treatment in eliminating the bacteria).

8.93 Likewise, the use of the term "evidence" must also be given full significance. Negotiators could have used the term "information", as in Article 5.7, if they considered that any material could be used. By using the term "scientific evidence", Article 2.2 excludes in essence not only insufficiently substantiated information, but also such things as a non-demonstrated hypothesis.

8.94 We note that the parties and the experts have discussed the notion of "circumstantial evidence". In this respect, we recall the view expressed by Dr Smith regarding the relevance of "circumstantial evidence" as far as the study of fire blight is concerned:

"... fire blight is a well studied disease, much observed and so that there is a very large body of direct evidence concerning fire blight. The existence of this body of direct evidence gives one a perspective in evaluating indirect evidence and in judging and insofar as you cannot necessarily draw a sharp dividing line in deciding whether circumstantial evidence is useful in trying to decide whether what is the risk of a certain scenario. In plant health it is important to keep one's feet on the ground, to consider the direct evidence first and to evaluate conjectural scenarios rather carefully in relation to what is really known about, for example, fire blight. We live in a world now in which various risks have been recently identified - risks of the entry of alien species from other continents, risks of the movement of living modified organisms - where there is little direct evidence and most of the evidence that has to be used is of a circumstantial kind. Where there is no direct evidence, it is not possible to use it as a kind of counterweight in one's judgements. But in plant health there is direct evidence. A lot of work has been done and it does assist one in making judgements in relation to evidence which is less certain."²⁵¹

8.95 We find that this statement supports, in this particular case, an approach that favours relying on scientifically produced evidence rather than on purely circumstantial evidence. At the very least, Dr Smith's statement suggests that, in the case of fire blight, any circumstantial evidence should be considered in the light of the substantial body of scientific evidence already available.

8.96 We do not believe that our approach is overly restrictive or that it could lead to the sort of scenario suggested by Japan, where a Member could only protect itself against known, well established dissemination pathways.

8.97 First, our approach is consistent with the structure of the *SPS Agreement*, which allows a Member to invoke Article 5.7 when it does not yet have "sufficient scientific evidence", and in those circumstances to rely on "available pertinent information". We recall in this respect that the Appellate Body stated that:

"Article 5.7 operates as a *qualified* exemption from the obligation under 2.2 not to maintain SPS measures without sufficient scientific evidence. An overly broad and flexible interpretation of that obligation would render Article 5.7 meaningless."²⁵²

8.98 Second, requiring "scientific evidence" does not limit the field of scientific evidence available to Members to support their measures. "Direct" or "indirect" evidence may be equally considered. The only difference is not one of scientific quality, but one of probative value within the legal meaning of the term, since it is obvious that evidence which does not directly prove a fact might not have as much weight as evidence directly proving it, if it is available.

²⁵¹ Transcript from Panel meeting with experts of 13 January (afternoon) and 14 January (morning) 2003 (hereafter Annex 3), para. 338.

²⁵² Appellate Body Report in *Japan – Agricultural Products II*, para. 80 (emphasis in the original).

8.99 On the basis of the above, we conclude that:

- (a) We will consider all relevant evidence that can be considered "scientific", and do not exclude *a priori* that "indirect" evidence may be pertinent to our assessment, provided that it is scientific in nature;**
- (b) This is without prejudice to the probative value to be ascribed to each piece of evidence in the course of our assessment.**

- "Sufficient" scientific evidence

8.100 The requirement that a measure not be maintained without sufficient scientific evidence has been addressed by panels and by the Appellate Body in other cases. Therefore, we find it appropriate to consider from the outset the conclusions they reached to the extent that they have already clarified the meaning of the terms in which we are interested. Indeed, reports adopted by the DSB have discussed the meaning of those provisions in accordance with the general principles of international law regarding the interpretation of treaties – as set out in Articles 31 to 33 of the Vienna Convention on the Law of Treaties – pursuant to Article 3.2 of the DSU. Therefore, we see no reason to perform the same analysis again if it is not necessary. We further interpret the provisions of Article 2.2 of the *SPS Agreement* only to the extent that their meaning has not been fully clarified in previous adopted reports, as was the case for the terms "scientific evidence".

8.101 We first note that the meaning of the term "sufficient" in the expression "sufficient scientific evidence" has been addressed by the Appellate Body in *Japan – Agricultural Products II* as follows:

"The ordinary meaning of 'sufficient' is 'of a quantity, extent, or scope adequate to a certain purpose or object'. From this, we conclude that 'sufficiency' is a relational concept. 'Sufficiency' requires the existence of a sufficient or adequate relationship between two elements, *in casu*, between the SPS measure and the scientific evidence."

...

"The context of the word 'sufficient' or, more generally, the phrase 'maintained without sufficient scientific evidence' in Article 2.2, includes Article 5.1, as well as Articles 3.3 and 5.7 of the *SPS Agreement*."

8.102 When addressing the meaning of the term "sufficient", we thus enter the realm of the relationship between the phytosanitary measure at issue and the "scientific evidence" relating to the risk that the phytosanitary measure is supposed to address. An *adequate relationship* is thus required between the restriction on imports of apples applied by Japan and the relevant scientific evidence. Such an adequate relationship would not be satisfied in a situation where only *patent insufficiency* would be considered as not "sufficient".²⁵³

²⁵³ Appellate Body Report in *Japan – Agricultural Products II*, para. 82.

8.103 It should be recalled that the adequate relationship between the SPS measure and the scientific evidence requires "a rational or objective relationship". As recalled by the Appellate Body,

"Whether there is a rational relationship between an SPS measure and the scientific evidence is to be determined on a case-by-case basis and will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence."²⁵⁴

8.104 From the above, it appears that the term "sufficient" is clearly to be considered in relation to the phytosanitary measure itself. This said, we should not leave aside the fact that scientific evidence relates to a risk and is supposed to confirm the existence of a given risk. In the present case, the United States denies that mature, symptomless apple fruit carry the risk of transmitting fire blight. The United States also argues that there would be possibilities to successfully eradicate fire blight, as suggested by the experience of Norway and Australia, if it were introduced by accident into Japan. Japan disputes this contention and identifies a series of risks that are ignored by the United States: contamination of mature, symptomless apples; contamination of crates; inclusion by mistake of a contaminated apple in an otherwise healthy consignment bound for Japan, transfer of bacteria by birds or insects and, ultimately, the risk of introduction of fire blight on a territory which is, for the moment, free from it.

8.105 However, neither party denies the ecological and economic impact that the introduction of fire blight could have in Japan. Under those circumstances, we should, when determining the weight of the evidence before us, "bear in mind that responsible, representative governments commonly act from a perspective of prudence and precaution when risks of irreversible ... damages ... are concerned".²⁵⁵

8.106 Japan argues that, in order for the United States to establish a *prima facie* case under Article 2.2, it has to positively prove the "insufficiency" of scientific evidence. The United States claims that there is simply no scientific evidence supporting the measure at issue. Under these circumstances, and in application of the reasoning of the Appellate Body in *Japan – Agricultural Products II*, we consider that the United States should raise a presumption that there are no *relevant* scientific studies or reports in order to demonstrate that the measure at issue is not supported by sufficient scientific evidence.²⁵⁶ If Japan submits elements to rebut that presumption, we would have to weigh the evidence before us.

8.107 Japan also argues that we should take into account the requirements of Article 4 of the *SPS Agreement* when considering whether the measure at issue is supported by sufficient scientific evidence. We agree that other provisions of the *SPS Agreement* are part of the context of Article 2.2, as recalled by the Appellate Body in *Japan – Agricultural Products II*.²⁵⁷ However, Article 4 deals with the specific question of the recognition of equivalence of measures. Unlike Articles 3.3, 5.1 and 5.7, the purpose of Article 4 is clearly different from that of Article 2.2. We also note that the United States did not raise any claim under Article 4 and that this Article is not a defence against violations of other provisions of the *SPS Agreement*. As a result, we see no reason to consider Japan's arguments regarding Article 4 in our assessment of

²⁵⁴ Appellate Body Report in *Japan – Agricultural Products II*, para. 84.

²⁵⁵ Appellate Body Report in *EC – Hormones*, para. 124.

²⁵⁶ Appellate Body Report in *Japan – Agricultural Products II*, para. 137.

²⁵⁷ Appellate Body Report in *Japan – Agricultural Products II*, para. 74.

Article 2.2, other than to the extent that Article 4 might form part of the relevant context in the interpretation of Article 2.2.

8.108 On the basis of the above, we conclude that:

- (a) **The United States should raise a presumption that there are no *relevant scientific studies or reports supporting the measure at issue in order to demonstrate that the measure at issue is not supported by sufficient scientific evidence. If Japan submits elements to rebut that presumption, we would have to weigh the evidence before us.***
- (b) **There is no reason to consider Japan's arguments regarding Article 4 in our assessment of Article 2.2, other than to the extent that Article 4 might form part of the relevant context in the interpretation of Article 2.2.**

3. Preliminary question: the relevance and consequences of the notion of "mature, symptomless" apple fruit in the assessment of the phytosanitary measure at issue under Article 2.2

- (a) Summary of the arguments of the parties²⁵⁸

8.109 The United States argues that the product it exports to Japan is "mature, symptomless apple fruit". It adds that there is a long established scientific, commercial and horticultural basis for the use of the concepts of physiological and commercial maturity. In the US view, this distinction is relevant because mature fruit, unlike immature fruit, is not susceptible to contamination by *E. amylovora* and cannot host or develop fire blight.

8.110 Japan challenges the concepts of "mature" and "symptomless" apples. Japan argues that the concept of maturity is inherently subjective and that there is an ambiguity in using it, since "physiological maturity" and "commercial maturity" should be distinguished. Japan considers that maturity is a continuing process. Japan is of the view that endophytic bacteria found in physiologically immature apples are likely²⁵⁹ to survive until "commercial maturity" in light of the ecology and other known properties of the bacteria. Japan adds that close-to-mature apples have been found to harbour *E. amylovora* and even display signs of serious infection, such as bacterial ooze. Japan also claims that the United States has not submitted any scientific explanation for the fact that the bacteria *E. amylovora* can be found in close-to-mature apples, but allegedly not in mature apples.

- (b) Analysis of the Panel

- (i) *Introduction*

8.111 When discussing the product at issue in this case in paragraphs 8.26-8.34 above, we considered that we could not prejudge our conclusions by unduly restricting, from the outset, the scope of our findings to mature, symptomless apple fruit. In the context of Article 2.2 we consider that the discussion of the parties raises two main issues: one is the relevance of the

²⁵⁸ A detailed account of the arguments of the parties can be found in paras. 4.90-4.102 and 4.192-4.198 of this Report.

²⁵⁹ Japan second submission, 13 November 2003, para. 27.

concept of "mature, symptomless" apple in terms of risk of fire blight transmission; the second is the risk related to apples other than mature, symptomless apples, such as immature or damaged apples.

8.112 If we find that there is pertinence in differentiating "mature, symptomless" apples from other apples (e.g. immature or damaged apples), we will proceed with a specific analysis of the risks attached to each category.

(ii) *Mature, symptomless apples v. other apples*

8.113 We note that the experts commented, at our request, on the concept of maturity and whether a naturally infected apple could develop into a healthy looking fruit.²⁶⁰ Regarding the concept of maturity, Dr Hale confirmed that there were accepted definitions for determining if an apple fruit is physiologically and commercially mature. An apple will be deemed to be physiologically mature when it reaches the point at which, if picked, it will ripen. If an apple is not mature at the time it is harvested, then it will not ripen. It will shrivel and be unacceptable.²⁶¹ Maturity assessment includes colour, starch index, soluble solid content, flesh firmness, acidity, and ethylene production rate. Dr Hayward stated that there were objective methods for the determination of the maturity of apples which formed the basis of the OECD international guidelines.²⁶² For Dr Hayward, as for Dr Hale, an apple fruit was physiologically mature when it was at the stage of development where, even when detached, it continued to develop and ripen.²⁶³ Having regard to the evidence submitted by the parties and the opinions of the experts consulted by the Panel, we consider that the concept of maturity is relatively well defined as the moment when the apple fruit is at a stage where it will ripen even if detached from the tree. We conclude from this that it is scientifically possible to differentiate between mature and immature apples.

8.114 However, the experts noted that maturation was a continuous process.²⁶⁴ We understand from the opinions of the experts that they considered this issue to be relevant with regard to the *susceptibility* of the apple to fire blight. Dr Smith agreed with Dr Geider that whatever made an immature apple permissive to the introduction of the bacteria did not necessarily have much to do with what later made it physiologically mature or commercially mature.²⁶⁵ According to these experts, it is clear that very young apples are susceptible to *E. amylovora*, but that by the time they have reached commercial maturity, they are no longer susceptible. At some point in between immaturity and commercial maturity, they lose that susceptibility.²⁶⁶

8.115 As a result, we consider that the differentiation between mature and immature apples is relevant in terms of the risk of contamination of the fruit.

8.116 We also note that the experts stated that fruits infected at fruitlet level would not develop into healthy looking fruit.²⁶⁷ Dr Geider considered that a dormant persistence of *E. amylovora* in fruit was not documented and was difficult to demonstrate.²⁶⁸ Naturally infected fruits would be

²⁶⁰ Paras. 6.5-6.10.

²⁶¹ Para. 6.5.

²⁶² Para. 6.6.

²⁶³ Ibid.

²⁶⁴ Annex 3, Dr Hale, para. 91.

²⁶⁵ Annex 3, Dr Geider, Dr Hale, Dr Smith, paras. 89, 91, 95.

²⁶⁶ Annex 3, Dr Smith, para. 95.

²⁶⁷ For the purpose of this case, the terms "symptomless" and "health-looking" will be used indifferently.

²⁶⁸ Para. 6.7.

small, shrivelled, might show some lesions, and would not mature. Consequently, they were highly unlikely to develop into healthy-looking fruit.²⁶⁹ In addition, when natural infections occur at an advanced growth stage in apples, e.g. as a result of hailstorms, the apples begin to rot and ooze (exudate).²⁷⁰

8.117 The experts did indicate that if the bacteria remained confined to the outside of the fruit, including in the calyx at the blossom end, a healthy looking fruit could develop. However, none of the experts reported knowing of any scientific studies where the bacteria on the surface of the fruit or harboured in the calyx had ever infected the inside of the apple. Likewise, attempts to develop infection by cutting the pedicel of the apple and placing a large quantity of *E. amylovora* on the cut pedicel failed to convincingly demonstrate infection of the inside of the apple.²⁷¹

8.118 As a result, we consider that the concept of "symptomless" is also scientifically pertinent. Indeed, insofar as dormant persistence of *E. amylovora* has not been documented, any infection is very likely to be visibly identifiable.

(iii) *Relevance of addressing the risks related to both mature, symptomless apples and other apples*

8.119 The above discussion tends to suggest not only that mature, symptomless apples may present a low risk of acting as an effective pathway, but also that apples other than mature, symptomless apples may carry a higher risk in terms of contamination. We recall that Annex A, paragraph 1 of the *SPS Agreement* defines as a phytosanitary measure "any measure applied to protect plant life or health within the territory of a Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms." This definition does not limit the scope of application of phytosanitary measures to the product that the exporting country claims to export. In order to be effective, a phytosanitary measure should cover all forms of a product that may actually be imported.

8.120 We recall in this respect that in *EC – Hormones*, the Appellate Body considered it legitimate for the European Communities to consider not only the *scientific risks* arising from the ingestion by human beings of residues of hormones in meat, but also the closely related risks arising from the failure to observe the requirements of good veterinary practice in the administration of hormones for growth promotion purposes, in combination with multiple problems relating to the detection and control of such failure.²⁷² We recognize that the Appellate Body expressed this view in the context of a risk assessment under Article 5.1 and 5.2. However, we first note the central role of Article 5.1 in the *SPS Agreement*.²⁷³ Second, the following

²⁶⁹ See also, Dr Hale, para. 6.8.

²⁷⁰ Dr Geider, para. 6.7.

²⁷¹ Annex 3, Drs Geider, Hale, Hayward, Smith, paras. 178, 180, 181, 182.

²⁷² Appellate Body Report in *EC – Hormones*, para. 205.

²⁷³ See Appellate Body Report in *EC – Hormones* para. 180, where the Appellate Body mentioned

that:

"180. At the outset, two preliminary considerations need to be brought out. The first is that the Panel considered that Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2 of the *SPS Agreement*¹⁶⁰, which 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. (underlining added)

statement of the Appellate Body is, in our view, indicative of a general application of this principle under the *SPS Agreement*:

"We consider that the object and purpose of the *SPS Agreement* justify the examination and evaluation of all such risks for human health, whatever their precise and immediate origin may be."²⁷⁴

8.121 Under those circumstances, it seems to us legitimate to consider all the aspects referred to by Japan in relation to the importation of apples from the United States, including human/technical errors in the sorting of apples or illegal actions which would lead to the importation of infested/infected apples.²⁷⁵

8.122 On the basis of the above, we conclude that it is not only useful, but also relevant to differentiate, in our assessment of the evidence regarding transmission of the disease, between the risks related to physiologically mature and apparently healthy apple fruit on the one hand, and the risks related to other apples (immature, mature but damaged) on the other hand, even if the latter may only accidentally enter the territory of Japan.

We agree with this general consideration and would also stress that Articles 2.2 and 5.1 should constantly be read together. Article 2.2 informs Article 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1."

²⁷⁴ Appellate Body Report in *EC – Hormones*, para. 206.

²⁷⁵ However, since the importation of immature, infected apples may only occur as a result of a handling error or an illegal action, we address the question of the contamination only in relation to the completion of the pathway.

4. Infestation and infection²⁷⁶ of mature, symptomless apple fruit

(a) Infestation

(i) *Endophytic bacteria*

8.123 According to the United States, numerous studies indicate that mature, symptomless apple fruit do not harbour endophytic populations of the bacteria, even when harvested from blighted apple trees. These results reflect the biology of the disease. Apples infected with the bacteria do not mature. Immature apples may contain detectable levels of endophytic fire blight, but mature, symptomless apples would not harbour internal populations of bacteria. Van der Zwet *et al.* (1990), on which Japan relies, did not distinguish between immature and mature fruits. The United States further argues that the attempt to recover endophytic bacteria by Tsukamoto *et al.* (2003) was not successful.²⁷⁷ The preliminary results showed that *E. amylovora* had not been found. The study did not provide additional information with respect to steps in Japan's hypothetical pathway, which experts have concluded could not be completed.

8.124 Japan argues that the United States only demonstrated that risk may not be present in certain, limited circumstances. The bacteria is capable of surviving in varying conditions. In addition, Japan, relying on van der Zwet *et al.* (1990), argues that endophytic *E. amylovora* had been found in mature apple fruit. Such findings were confirmed by Roberts *et al.* (1998). Japan argues that the United States has not explained how endophytic *E. amylovora* could be found in close-to-mature apples and disappear in the few days or weeks before maturation. Japan also recalls that Tsukamoto *et al.* (2003) have conducted experiments to clarify the ability of *E. amylovora* to invade and multiply through the pedicel (stem).²⁷⁸

8.125 We note that the views of the experts on this question is that there is no evidence that mature apple fruit will harbour endophytic bacteria.²⁷⁹ Dr Smith added that a few papers described endophytic bacteria, but the experts consulted by the Panel were not convinced by those descriptions.²⁸⁰

8.126 The experts consulted by the Panel also stated that *E. amylovora* did not occur as an endophyte in healthy-looking mature fruit.²⁸¹

8.127 Based on the scientific evidence available to us in these proceedings, we note that the observation of the existence of endophytic populations in mature apple fruit is based essentially

²⁷⁶ In para. 6.8 above, Dr Hale stated that it was important to make a distinction between infected and infested fruit. Infected fruit were diseased whereas infested fruit were contaminated with *E. amylovora* but not diseased. See also Dr Smith, para. 6.10, who defined infection as meaning not just the presence of bacteria, but an active process of pathogenesis. Dr Hayward, Annex 3, para. 67: "if I can quote definitions given in a guide to the terms in use in plant pathology: 'Infection is the entry of an organism or virus into a host, the plant, and the establishment of a permanent or temporary parasitic relationship'. Whereas infestation means, or to infest: 'To overrun the surface of a plant. When used in reference to micro-organisms or virus particles on plant surfaces, there is no implication that infection has occurred.'" As indicated in para. 2.15, the Panel will use the definition used by the experts.

²⁷⁷ Exhibits JPN-39 and JPN-42.

²⁷⁸ *Ibid.*

²⁷⁹ Annex 3, paras. 28, 29, 54, 57, 59, 63, 75, 76, 80, 82, 83, 360-363. See also paras. 6.72-6.75.

²⁸⁰ Annex 3, para. 363.

²⁸¹ Paras. 6.15-6.19 and 6.72-6.75; Annex 3, paras. 59, 76 and 82.

on one single study whose findings in this respect are not clear and are disputed: van der Zwet *et al.* (1990).²⁸² That study, although it recorded the isolation of *E. amylovora* from harvested fruit, did not specify the degree of maturity of the fruit or whether it was symptomless or not.²⁸³ The study also appeared to report in a single paper different series of experiments in different locations and conditions, and not to contain a sufficiently precise description of the conditions of the experiment to allow for a precise conclusion to be drawn from them.²⁸⁴ This in itself made its conclusions relatively confused, difficult to interpret or even unconvincing, as was suggested by the experts consulted by the Panel.²⁸⁵ Furthermore, clarifications sought by the United States from the main authors of this study cast further doubt on conclusions that *E. amylovora* was found inside commercially mature fruit.²⁸⁶ The Roberts *et al.* (1998) study cited by Japan simply reports on the findings in van der Zwet *et al.* (1990) and does not report on any new evidence in this regard. The fact that van der Zwet collaborated in Roberts *et al.* (1998) does not, in our view, affect the conclusion drawn from the experts' views and the author's comments of 16 July 2002.

8.128 We therefore conclude, on the basis of the information made available to the Panel, that there is not sufficient scientific evidence to conclude that mature, symptomless apples would harbour endophytic populations of bacteria.

(ii) *Epiphytic bacteria*

8.129 The United States claims that a review of the scientific literature suggests that the presence of epiphytic bacteria on mature, symptomless fruits at harvest is extremely rare. In those few instances where external bacteria had been detected, the fruit had been harvested from or within 10 meters of an infected tree in severely infected orchards. The United States concludes that in most cases, mature, symptomless apples, even when harvested from infected trees or orchards, would not be externally contaminated with fire blight bacteria.

8.130 The United States also argues that the biology of the fire blight bacteria and the disease cycle is such that the bacteria shows a decline in population counts as the season advances and the conditions turn less hospitable, becoming extremely rare on fruits at the time of harvest. The scientific evidence indicates that bacteria on the surface of fruits die within a short time.²⁸⁷

8.131 Japan does not agree with the conclusion that the external presence of the bacteria is extremely rare. Japan refers to Sholberg *et al.* (1988) to claim that *E. amylovora* may be present on symptomless fruit at harvest under certain conditions.

8.132 In this regard, we note Dr Hayward's remark that Sholberg's study showed susceptibility only when apple trees were inter-planted with heavily infected pear trees²⁸⁸ and that the very different management practices pertaining to apple and pear fruit apparently preclude interplanting of the two crops.²⁸⁹

²⁸² Paras. 6.72-6.75.

²⁸³ Annex 3, Dr Smith, para. 53.

²⁸⁴ Dr Smith and Dr Geider, Annex 3, paras.54, 56, 57.

²⁸⁵ Dr Hale and Dr Smith, paras. 6.77-6.79, 6.81-6.84, 6.86-6.87 and 6.89, respectively.

²⁸⁶ We note that while these declarations confirm our conclusion that the results of this study are unclear, our conclusions in this respect are not dependent on them.

²⁸⁷ Dr Hayward, para. 6.36, Dr Hale, para. 6.121, Dr Hayward, para. 6.122, Dr Smith, para. 6.123.

²⁸⁸ Annex 3, Dr Hayward, para. 205.

²⁸⁹ US answers to Additional Questions from the Panel, 28 January 2003, para.44.

8.133 The United States argued that mature apples will rarely harbour epiphytic bacteria, even when harvested in heavily blighted orchards.

8.134 We recall that the experts did not exclude that bacteria could be found on the surface of apples in heavily infected orchards.²⁹⁰ They also observed that epiphytic bacteria could result when early infection of blossoms did not lead to the development of fire blight and some of the bacteria remained confined in the calyx. Some of the experts questioned whether these surface or calyx populations could be considered as real epiphytic populations capable of transmitting fire blight. Indeed, "epiphytic" implied that the bacteria could persist and even reproduce at low levels over a period of weeks or months, which did not seem to be the case with surface *E. amylovora*.²⁹¹

8.135 We note in this regard that the experts concurred in considering that even apples harvested very close to sources of inoculum did not harbour large populations of epiphytic bacteria.²⁹²

8.136 We therefore conclude, on the basis of the information made available to the Panel, that there is not sufficient scientific evidence to conclude that mature, symptomless apples are likely to harbour epiphytic populations of bacteria capable of transmitting *E. amylovora*.

(b) Infection

8.137 Japan argues that there could exist mature, apparently healthy, but infected fruits. The United States claims that scientific evidence shows that mature apples cannot be infected.

8.138 We note that the information before the Panel tend to demonstrate that it is unlikely that a mature apple will be infected. If an immature apple is infected, it will not develop into a mature, healthy-looking fruit. If it does, then it is likely that the bacteria will not have developed.²⁹³ The experts consulted by the Panel have also agreed that there was no scientific evidence that a mature harvested apple fruit will be subsequently infected.²⁹⁴

8.139 We therefore conclude, on the basis of the information made available to the Panel, that mature apples are unlikely to be *infected* by fire blight if they do not show any symptoms.

5. Risk of entry, establishment or spread of fire blight within Japan by imported US apple fruit (apple fruit as a pathway)

(a) Introduction

8.140 The United States argues that not only is there no evidence that mature, symptomless apples have ever spread fire blight, but there is also no evidence that mature fruit could be a pathway for the spread of the bacteria. The evidence concerning infestation and infection of mature apples does not support Japan's proposed pathways. Japan contends that pathways may or

²⁹⁰ Dr Hale, paras. 6.24-6.25 and 6.113-6.114

²⁹¹ Dr Smith, paras 6.18-6.19.

²⁹² Para. 6.17; Annex 3, paras. 364-367; see also paras. 223-236.

²⁹³ Dr Smith, paras. 6.10 and 6.19.

²⁹⁴ Annex 3, paras. 355, 356, 357, 358.

may not be direct; contaminated cargo crates were a possibility, as was propagation from fruit to other plants in the environment.

8.141 The parties and experts have primarily discussed the risk of transmission by mature apples, because this is the commodity normally exported and on which scientific experiments have been performed. However, for the reasons mentioned above, we also find it necessary to assess the risk of transmission through apples other than mature, symptomless apples: essentially immature, infected or infested apples.

8.142 Since we have reached the conclusion that infection of mature apples has not been established, that populations of endophytic bacteria have not been found in mature apples and that ephithytic bacteria populations are very rare, we need to address at this stage only the two last steps of the pathway for fire blight transmission: (a) the survival of the bacteria through commercial handling, storage and transportation; and (b) the existence of a vector permitting the contamination of a host plant in Japan by the imported apple.

8.143 We are mindful of the indirect pathways suggested by Japan. However, with the exception of the contamination by blighted apples of crates subsequently re-used in Japan, we consider that they are all dependent on the existence of a vector allowing the contamination of a host plant by an imported apple once in Japan. With respect to indirect contamination by infested or infected cargo crates, we consider that the evidence before us does not support the opinion that they could operate as a vector of transmission. On the contrary, the evidence shows that *E. amylovora* is not likely to survive on crates.²⁹⁵

(b) Mature, symptomless apple fruit

8.144 The United States argues that the scientific literature reveals that there is no evidence that mature, symptomless apple fruit ever transmitted fire blight disease, i.e. provided inoculum for an outbreak of fire blight.²⁹⁶ The risk is, according to the authors, "negligible", "unlikely", "very remote", "insignificant", "extremely low" or "extremely unlikely". The United States considers that by describing the risk of transmission as "negligible" rather than "zero", the scientific reports merely reflected "the uncertainty that theoretically always remains [that an event may occur] since science can never provide absolute certainty" that an event may never occur.²⁹⁷ Both the panel and the Appellate Body in *EC – Hormones* concluded that theoretical uncertainty is not the kind of risk which a risk assessment and, therefore, an SPS measure, is to address.²⁹⁸

8.145 The United States argues that it is not established that the four instances identified of trans-oceanic dissemination of fire blight were attributable to apple fruit.²⁹⁹ Indeed, in relation to one of these, it disputes that it even constitutes a case of trans-oceanic dissemination.

8.146 Japan argues that there is no ecological study available on the possible dissemination of fire blight via apple fruit. Japan argues that, as a matter of common sense, it could be envisaged that *E. amylovora* could be transmitted to nearby host plants, either by way of rain, wind, insects, etc. Once such fruit was introduced into Japan, the bacteria would be exposed to its environment

²⁹⁵ Paras. 6.26, 6.32-6.35, 6.166-6.169, Annex 3, Dr Smith, para. 241.

²⁹⁶ Exhibits USA-4; USA-5; USA-28; USA-42.

²⁹⁷ The United States refers to the Appellate Body Report in *EC – Hormones (United States)*, para. 186.

²⁹⁸ Appellate Body Report in *EC - Hormones (United States)*, para. 186; Panel Report in *EC - Hormones*, paras. 8.152-8.153.

²⁹⁹ Paras. 4.68-4.72.

at all the stages of distribution, storage, consumption and disposal of the fruit, causing a real risk of dissemination.³⁰⁰ Japan adds that there is no scientific evidence documenting trans-oceanic dissemination. The absence of evidence attributing the cause to apple fruit does not demonstrate that the bacteria was transmitted only via budwood or nursery stock. This indirect or circumstantial evidence, together with van der Zwet *et al.* (1990), suggests a risk that endophytic *E. amylovora* in fruit could survive trans-oceanic shipment and later cause fire blight in foreign destinations.

8.147 In light of the elements before us in these proceedings, we conclude that there is scientific evidence suggesting that epiphytic bacteria could be found on mature, symptomless apples. However, the number of apples contaminated with epiphytic bacteria in severely blighted orchards has been found to represent a very small percentage³⁰¹ and it is not clear whether this form of bacteria could actually transmit the disease to a host, in other words, whether the successive steps of the pathway could be completed.³⁰² In fact, Dr Hale and others reported that large-scale experiments to cause infection via surface and calyx-infested fruits had all been unsuccessful.³⁰³ We note in this respect that in its risk assessment under Article 5.1, Japan itself failed to clearly identify transmission pathways for apples.³⁰⁴

8.148 Japan also insists on the resilience of the bacteria and its capacity for rapid reproduction. However, the experts consulted by the Panel have expressed doubt on this matter and contested the notion that the bacteria is actually that resistant.³⁰⁵ *E. amylovora* does not seem to be capable of surviving the competition with other bacteria involved in the apple decomposition process.³⁰⁶

8.149 Drs Geider, Hale, Hayward and Smith 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.³⁰⁷ The experts further agreed that the historic and scientific evidence suggested that the likelihood of fruit being a pathway for introduction of fire blight was negligible.³⁰⁸ Dr Hayward indicated that the standard scientific definition of "negligible" was a likelihood of between zero and one in one million.³⁰⁹ In Dr Smith's view, "not only was there no evidence that fruits had ever introduced fire blight to an area, but there was also no necessity to invoke such an improbable pathway since there were much more probable alternatives".³¹⁰ Dr Geider explained "new establishment of the disease by other than sequential distribution was so rare that it was not possible to conduct ecological studies".³¹¹

³⁰⁰ Exhibit JPN-14.

³⁰¹ Annex 3, Dr Hale, para. 202.

³⁰² Paras. 6.69-6.71.

³⁰³ Annex 3, Dr Hale, para. 238; paras. 364-381; see also para. 6.101, Exhibits JPN-8 and JPN-29.

³⁰⁴ See section F.2 below.

³⁰⁵ Paras. 6.36, 6.108-6.111, 6.124-6.127.

³⁰⁶ Paras. 6.71, 6.109-6.111.

³⁰⁷ Paras. 6.20-6.23.

³⁰⁸ Paras. 6.37-6.40, also Annex 3, paras. 382-385.

³⁰⁹ Annex 3, para. 332.

³¹⁰ Para. 6.31. The most probable route identified by the experts was the entry of infected planting materials.

³¹¹ Para. 6.61.

8.150 We also note the comment of Dr Geider that in his view, the highest risk of fire blight contamination is from travellers to Japan bringing in contaminated plants or fruits which are not likely to be detected by phytosanitary controls.³¹²

8.151 We note, however, that Dr Geider has expressed the view that apples should not be exported if they were picked from a fire blighted orchard, so as to avoid the probably very low risk of accidental contamination.³¹³ He added that it was not advisable for phytosanitary reasons to export apples picked in orchards with severe fire blight, although such apples might be harmless as regards disease distribution.³¹⁴

8.152 We also note that many factors can interfere in the transmission process described by Japan, and we are mindful that, as recalled by the experts, it may be very difficult to experimentally replicate all possible pathways and combinations of circumstances and thus exclude categorically all possibilities of transmission.

8.153 We conclude from these elements that the scientific evidence presented to the Panel show that, with respect to mature, symptomless apple fruits, the risk that the transmission pathway be completed is "negligible". Nevertheless, the experts consulted by the Panel, while firmly considering that transmission by mature apple fruit is unlikely, suggested, *inter alia*, that apples from severely blighted orchards (the only documented situation of relatively heavy infestation of mature apples) not be exported.

(c) Apples other than "mature, symptomless apple fruit"

(i) *Capacity of infected apple fruit to serve as pathway*

8.154 We have already concluded above that the risk that mature, symptomless apple fruit be a vector for the entry, establishment or spread of fire blight within Japan is negligible, even if infested with epiphytic *E. amylovora*. We understand Japan's argumentation to imply that an infected apple could serve as a vector for the entry, establishment or spread of fire blight within Japan. We note that the United States did not claim that infected apples would not act as a pathway. As we have mentioned above, the US position in this case is that it exports only mature, symptomless apple fruit to Japan. Even though the United States did not submit evidence regarding transmission of fire blight through immature apple fruit, it argues that the pathway is unlikely to be completed. Having regard to the arguments of the parties, it is necessary to determine, even before we proceed to address the possibility of an error or illegal action, whether there is a more than theoretical possibility that infected apple fruit could be a vector for the introduction of fire blight into Japan.

8.155 According to the experts, the primary condition for transmission of fire blight is heavy contamination, either on the surface³¹⁵, or internally, in order for the bacteria to survive through all the various steps in a sufficiently large number to be capable of later contaminating a host plant or fruit. However, this does not mean that large numbers of bacteria are necessary to contaminate a host plant.³¹⁶

³¹² Annex 3, paras. 263, 398 and 431.

³¹³ Para. 6.42.

³¹⁴ Para. 6.112.

³¹⁵ Dr Geider, para. 6.68, Dr Hale, para. 6.69, Dr Smith, para. 6.71.

³¹⁶ Dr Geider, Annex 3, para. 235.

8.156 The information before the Panel relates essentially to mature apples. Immature apples are hardly ever used in scientific experiments. We have noted that most of the obstacles to the survival of the bacteria and, later, the contamination of a host plant referred to by the experts relate to the progressive disappearance of bacteria capable of reproducing and contaminating a host plant (lengthy storage in cold but humid conditions³¹⁷, handling, limited capacity of *E. amylovora* to compete in a hostile bacterial environment, such as in decaying fruit or unsterilized soil). We recall, however, the prudence expressed by the experts regarding the exportation of apples harvested in blighted orchards. Under these circumstances, if survival of epiphytic bacteria on mature apples throughout their commercial handling, transportation and storage cannot be totally excluded, *a fortiori*, survival in an *infected*, immature apple of most probably much larger quantities of bacteria is possible too. We note in this respect the comment of Dr Smith that "a conceivable short-cut [to contamination through epiphytic populations harboured by mature, symptomless apples] might occur if fruits became internally infected and these fruits were not detected. If this ever happened (which is debatable), then there was a stronger possibility that viable bacteria remained in the fruit during storage and shipping".

8.157 We therefore conclude that infected apples are capable of harbouring populations of bacteria which could survive through the various stages of commercial handling, storage and transportation.

(ii) *Error of handling and illegal action*

8.158 Japan further argues that the risk of accidental contamination or erroneous grading is very real, and cites as an example the recent report of codling moth being found in a shipment of US apples to Chinese Taipei.³¹⁸

8.159 The United States argues that fruit for export are subject to multiple human and machine-based examinations, which along with the strict grading requirements it applies, make it extremely unlikely that immature fruit would be exported. Furthermore, the United States contends that Japan's current measures do not counter the "unestablished and hypothetical" risk of accidental or intentional shipment of immature, infected fruit.³¹⁹

8.160 We recall that the Appellate Body in *EC – Hormones* deemed consideration of the risk of error of handling or of illegal action legitimate in the SPS context.³²⁰ We note that in this case too, the experts have admitted the possibility of an error of handling. The Panel recalls the comments by Dr Smith that:

"... people often suppose that inspection is efficient, 100 per cent efficient even, at a given moment. Sometimes, in special cases, it is. There are some pests which you can be certain to find when you examine an infested item, but this is exceptional. In plant quarantine, in general terms, whether you are inspecting trees in an orchard or fruits in a crate or plants being shipped you cannot be 100 per cent certain by inspection that the unit you are inspecting is healthy. So you automatically in the system have a certain tolerance and run a certain risk of some infected plants. The only way you can improve your chances is to look at

³¹⁷ Annex 3, paras. 208-216.

³¹⁸ Para. 4.191.

³¹⁹ Paras. 4.188-4.190, 4.192-4.193.

³²⁰ Appellate Body Report in *EC – Hormones*, para. 205.

more plants so basically you have to select a sampling system which gives you a certain level of security. This is what is inherent in the idea of managed risk which I mentioned earlier yesterday. Managed risk implies that whatever you do, there is a small risk of missing what you are looking for. You recognize that what you are doing is not 100 per cent efficient but you have to do a trade-off between practicality and cost on the one hand and the risk which you are running on the other."³²¹

Furthermore, Dr Smith stated that:

" ... there will be a certain small risk that, if such infected fruit were present, they will not be detected but will in some way pass through the system."³²²

Moreover, Dr Geider considered that surface contamination could not be excluded and might be caused naturally by insects but also by handling during or post harvest.³²³ On the other hand, the Panel recalled the view of Dr Geider that the highest risk of fire blight contamination was from travellers to Japan bringing in contaminated plants or fruits.³²⁴

8.161 We therefore conclude that errors of handling or illegal actions are risks that may be, in principle, legitimately considered by Japan. These risks have been acknowledged by the experts, even though they consider them to be "small" or "debatable".³²⁵

8.162 We now need to determine whether one or more infested or infected apple fruit entering Japanese territory could actually transmit fire blight to a host plant, i.e. complete the pathway.

(d) Risk of completion of the pathway

8.163 It is our understanding that epiphytic bacteria could apparently survive commercial handling, storage and transport in the calyx, but their number would be reduced by commercial storage that combines cool temperatures and high humidity to avoid desiccation.³²⁶ In some circumstances, bacteria will apparently no longer be discernible.³²⁷ According to Dr Smith, there is a stronger possibility that viable bacteria remained in the fruit during storage or shipping if the fruit was internally infected.³²⁸ Survival of an epiphytic population of *E. amylovora* seems to depend also on the quantity of bacteria in the calyx. The chance of retrieving bacteria after commercial storage depends on the quantity that existed originally. The experts mentioned in this respect that experiments use artificial inoculation of large quantities of bacteria.³²⁹

8.164 This seems to imply that the likelihood that a naturally infested apple will contain a population capable of transmitting fire blight when it reaches Japan is apparently limited, even

³²¹ Annex 3, para. 303.

³²² Annex 3, para. 266. See also para. 327.

³²³ Para. 6.15.

³²⁴ Annex 3, paras. 263, 398 and 431.

³²⁵ Annex 3, Dr Smith, para. 266; and para. 6.71.

³²⁶ Annex 3, paras. 208-216. Diminution in the number of bacteria is less in cold but dry conditions.

³²⁷ Annex 3, Drs Hale, Hayward, Annex 3, paras. 209, 212.

³²⁸ Para. 6.71.

³²⁹ Annex 3, Drs Hale, Geider, Annex 3, paras. 211, 215.

though survival is not excluded.³³⁰ The risk seems to be more important in the case of infected apples.

8.165 The second point to address is the existence of a vector to transmit the bacteria to a host plant. The parties have addressed the situation where the fruit would be released as juice or discarded. They have also addressed contamination through rain splashes, insects or birds.

8.166 We note that experiments trying to reproduce the conditions applicable to discarded apples have not led to any visible contamination,³³¹ even when ooze was reported to exist. The experts themselves listed a number of cumulative conditions for a successful completion of the pathway.³³² While the experts agreed that short distance contamination was possible through rain splash or bees, this essentially related to contamination at the flowering stage, not to contamination from apple fruit. Contamination by birds was not established.³³³ In light of these conditions, the experts considered the completion of the pathway to be unlikely.

8.167 We note in this respect that Japan did not submit sufficient scientific evidence in support of its allegation that the last step of the pathway had been completed or was likely to be completed. The evidence submitted by Japan was essentially circumstantial or deemed unconvincing by the experts.

8.168 We therefore conclude, on the basis of the evidence submitted to the Panel, that it has not been established with sufficient scientific evidence that the last stage of the pathway (i.e. the transmission of fire blight to a host plant) would likely be completed.

6. Intermediate conclusion

8.169 On the basis of the above, we note, in light of the elements placed before us by the parties, as well as in light of the comments of the experts appointed by the Panel, that the scientific evidence suggests a negligible risk of possible transmission of fire blight through apple fruit.

8.170 In making our assessment, we consider that the quality and quantity of scientific evidence at issue is relevant. We note in this respect that, although we did not exclude the relevance *a priori* of indirect evidence, there appears to be, in this instance, a significant amount of direct evidence, including through extensive trade in apples to blight free areas, suggesting that such contamination is unlikely. By contrast, scientific evidence, direct or indirect, to suggest the possibility of contamination in the various scenarios envisaged above is significantly more limited. The elements submitted by Japan are in fact largely hypothetical or circumstantial.³³⁴

8.171 In particular, the following points can be highlighted:

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

³³⁰ Annex 3, Dr Hale, para. 211.

³³¹ Dr Hale, para. 6.69.

³³² Dr Hayward, para. 6.70, Dr Smith, para. 6.71.

³³³ Annex 3, Dr Smith, para. 241 and Dr Geider, para. 263.

³³⁴ Exhibit JPN-40.

- (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.

8.172 We further recall the opinion of the experts that due to the development of new scientific research tools, in particular DNA-based methods, they were more confident than ever before that there was only a negligible chance of fire blight being transmitted through apple fruit.³³⁵

8.173 Nonetheless, we note that even if the scientific evidence before us demonstrates that apple fruit is highly unlikely to be a pathway for the entry, establishment and spread of fire blight within Japan, it does suggest that some slight risk of contamination cannot be totally excluded. The experts all categorized this risk as "negligible".³³⁶ Dr Smith observed that "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".³³⁷ However, none of the experts were comfortable with the notion of eliminating "in one step" all phytosanitary controls, taking into account Japan's island environment and climate.³³⁸

8.174 Furthermore, we note that Japan is concerned as well with the risk that something other than mature, symptomless apples may actually be imported. The latter risk would seem to arise primarily as a result of human or technical error, or illegal actions. Responding to a question from Japan regarding "uncontrollable risks based on real world experience" such as the finding of codling moth in US apples exported to Chinese Taipei, Dr Smith replied "... when the phytosanitary system is changed it should be changed under circumstances that retain some degree of control on what is happening and not in a single step that removes control altogether".³³⁹

8.175 We do not agree with the United States that the scientific prudence displayed by the experts should be completely assimilated to a "theoretical risk" within the meaning given to that terms by the Appellate Body in *EC – Hormones*. On the other hand, we can only note that Japan did not submit "sufficient scientific evidence" in support of its allegation that the pathway could be completed.

8.176 On the basis of the information made available to the Panel, we conclude that there is not sufficient scientific evidence that apple fruit are likely to serve as a pathway for the entry, establishment or spread of fire blight within Japan.

³³⁵ Annex 3, para.342; Dr Smith, para. 343.

³³⁶ Annex 3, paras. 382-386.

³³⁷ Annex 3, para. 419.

³³⁸ Annex 3, paras. 386, 389, 409, 411, 413, 414, 419, 423, 424, 426 and 429.

³³⁹ Annex 3, para. 423.

7. Conformity of the phytosanitary measure at issue with Article 2.2 of the SPS Agreement

- (a) Absence of a "rational relationship" between the scientific evidence available and the measure at issue

8.177 We recall that the claim of the United States under Article 2.2 is that the phytosanitary measure at issue is maintained "without sufficient scientific evidence" We also recall that the United States argues that *none of the requirements* contained in the measure has a basis in science.

8.178 We recall the position of Japan that each individual requirement contained in the phytosanitary measure at issue is essential to prevent the risks of entry, establishment or spread of fire blight within Japan and that all these requirements are applied cumulatively, and not alternatively, by Japan to apple fruit imported from the United States.

8.179 In paragraph 8.20 above, we concluded that we should consider the requirements identified by the United States together as the phytosanitary measure at issue in this dispute. Our finding of whether the phytosanitary measure at issue is not maintained without sufficient scientific evidence pursuant to Article 2.2 should, consequently, relate to the measure as a whole, not to individual requirements thereof, even though, as acknowledged by the Panel, each of these elements may be considered to individually constitute a phytosanitary measure within the meaning of paragraph 1 of Annex A to the *SPS Agreement*.

8.180 As mentioned in paragraphs 8.101-8.103, above, a *rational or objective relationship* is required between the phytosanitary measure at issue applied by Japan and the relevant scientific evidence. Such a rational or objective relationship is to be determined on a case-by-case basis and depends on the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence.³⁴⁰ We understand this requirement to mean that a measure as a whole should be considered to be maintained "without sufficient scientific evidence" if one or more of its elements are not justified by the relevant scientific evidence addressing the risk at issue.

8.181 In paragraph 8.176 above, we concluded, on the basis of the elements before us, that there was *not sufficient scientific evidence* to support the view that apples are likely to serve as a pathway for the entry, establishment or spread of fire blight within Japan. Given the negligible risk identified on the basis of the scientific evidence and the nature of the elements composing the phytosanitary measure at issue, the measure on the face of it is disproportionate to that risk.

8.182 More particularly, having regard to the arguments of the parties and the opinions of the experts, we have found that the following requirements are instances of elements of the measure at issue which are most obviously "maintained without sufficient scientific evidence", either as such or when applied in cumulation with others, taking into consideration the risks to be addressed:

- (a) The prohibition of imported apples from any orchard (whether or not it is free of fire blight) should fire blight be detected within a 500-meter buffer zone surrounding such orchard; and

³⁴⁰ Appellate Body Report in *Japan – Agricultural Products II*, para. 84.

- (b) the requirement that export orchards be inspected at least three times yearly (at blossom, fruitlet, and harvest stages) for the presence of fire blight for purposes of applying the above-mentioned prohibitions.³⁴¹
- (i) *The prohibition of imported apples from any orchard (whether or not it is free of fire blight) should fire blight be detected within a 500-meter buffer zone surrounding such orchard*

8.183 The United States argues that since mature, symptomless apples are not a pathway for the introduction of fire blight, even if picked from a highly infected tree, buffer zones are not relevant. According to the United States, the EPPO requirements on which Japan relies to justify the obligation to set up a 500-meter buffer zone around orchards are part of an eradication programme, not a protection against transmission through imported fruits.

8.184 Japan argues that the practice of buffer zones is recognized by the IPPC Requirements for the Establishment of Pest-Free Places of Production and Pest Free Production Sites.³⁴² The 500-metre buffer zone is supported by scientific evidence that *E. amylovora* could be found at some distance from points of inoculum.³⁴³ Furthermore, buffer zones are necessary to ensure that host plants are grown in a disease-free environment. Japan submitted a number of elements justifying in its view a 500-meter buffer zone.³⁴⁴

8.185 We have found above that there is not sufficient scientific evidence supporting the view that infested or infected apples are likely to serve as a pathway for the entry, establishment or spread of fire blight within Japan. However, even if this were not the case, we are of the opinion that the prohibition of imported apples from any orchard (whether or not it is free of fire blight) should fire blight be detected within a 500-meter buffer zone surrounding such orchard is not supported by sufficient scientific evidence.

8.186 We note that the agreed purpose of a buffer zone is to avoid the contamination of a fire blight-free orchard by bacteria carried from outside by creating a zone that will be difficult for the bacteria to cross, e.g. by removing any potential host plants from the buffer zone.³⁴⁵

8.187 We recall that the experts have noted the relevance of a buffer zone for disease eradication purposes.³⁴⁶ However, measures for an eradication programme are not necessarily the same as those required to reduce the risk of fire blight transmission through imported, mature, symptomless apple fruit. In that context, we cannot assume, as Japan does, that the suggestion made in the studies of Meijneke (1979)³⁴⁷ and Zeller (1987)³⁴⁸ for a 500-meter *eradication countermeasure* in Europe is necessarily relevant for justifying a buffer zone to ensure that apple

³⁴¹ Para. 8.25.

³⁴² *International Standard for Phytosanitary Measures No.10: Requirements for the Establishment of Pest Free Places of Production and Pest Free Production Sites*, FAO, Rome 1999 (Exhibit JPN-24).

³⁴³ Exhibit JPN-25; JPN-26; JPN-27; JPN-19.

³⁴⁴ Japan First Submission, paras. 158-165.

³⁴⁵ Annex 3, Dr Geider, para. 319. Dr Hayward quoted ISPM 5 (1999) Glossary of Phytosanitary terms, according to which a buffer zone was "An area in which a specified pest does not occur or occurs at a low level and is officially controlled, that either encloses or is adjacent to ... 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."

³⁴⁶ Annex 3, paras. 314, 319 and 320.

³⁴⁷ Exhibit JPN-19.

³⁴⁸ Exhibit JPN-27.

fruit is free of bacteria. Even if one were to rely, as proposed by Japan, on van Vaerenbergh *et al.* (1987),³⁴⁹ which showed dispersion of *E. amylovora* for 250 meters in humid weather, and on the measures required by the United States against citrus canker for Unshu oranges (400-meter buffer zone), a 500-meter buffer zone for apples is still not scientifically supported.³⁵⁰

8.188 We also note that the experts have stated that buffer zones are useful to protect nursery stocks over several years. Dr Smith noted that buffer zones are more suitable for nurseries where one is looking at a situation where the nursery should be free and remain free over a period of years, since fire blight can develop rather slowly on planting material.³⁵¹ At the same time, infected nursery stocks are known to be the most common pathway for the introduction of fire blight into regions not adjacent to infected areas.³⁵²

8.189 However, the experts expressed doubts as to the usefulness of a buffer-zone to protect an orchard from fire blight. Dr Hale recalled that Roberts (2002)³⁵³ 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*.³⁵⁴ Dr Smith considered that, as far as fire blight is concerned:

"the possibility that fire blight should enter an orchard during a given growing season from outside the orchard from a canker infection in which the bacteria multiplies and from that multiplication infects fruit is almost impossible. We already query the possibility that fruits can be significantly infected within the orchard so the fruits are very unlikely to be directly infected by inoculum coming from a joining orchard and if the inoculum comes into the orchard what it first has to do is establish itself, establish the disease in the orchard and from that the disease has to spread to the fruit and in the most favourable circumstances this could not happen until the following growing season. So for that reason I doubt whether a buffer zone is really necessary in the case of fire blight."³⁵⁵

8.190 Both the United States and the experts consulted by the Panel also referred to studies examining 30,900 mature, symptomless fruits harvested between 0 and 300 meters from fire blight inoculum sources which found that none of the fruits that were subsequently cool-stored had developed fire blight symptoms and none of the sliced fruit had yielded *E. amylovora*, even when harvested from trees directly adjacent to fire blight sources.³⁵⁶

³⁴⁹ See para. 4.115.

³⁵⁰ Dr Hale, Dr Hayward and Dr Smith concur in their assessment that the epidemiology of fire blight was different from that of many bacterial diseases such as citrus canker (Dr Hale, para. 6.139, Dr Hayward, para. 6.140, Dr Smith, para. 6.141). The experts also considered that the zone size recommended for citrus canker had no relevance for fire blight (Dr Hayward, para. 6.140; Dr Smith, para. 6.141).

³⁵¹ Annex 3, para. 320, see also para. 6.137.

³⁵² Paras. 6.28, 6.29, 6.31, 6.32, 6.41, 6.47.

³⁵³ Exhibit USA-16.

³⁵⁴ Dr Hale, paras. 6.134-6.135; Dr Hayward also refers to Roberts (2002, in press) which has obtained results that have indicated that a buffer zone of any size provides no phytosanitary security (Annex 3, para. 315).

³⁵⁵ Annex 3, para. 314, see also Dr Geider, para. 319.

³⁵⁶ Paras. 6.134-6.136.

8.191 We therefore conclude that, on the basis of the evidence before us, the requirement by Japan of a 500-meter buffer zone, to prevent contamination of US apple fruit with fire blight, does not bear a rational relationship to the scientific evidence available.

8.192 Even if a buffer zone were sufficiently justified scientifically to avoid the contamination of apple fruit, we also recall that it is applied cumulatively with other measures which are intended to ensure that the apple fruit is free of fire blight when exported, such as the surface treatment requirement or orchard inspections. In that context, the requirement of a buffer zone would be redundant.

(ii) *The requirement that export orchards be inspected at least three times yearly (at blossom, fruitlet, and harvest stages) for the presence of fire blight*

8.193 The United States recalls that Japan requires that the orchards and buffer zones be inspected at least three times yearly, at the blossom, fruitlet and harvest seasons. The United States also notes that additional inspections are required following any strong storm (such as a hail storm). The United States argues that only a harvest season inspection that detected severely blighted orchards might be relevant for assessing the likelihood that there could be fire blight bacteria on the surface of mature, symptomless apples. However, the United States contends that even that inspection is unnecessary because there is no scientific evidence that mature, symptomless apple fruit can act as a pathway for the entry, establishment or spread of fire blight within Japan.

8.194 Japan argues that field inspections are necessary to ensure the efficacy of the systems approach. Inspection at the blossom stage was necessary because this was when the trees were most susceptible to infection. However, infection by *E. amylovora* was most visible at the fruitlet stage. A third inspection at the harvest stage was necessary because infection could occur after the fruitlet stage and the mechanism of invasion of *E. amylovora* inside apples was not known.

8.195 We have found above that there is not sufficient scientific evidence supporting the view that infested or infected apples are likely to serve as a pathway for the entry, establishment or spread of fire blight within Japan. However, even if this were not the case, we are of the opinion that the requirement that export orchards be inspected at least three times yearly (at blossom, fruitlet, and harvest stages) for the presence of fire blight is not supported by sufficient scientific evidence.

8.196 Whilst the experts considered that inspection was necessary for identification of the disease-free status of an orchard, all of them said that three inspections were more than what was necessary to detect whether there was significant fire blight infection.³⁵⁷ Even 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.³⁵⁸

8.197 We therefore conclude that the requirement by Japan that US export orchards be inspected at least three times yearly (at blossom, fruitlet, and harvest stages) for the presence of fire blight does not bear a rational relationship to the scientific evidence available.

³⁵⁷ Annex 3, paras. 268, 273-283, 303.

³⁵⁸ Dr Hayward, para. 6.74; Dr Hale, paras. 6.25, 6.113, 6.139, 6.145, 6.150; see also Annex 3, Dr Smith, para. 310.

(b) Conclusion

8.198 For the reasons mentioned above, we conclude that the phytosanitary measure at issue is clearly disproportionate to the risk identified on the basis of the scientific evidence available. In particular, some of the requirements applied by Japan as integral parts of the measure at issue are, either individually or when applied cumulatively with the other requirements of that measure, not supported by sufficient scientific evidence within the meaning of Article 2.2 of the SPS Agreement.

8. Provisional conclusion on Article 2.2 of the SPS Agreement

8.199 On the basis of the above, we conclude that the phytosanitary measure at issue is, as a whole, maintained "without sufficient scientific evidence" within the meaning of Article 2.2 of the SPS Agreement.

8.200 We note that Article 2.2 of the *SPS Agreement* provides that "Members shall ensure that any ... phytosanitary measure ... is not maintained without sufficient scientific evidence, *except as provided for in paragraph 7 of Article 5*". We recall that the panel in *Japan – Agricultural Products II*, having found that the phytosanitary at issue violated Article 2.2 but noting that the defendant was also invoking Article 5.7, concluded that it had to examine next whether that measure met the requirements in Article 5.7. The panel concluded that if the phytosanitary measure at issue met these requirements, it could not find that it violates Article 2.2.³⁵⁹

8.201 We agree with this approach and refrain from making final findings with respect to the consistency of the measure at issue with Article 2.2 until we have completed our analysis under Article 5.7.

8.202 We therefore proceed with our analysis of the applicability of Article 5.7 of the *SPS Agreement* to the phytosanitary measure at issue.

E. ARTICLE 5.7 OF THE SPS AGREEMENT

1. Summary of the arguments of the parties³⁶⁰

8.203 Japan argues that should the Panel find the scientific evidence insufficient to support Japan's measure under Article 2.2, the measure could be considered to be a provisional measure in the context of Article 5.7 since the date of entry into force of the *SPS Agreement*.

8.204 The United States argues that the Panel's analysis of Japan's alternative defence under Article 5.7 can begin and end with the first requirement of that Article that the provisional measure be imposed only "[i]n cases where relevant scientific evidence is insufficient". The United States contends that Japan had not demonstrated that the relevant scientific evidence was insufficient. Indeed, the United States argues that there has never been scientific evidence that mature apple fruit transmitted the disease.

³⁵⁹ Panel Report in *Japan – Agricultural Products II*, para. 8.48.

³⁶⁰ A detailed account of the arguments of the parties can be found in paras. 4.201-4.221 of this Report.

8.205 The United States contends that the scientific evidence predated the entry into force of Japan's fire blight measures in 1994 and continued to be the same thereafter. Thus, Japan has been acting inconsistently with its commitment under Article 2.2 not to maintain its fire blight measures without sufficient scientific evidence since the entry into force of the *SPS Agreement* in 1995.

8.206 Japan recalls that its current phytosanitary requirements were introduced on the basis of an agreement between the Governments of Japan and the United States, in order to allow importation of US apple fruit while preserving Japan's appropriate level of protection. The measures were developed on the basis of proposals from the United States. As such, Japan contends that it is unreasonable for the United States to now claim that the evidence had been insufficient from the beginning.

8.207 The United States argues that it acquiesced to the fire blight measures which Japan introduced in 1994 as preferable to an outright ban on imported apple fruit, although it had recognized that the scientific evidence did not support the restrictions imposed by Japan. The United States contends that it never accepted the consistency of these measures with Japan's WTO obligations.

8.208 Japan believes that considerable scientific evidence exists to support its measure to control the risk of fire blight in US apples. And, if the Panel were to find that this evidence was not sufficient under Article 2.2, it is nonetheless "available pertinent information" in the context of Article 5.7. Together, these pieces of evidence demonstrate that a phytosanitary measure is needed to counter the risk of dissemination of fire blight via imported US apples.

2. Analysis of the Panel

8.209 Article 5.7 reads as follows:

"In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measures accordingly within a reasonable period of time."

8.210 We understand Japan to be claiming that the phytosanitary measure at issue is justified under Article 5.7 "in the alternative", should the Panel find that the measure is maintained without sufficient scientific evidence within the meaning of Article 2.2. We first note that arguing in the alternative is a well-established judicial practice and arguing a point in the alternative of another point often implies that there may be some contradictions between the two lines of argumentation if they were presented concurrently.

8.211 In this instance, we have determined above that Japan's measure is maintained without sufficient scientific evidence within the meaning of Article 2.2, which is the circumstance in which Japan invokes Article 5.7 in the alternative and claims that this provisional measure has been in place since the date of entry into force of the *SPS Agreement* in 1995.

8.212 We will therefore now consider whether the measure at issue can be justified as a provisional measure within the meaning of Article 5.7 of the *SPS Agreement*. Before doing so,

however, we find it relevant to recall that the burden is on Japan, as the party invoking Article 5.7 to make a *prima facie* case in support of its position.

8.213 We recall that the Appellate Body in *Japan – Agricultural Products II* noted that Article 5.7 sets out four requirements which have to be met in order for a measure to be justified as a provisional measure. These requirements, cumulative in nature, are the following:

- (i) The measure is imposed in respect of a situation where "relevant scientific evidence is insufficient";
- (ii) the measure is adopted on the basis of "available pertinent information".

Pursuant to the second sentence of Article 5.7, such a provisional measure may not be maintained unless the Member which adopted the measure:

- (iii) "seek[s] to obtain the additional information necessary for a more objective assessment of risk; and
- (iv) "review[s] the ... measure accordingly within a reasonable period of time."

The Appellate Body added that "whenever *one* of these four requirements is not met, the measure at issue is inconsistent with Article 5.7".³⁶¹

8.214 We note that we may begin our examination with either the requirements of the first sentence or of the second sentence of Article 5.7.³⁶² However, in the light of the arguments of the parties, we proceed to consider the first requirement under Article 5.7, first sentence, i.e. that the measure is imposed in respect of a situation where "relevant scientific evidence is insufficient".

8.215 We first note that the existence of a situation where "relevant scientific evidence is insufficient" cannot be merely presumed on the basis of the fact that the measure at issue has been found to be maintained "without sufficient scientific evidence" pursuant to Article 2.2. The fact that a particular measure, in this instance the set of requirements applied by Japan to the importation of US apple fruit, is found to be maintained without sufficient scientific evidence may not necessarily dispose of the separate question, under Article 5.7, of whether the situation is one where "relevant scientific evidence" is insufficient.

8.216 We recall from our discussion regarding Article 2.2 that the "situation" addressed by the measure at issue in this case is not one where the measure is imposed in respect of a situation where "relevant scientific evidence is insufficient", but where, on the contrary, a wealth of information is available. It should be noted first that Article 5.7 refers to "relevant scientific

³⁶¹ Appellate Body Report in *Japan – Agricultural Products II*, para. 89 (emphasis in the original).

³⁶² In *Japan – Agricultural Products II*, the Appellate Body confirmed that the panel could begin its analysis with any one of the four requirements mentioned above. It concluded that:

"...the Panel did not err in its application of Article 5.7 by first examining whether the varietal testing requirement meets the requirements of the second sentence of Article 5.7. Having established that the requirements of the second sentence of Article 5.7 are not met, there was no need for the panel to examine the requirements of the first sentence." (Appellate Body Report in *Japan – Agricultural Products II*, para. 91).

evidence" which implies that the body of material that might be considered includes not only evidence supporting Japan's position, but also evidence supporting other views. In the course of our analysis under Article 2.2 we have come across an important amount of relevant evidence, including scientific studies and reports on the risk of transmission of fire blight through apples. This information was submitted not only by the parties but also by the experts consulted by the Panel. The fact that this information may not all support Japan's opinion is in our view not pertinent in the context of this first requirement of Article 5.7. It is indisputable that a large amount of relevant scientific evidence is available.³⁶³

8.217 We note that Japan argues that, on certain aspects of the dissemination of the bacteria, the evidence is not sufficient. Japan argues, for instance, that there is limited evidence on what happens to *E. amylovora* inside immature apples that would ensure it was not found in mature apples. Likewise, Japan argues that not enough studies have been performed on the potential completion of contamination pathways.

8.218 We recall that the requirement concerning scientific evidence relates to the insufficiency of relevant scientific evidence regarding what the Appellate Body in *Japan – Agricultural Products II* describes as a "situation"³⁶⁴ and Article 5.7 even more generally as a "case". From the use of these terms, we conclude that the term "insufficient relevant scientific evidence" is meant to refer to evidence *in general* on the phytosanitary question at issue, in this instance the risk of transmission of fire blight through apple fruit.

8.219 The current "situation", where scientific studies as well as practical experience have accumulated for the past 200 years, is clearly not the type of situation Article 5.7 was intended to address. Article 5.7 was obviously designed to be invoked in situations where little, or no, reliable evidence was available on the subject matter at issue. With regard to fire blight, not only a large quantity but a high quality of scientific evidence has been produced over the years that describes the risk of transmission of fire blight through apple fruit as negligible.³⁶⁵ Moreover, this is evidence in which the experts have expressed strong and increasing confidence. We therefore are of the view that the first condition of the first sentence of Article 5.7 is not met.

8.220 Even if we were to accept Japan's arguments that "relevant scientific evidence" in Article 5.7 may refer to a specific aspect of a phytosanitary problem, we recall that the experts have indicated that even on the specific scientific questions raised by Japan, there is a large volume of relevant scientific evidence. This is the case regarding the absence of endophytic bacteria in mature apple fruit³⁶⁶ and the risk of transmission of fire blight by apple fruit.³⁶⁷ As mentioned above, the fact that it does not support Japan's views is of no relevance. Article 5.7 does not refer to evidence supporting the views of the Member wishing to impose SPS measures.

8.221 For these reasons we conclude that the present "situation" is one where there is sufficient relevant scientific evidence available, and that the first condition for invoking Article 5.7 is consequently not met.

³⁶³ See, for example, Annex 3, Dr Smith, para. 338:

"Well, I would certainly support Geider in his view that fire blight is a well studied disease [Annex 3, para. 336], much observed and so that there is a very large body of direct evidence concerning fire blight."

³⁶⁴ Appellate Body Report in *Japan – Agricultural Products II*, para. 89.

³⁶⁵ Annex 3, Dr Hale and Dr Smith, paras. 342 and 343.

³⁶⁶ Annex 3: Dr Geider, paras. 63, 115, 355, 360; Dr Hale, paras. 356, 361; Dr Hayward, paras. 357, 362; Dr Smith, paras. 358, 363. See also paras. 6.7-6.10, 6.15-6.19.

³⁶⁷ Paras. 6.20-6.25 and 6.37-6.40.

8.222 We therefore find that, since the first requirement of the first sentence of Article 5.7 is not met, and since the requirements of Article 5.7 are cumulative, Japan has failed to establish that the phytosanitary measure at issue is a provisional measure justified under Article 5.7 of the SPS Agreement.

3. Final conclusion on Article 2.2 of the SPS Agreement

8.223 In paragraph 8.199 above, we provisionally concluded that the phytosanitary measure at issue is maintained without sufficient scientific evidence, within the meaning of Article 2.2. We have found in the preceding section that the phytosanitary measure at issue was not a provisional measure maintained in accordance with the requirements of Article 5.7.

8.224 Consequently, we conclude that the United States has made a prima facie case that, by maintaining the measure at issue "without sufficient scientific evidence", Japan has violated its obligations under Article 2.2 of the SPS Agreement. Japan has failed to rebut that presumption.

8.225 We note in this respect that our conclusion is based on the evidence submitted by the parties and the opinions of the experts consulted by the Panel. This conclusion relates to the application of the measure at issue *as a whole*. This conclusion does not imply that no SPS measure would be compatible with Article 2.2, nor does it prejudge the question whether certain elements of the measure at issue could, individually or in combination with others, be compatible with Article 2.2.

8.226 Indeed, we recall that the experts considered, *inter alia*, that it would be appropriate not to export apples from (severely) blighted orchards³⁶⁸ 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.³⁶⁹

8.227 For the reasons mentioned in paragraph 8.4(c) above, we now proceed with an examination of the US claims regarding Japan's risk analysis.

F. ARTICLES 5.1 AND 5.2 OF THE SPS AGREEMENT

1. Introduction

8.228 The United States submits that the measure at issue is inconsistent with Articles 5.1 and 5.2 of the *SPS Agreement*, in that it is not based on a risk assessment, as required under these provisions.

8.229 The relevant paragraphs of Article 5 read as follows:

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

³⁶⁸ Annex 3: Dr Smith, paras 266, 411 and 429; Dr Hale, paras. 269, 410 and 414; Dr Geider, paras. 409 and 413.

³⁶⁹ Annex 3: Dr Geider, paras. 409 and 424; Dr Hale, para. 410; Dr Smith, para. 419.

2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine and other treatment."

8.230 These provisions directly inform each other, in that paragraph 2 sheds light on the elements that are of relevance in the assessment of risks foreseen in paragraph 1. In addition, the notion of risk assessment is defined in Annex A of the *SPS Agreement*. The relevant part of paragraph 4 of Annex A 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; ..."

8.231 We also recall the Appellate Body's observation that Article 2.2 informs Article 5.1 and that they should "constantly be read together".³⁷⁰ We will therefore examine the US claims under Article 5 paragraphs 1 and 2 in light of each other, bearing in mind also, to the extent relevant, our analysis under Article 2.2 above.

8.232 We will first turn to Article 5.1, which contains the general requirement for Members to base their measures on a risk assessment. However, because Article 5.2 imparts meaning to the general obligation contained in paragraph 1 to base measures on an "assessment ... of risks", we may also consider elements contained in Article 5.2 in the course of our analysis under Article 5.1.

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

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

8.234 These two elements will be considered in turn.

2. Japan's risk assessment

- (a) Requirements of a risk assessment under Article 5.1

8.235 As noted above, Article 5.1 requires an assessment "as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations". In this instance, the measure at issue is a phytosanitary measure.

8.236 Accordingly, taking into account the relevant definition of a risk assessment in Annex A paragraph 4, the risk assessment in relation to the measure at issue involves an evaluation of:

³⁷⁰ Appellate Body Report in *EC – Hormones*, para. 180.

- (a) "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" (Annex A paragraph 4);
- (b) whether this risk assessment is "as appropriate to the circumstances";
- (c) whether the risk assessment takes "into account risk assessment techniques developed by the relevant international organizations".

8.237 The last two factors, in our view, pervade the entire assessment of the risk, as defined in Annex A, paragraph 4. Their consideration is therefore generally relevant to our assessment of the risk assessment itself as a whole, and we will consider them first.

- (b) A risk assessment "as appropriate to the circumstances"

8.238 As noted above, the measure at issue is a phytosanitary measure, where the risks are with regard to plant life and health. Neither party contends that there is any risk to human or animal health from fire blight disease, nor risk of "other damage to the territory" of Japan. An appropriate risk assessment must therefore focus on the risks related to plant life and health.

8.239 It might be observed, in this context, that the requirement that the risk assessment be "appropriate to the circumstances" has been considered to leave some flexibility for an assessment of risk "on a case by case basis, in terms of product, origin and destination, in particular country-specific situations".³⁷¹

8.240 A relevant circumstance in this case is, in our view, the fact that Japan is considered to be fire blight-free, as well as its specific climatic conditions, which make it a potentially favourable environment for the spread of fire blight, should the disease enter the country.³⁷²

- (c) International risk assessment techniques developed by relevant international organizations.

8.241 We recall that Article 5.1 requires the "risk assessment techniques developed by the relevant international organizations" to be "taken into account". We note first that this expression does not impose that a risk assessment under Article 5.1 be "based on" or "in conformity with" such risk assessment techniques. This suggests that such techniques should be considered relevant, but that a failure to respect each and every aspect of them would not necessarily, *per se*, signal that the risk assessment on which the measure is based is not in conformity with the requirements of Article 5.1. Nonetheless, reference to these risk assessment techniques can provide very useful guidance as to whether the risk assessment at issue constitutes a proper risk assessment within the meaning of Article 5.1. In particular, it can shed useful light, in this dispute, on the US argument that Japan has failed to evaluate the likelihood of entry because it failed to consider all the steps in the pathway that would lead to apple fruit being a vector for the entry and transmission of the disease.

³⁷¹ Report of the Panel in *Australia- Salmon*, para. 8.71.

³⁷² We note in this respect that these factors relate to some of the factors required to be taken into account under Article 5.2 of the *SPS Agreement*, which refers *inter alia* to "prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions".

8.242 In this instance, it is not disputed that the relevant international organization is the IPPC.³⁷³ However, the parties have referred to two separate instruments. The United States has referred to the most recent International Standard for Phytosanitary Measures (ISPM) developed by the IPPC for Quarantine Pests, namely ISPM 11 on Pest Risk Analysis for Quarantine Pests, adopted in 2001. Japan, on the other hand, has noted that the relevant standard at the time of conduct of its own pest risk analysis was ISPM 2 on Guidelines for Pest Risk Analysis. Both of these instruments are described in more detail in section II. C. 2 above.³⁷⁴

8.243 With regard to the question of whether ISPM 2 or ISPM 11 should be taken into account in this case, we note that both instruments describe pest risk analysis as involving three stages: (1) the identification of a pathway that may allow the introduction and/or spread of a quarantine pest, and the identification of that pest; (2) an examination of the specific pest in light of the criteria for quarantine pest status; and, finally, (3) the determination of the appropriate phytosanitary measure. Compared to the previous guidelines, ISPM 11 sets out in more detail (and in a manner more closely resembling the definition of a risk assessment under the *SPS Agreement*), the specific steps involved in a PRA which include an assessment of the probability of introduction and spread. The assessment of the probability of introduction itself is indicated as requiring an analysis of each of the pathways for entry with which a pest might be associated.³⁷⁵

8.244 Although the 2001 ISPM provides a greater degree of detail to guide the conduct of a specific PRA, both parties agree that both build on the same framework, and that the detailed differences between them are not significant to this dispute, although for opposite reasons. In Japan's view, the Japanese PRA took into account the 1996 guidelines and did not need any review as a result of the 2001 instrument. In the US view, Japan's PRA does not meet the standard of either of the two instruments. We shall therefore not seek to analyse *a priori* the details of the differences between the two guidelines, but rather focus on the key issue of whether Japan's PRA sufficiently identifies and assesses, as suggested under both instruments, the possible pathways for the introduction and spread of fire blight through apple fruit and the likelihood/probability for their being realized.

(d) Japan's risk assessment in light of the requirements under Annex A, paragraph 4 of the *SPS Agreement*

(i) *Introduction*

8.245 As noted by the panel in *Australia – Salmon* and endorsed by the Appellate Body, an 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 consequence" encompasses two distinct elements, which together constitute the relevant risk assessment in relation to phytosanitary measures: (1) an 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 (2) an evaluation of the "potential biological and economic consequences associated with such entry or spread".³⁷⁶

³⁷³ See para. 2.20.

³⁷⁴ Paras. 2.24 ff.

³⁷⁵ *Ibid.*

³⁷⁶ Panel Report in *Australia – Salmon*, para 8.72, and Appellate Body Report in *Australia – Salmon*, para 120.

8.246 These elements will be considered in turn. First, however, we should determine the factual elements on which our assessment of Japan's risk assessment should be based. In this respect, we note that Japan has conducted two risk assessments of relevance to the entry and spread of fire blight: one in 1996, concerning various pests, including fire blight, and another in 1999 concerning specifically fire blight on apples imported from the United States (hereafter the "1999 PRA").

8.247 We note that the parties agree that the 1999 PRA is the main relevant document. Contrary to the United States, however, Japan does not agree that conformity with Article 5.1 can be also assessed in light of subsequent information. We also recall that a Member is not required to perform its own risk assessment under Article 5.1, but to base its measure on a risk assessment appropriate to the circumstances.

8.248 In this instance, Japan has conducted its own risk assessments, and the parties have particularly focused on Japan's most recent and most specific PRA, conducted in 1999. We will thus consider principally the 1999 PRA as the relevant risk assessment in this case, but we do not exclude that other elements, including subsequent information, could also be of relevance.

8.249 Having determined that these are the relevant elements to consider, we now turn to an examination of the various elements of Japan's risk assessment in order to assess whether the United States has made a prima facie case that Japan's measure is not based on a risk assessment within the meaning of Article 5.1.

8.250 The Appellate Body has clarified that, on the basis of the definition of a risk assessment contained in Annex A, paragraph 4, first sentence (which is the relevant one in this instance):

"a risk assessment within the meaning of Article 5.1 must:

- (1) *identify* the diseases whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases;
- (2) *evaluate the likelihood* of entry, establishment or spread of these diseases, as well as the associated potential biological and economic consequences; and
- (3) *evaluate the likelihood* of entry, establishment or spread of these diseases *according to the SPS measures which might be applied.*³⁷⁷

8.251 These will be considered in turn.

³⁷⁷ Appellate Body Report in *Australia – Salmon*, para. 121. In *Japan – Agricultural Products II*, the Appellate Body endorsed the aforesaid three-pronged test. See para. 112. This test was also used by the Panel in *Australia – Salmon (Article 21.5 – Canada)*, para. 7.41.

(ii) *The disease at issue and the potential biological and economic consequences associated with its entry, establishment or spread*

8.252 The United States does not dispute, in this instance, that Japan's risk assessment fulfils the first of the three conditions listed in paragraph 8.250, in that it has "identified fire blight as the disease whose entry, establishment, or spread Japan wants to prevent within its territory as well as potential associated biological and economic consequences".³⁷⁸

8.253 However, the United States considers that Japan has failed to meet the other requirements of a risk assessment under Article 5.1, namely the evaluation of the likelihood of entry, establishment or spread of that disease (item (iii) below); according to the SPS measures which might be applied (item (iv) below).

(iii) *The likelihood of entry, establishment or spread of the disease*

8.254 The United States argues that Japan has failed to evaluate the likelihood of entry, establishment or spread of fire blight within Japan, in particular because it has, in its view, "fail[ed] to focus on scientific evidence relating to the importation of apples, making only general statements of possibility rather than an assessment of probability of entry, establishment or spread".³⁷⁹ The United States recalls in particular the Appellate Body's observation that "it is not sufficient that a risk assessment conclude that there is a possibility of entry, establishment or spread of diseases and associated biological and economic consequences" ... it "must evaluate the 'likelihood', i.e., the 'probability' of entry, establishment or spread ...".³⁸⁰

8.255 Japan responds that the US arguments are groundless, and that Japan's risk assessment "reflects available evidence and reasonably supports its current phytosanitary requirements".³⁸¹ Japan considers that the 1999 PRA had addressed not a theoretical possibility but the likelihood of the introduction and spread of fire blight through apple fruit.

8.256 We understand the United States to argue both that the risk assessment at issue lacks the required "specificity" in relation to the product at issue/the source of the risk, i.e. the importation of apples, and also that the assessment performed does not sufficiently evaluate the *likelihood* of entry, establishment or spread, as required under Article 5.1.

8.257 With regard to the specificity required of a risk assessment under Article 5.1, we note first that it has been clarified on previous occasions that the risk assessment must be specific to the disease at issue, and, where several diseases are at issue, specific to each disease.³⁸² In this instance, the United States does not challenge the specificity of the risk assessment in relation to the disease at issue, but rather in relation to the product whose importation would lead to the introduction of the disease at issue: the United States thus argues that no evidence is presented as to the probability of entry, establishment or spread of the bacteria *through apple fruit*³⁸³, and, in particular, the relevant paragraph entitled "Probability of Transmission via fresh apples", does not "distinguish between evidence relevant to the exported commodity from other evidence".³⁸⁴ More generally, the United States notes that a proper risk analysis should have focused on the

³⁷⁸ US first submission, para. 66.

³⁷⁹ US first submission, para. 69.

³⁸⁰ Appellate Body Report in *Australia – Salmon*, para. 123.

³⁸¹ Japan first submission, para. 211.

³⁸² Panel report in *Australia – Salmon*, para. 8.74.

³⁸³ US first submission para. 73.

³⁸⁴ *Ibid.*, para 74.

probability of US apples being infested or infected with fire blight, rather than focusing on damaged fruit, immature fruit, apple leaves, etc.³⁸⁵

8.258 Japan notes in response that the risk analysis "obviously took into account all available scientific evidence that relates not only to apple trees but mature and immature, visibly blighted and symptomless apple fruit as well – including van der Zwet *et al.* (1990)".³⁸⁶

8.259 With regard to the assessment of the "likelihood" of the entry, establishment or spread of the disease, the United States argues that there is no evidence of spread from apples in the past, and no evidence that the hypothetical pathway of spread through mature apples could be completed. The United States also argues that Japan's PRA ignores key steps in the assessment, and in this respect also has failed to evaluate the likelihood of entry, establishment and spread of the disease.

8.260 Japan contends that the 1999 PRA identified the steps in the pathway necessary for fire blight to be disseminated via mature, apparently healthy apple fruit imported from the United States.³⁸⁷ Japan notes that the very objective of the assessment in the 1999 PRA was to assess US apple fruit as a potential pathway. Furthermore, while the 1999 PRA did not estimate numerical probabilities of contamination by the bacteria, the PRA had qualitatively evaluated the probability.³⁸⁸

8.261 We will first examine the relevant parts of Japan's 1999 PRA before assessing it in light of the parties' arguments.

- Japan's 1999 PRA

8.262 Examining Japan's 1999 PRA, we first note that it refers in its subtitle to "Fresh apples produced in the United States of America". We note that the structure of this document is to focus first on a description of the disease, followed by a general pest risk analysis for *E. amylovora*, before addressing quarantine measures for "US fresh apple fruit", and finally including a chapter on "Pest risk analysis for quarantine measures on *E. amylovora* for US fresh apple fruit". The initial chapter describing fire blight contains a section entitled "Probability of transmission via fresh apples". In this section, reference is made to the possibility for immature fruit to be infected through natural openings in the skin, lenticels or diseased branches. Reference is also made to a number of studies describing the isolation of *E. amylovora* from apple fruit ("mature fruits harvested in severely infected orchards" (Hale *et al.* 1997), "fresh apple fruit" (van der Zwet *et al.* 1990) or "young apples") as well as reports describing the survival of *E. amylovora* on fresh mature apple fruit (McLarty, 1922).³⁸⁹

8.263 The general PRA contained in Chapter 2 begins with an analysis of the susceptibility of Japan to fire blight, were it to be introduced into the country (i.e. the presence of host plants, favourable climatic conditions, and an estimation of the probability for expansion) and on the potential impact, should this expansion occur (Section 2-2-3). A subsequent section focuses on the "Introduction potential" (Section 2-2-4). In the first part of that section, "the parts of plants

³⁸⁵ US first submission, para. 75.

³⁸⁶ Japan first submission, para, 203.

³⁸⁷ Japan first submission, paras. 202-211.

³⁸⁸ Japan second submission, paras. 58-67.

³⁸⁹ Exhibit JPN-32, para 1-1, page 5.

which can be infected with *E. amylovora*, namely, fresh plants (including fresh fruit, flowers ...) are identified as some of those that can introduce *E. amylovora* into Japan.³⁹⁰ In this section, it thus appears that fresh fruit is considered to be a "host plant", alongside cut flowers or nursery stock. Within the same section, under the heading "Main uses of plants after importation" the different types of "plants" are referred to. With regard to fruit, it is noted that :

"fresh fruit are used for raw food or processing and supplied through markets However, not all of them are distributed or consumed completely by such usages. In the course of the distribution, processing and consumption, some can be released to the natural environment as leftovers, waste or useless materials.

In this way, if imported stocks and pollen are contaminated with *E. amylovora*, they become the direct cause for the occurrence of fire blight because they are directly brought into agricultural production area. When contaminated cut flowers and fresh fruit are released as juice, leftovers, waste, useless materials in the fields surrounding ranches or in a natural environment, they can be the source of the disease."³⁹¹

8.264 The conclusions reached in light of the general PRA for *E. amylovora*, were that imported host plants should not be infected with *E. amylovora* and that "to avoid the introduction of *E. amylovora*, it must be designated as pathogen subject to importation prohibition ...".³⁹²

8.265 The following and final chapter of the 1999 PRA is devoted to a "Pest risk analysis for quarantine measures on *E. amylovora* for US fresh apple fruit". The introduction to this section indicates that Japan needs "to review whether or not 'plant quarantine measures against *E. amylovora* concerning US fresh apple fruit', which have been taken by Japan based on the proposal by the US government since 1994³⁹³, are adequate as an alternative to lift the import prohibition measures against *E. amylovora*"³⁹⁴ A section is then devoted to each of the measures in place, which concludes that they provide a level of protection equivalent to the import ban.

- Assessment of Japan's risk assessment

Specificity of the PRA

8.266 We first turn to the US argument that the 1999 PRA fails to focus specifically on the product at issue, namely fresh apple fruit.

8.267 We first note in this respect that it has been recognized, in prior cases, that a risk assessment conducted under Article 5.1 of the *SPS Agreement* should be sufficiently specific to the risk at issue. In particular, we recall the findings of the panel in *EC - Hormones*, as upheld by the Appellate Body, that studies relating to the carcinogenicity of certain hormones in general, without an evaluation of the specific potential for carcinogenic effects arising from the presence of hormones in food or meat products, were insufficient to support the measure at issue.

³⁹⁰ Ibid, para. 2-2-4-1.

³⁹¹ Ibid, para. 2-2-4-3.

³⁹² Ibid, para. 2-3-2.

³⁹³ The United States, however, argues that it accepted the fire blight measures imposed by Japan only reluctantly, recognizing that the scientific evidence did not support the restrictions. See para. 4.29 above.

³⁹⁴ Exhibit JPN-32, para. 3-1.

8.268 In this instance, the United States notes that Japan's PRA refers to a number of possible hosts of fire blight (such as cut flowers, shoots, plants), rather than focusing on apples. We first note in this respect that Japan's PRA, which in part describes in general terms the risk of entry, establishment or spread of the disease through various possible hosts, including but not exclusively apple fruit, often either addresses these other hosts or includes the consideration of apple fruit within a broader category, as one of the possible "plant hosts", without specifically distinguishing it from other potential sources of infection, for the purposes of evaluating the general likelihood of entry, establishment and spread of the disease. Japan states that while the objective of the 1999 PRA was to assess US fruit, all potential pathways were considered.

8.269 While we do not exclude that a consideration of other possible hosts of the disease may be relevant in a risk assessment directed at the evaluation of the likelihood of entry, establishment and spread through apple fruit, it could be expected that the possible relevance of these other hosts/factors to contamination through apple fruit would be explained, and that conclusions relating to the likelihood of entry, establishment or spread specifically through apple fruit would be clearly identified, since the announced objective of the assessment is precisely to evaluate the risk in relation to that particular product.

8.270 In this respect, we note in particular that Chapter 2 of the 1999 PRA, which contains the general pest risk analysis concerning *E. amylovora*, includes very general conclusions that "*E. amylovora* is risk Grade A (extremely high)". This conclusion, however, is based on an overall assessment of possible modes of contamination, where apple fruit is only one of the possible hosts/vectors considered. As cited above, only one paragraph in that chapter specifically addresses fresh fruit, simply noting that not all fruit are distributed or consumed totally and "in the course of distribution, processing and consumption, some can be released to the natural environment as leftovers, waste or useless materials".³⁹⁵ Thus, although the risk assessment is intended to be conducted, as indicated by its very title, in relation to the importation of US fresh apple fruit, the main portion of the PRA is conducted on the basis of a general assessment of possibilities of introduction of fire blight into Japan, through a variety of hosts, including - but not exclusively - apple fruit.

8.271 There is no clear indication in the document as how the other possible vectors might be of relevance to an assessment of the likelihood of entry, establishment or spread through apple fruit specifically. Indeed, the conclusion of the PRA does not purport to relate exclusively to the introduction of the disease through apple fruit, but rather more generally, apparently, through any susceptible host/vector. The scientific evidence submitted by both parties leaves no doubt that the risk of introduction and spread of the disease varies considerably according to the host plant, with nursery stock and budding material identified as known sources for the spread of fire blight in some cases. We therefore conclude that, in this respect, the 1999 PRA is not sufficiently specific to the matter at issue to constitute a proper risk assessment under Article 5.1 of the *SPS Agreement*.

Evaluation of likelihood (possibilities vs. probabilities)

8.272 Turning now to the actual evaluation of "likelihood" of entry, or spread of fire blight through the importation of apple fruit, as reflected in the 1999 PRA, we recall the US argument that Japan's risk assessment falls short of the requirements of Article 5.1 in that it identifies mere

³⁹⁵ Ibid, para 2-2-4-3.

"possibilities" rather than "probabilities" of entry, establishment or spread, as required under Article 5.1.

8.273 We recall in this respect that Annex A, paragraph 4, requires a risk assessment, with respect to phytosanitary measures, to contain an evaluation of the "likelihood" of entry, establishment or spread of the disease. As has been clarified by the Appellate Body, this evaluation of likelihood involves more than a mere identification of "possibilities". It requires an assessment of *probability* of entry, and, in the words of the Appellate Body, "probability implies a higher degree or a "threshold of potentiality or possibility".³⁹⁶ It is also understood, however, that such probability need not be expressed in quantitative terms, but may be expressed in qualitative terms.

8.274 Japan has used in the context of its PRA, a general "scale" of grades in order to rank the risks at issue, ranging from A (extremely high) to D (extremely low). In this instance, the general PRA on *E. amylovora* leads, as already mentioned, to an overall ranking for the "total assessment of *E. amylovora*" of a "Grade A (extremely high)" risk. However, as noted above, that conclusion does not appear to specifically evaluate the likelihood of entry, establishment or spread through apple fruit, which is at issue here. In those parts of the PRA that do relate directly to the probability of entry specifically through apple fruit, the report does not suggest any precise evaluation of the "degree of potentiality" or probability for the occurrence of the event. Thus, in a section entitled "Probability of transmission via fresh apples", it is noted that "immature apples *can* be infected ..." (emphasis added), and that a number of studies report the presence of *E. amylovora* in association with apple fruit. In conclusion, it is noted that:

"Those reports, therefore, *suggest the probability* of transmission via fresh apple fruit. Although several reports have described that the *possibility* of transmission of *E. amylovora* by fresh apple fruit can be denied or ignored, these reports have only mentioned that 'symptomless mature fruit' (McLarty 1922, Dueck 1974) 'apparently healthy mature fruit' (Roberts et al. 1989), and 'the fruit harvested in fire blight symptomless orchards' (van der Zwet *et al.* 1990) are safe."³⁹⁷ (emphasis added)

8.275 Although the term "probability" is used here to describe the conclusion to be drawn from the cited studies³⁹⁸, it does not seem to reflect any particular assessment of the degree of likelihood of the event. Indeed, the reference to "probability" is even made in a somewhat hypothetical mode (probability is "suggested"). Similarly, the following paragraph appears to confirm that the cited studies lead to the identification of a possibility of apple fruit acting as a possible pathway for the entry of fire blight, but it does not indicate any quantitative or qualitative assessment of the probability of this occurring:

"As mentioned above, the mature apple fruit harvested in fire blight occurring orchards can carry *E. amylovora* and, in addition, the mature fruit not carrying *E. amylovora* can be contaminated by harvesting operation, etc., in the orchard where there are sources. In particular, when scarred fruit is infected with *E. amylovora* and becomes rotten, it *can* be considered to exude bacterial ooze.

³⁹⁶ Appellate Body Report in *EC – Hormones*, para 184.

³⁹⁷ Exhibit JPN-32, para. 1-1, p.7.

³⁹⁸ Note this is translated from the Japanese language. The text used here is the version provided by Japan.

Such fruit can be the source of transmission after being imported."³⁹⁹ (emphasis added)

8.276 These terms clearly point to the identification of a possibility of entry, establishment and spread, but do not, in our view, amount to an evaluation of the likelihood of entry within the meaning of Article 5.1 of the *SPS Agreement*, in that they do not assess the probability of such entry beyond the identification of the potential for entry, establishment or spread. In particular, they do not address the likelihood of an apple becoming contaminated by the harvesting operation, nor the likelihood that a damaged fruit will be included in the export shipment, nor the likelihood that such a fruit, were it to be shipped, would become rotten.

8.277 Another section of Japan's PRA purports to consider the probability of introduction through "normal transport method". Fruit is mentioned as one of the potential sources of entry along with other "host plants" through "normal transport method", so that if the importation of these plants is not prohibited, "it can easily increase the probability of introduction of *E. amylovora* into Japan together with host plants".⁴⁰⁰ Finally, the PRA identifies the possibility for fruit to be disposed of, or discarded in, possible host areas and concludes that it thus "can" be the source of contamination after importation. These elements, which are dispersed throughout the PRA along with consideration of other possible vectors for the entry, establishment or spread of fire blight within Japan, provide some evaluation of various possible steps for the entry, establishment and spread of fire blight through the importation of apple fruit.

8.278 However, these appear to be intertwined with other possible vectors, which have otherwise been identified much more clearly as potential sources of contamination (such as nursery stock or plants), and it is difficult to discern, from the structure and contents of the PRA, an effort to evaluate specifically the likelihood of entry, establishment or spread from the importation of apple fruit. Furthermore, to the extent that it might be considered to identify the potential for each of the relevant steps to be completed, the PRA fails, as noted above, to provide more than an indication of a potential for entry, establishment or spread, and does not assess the probability for such events to occur, as required under Article 5.1.

8.279 We further recall the inadequacies in the 1999 PRA identified by Dr Hale and Dr Smith. According to Dr Hale, the following key steps had been overlooked for the probability of entry:

- *identification of the relevant pathways;*
- *probability of fire blight being associated with the pathway of origin;*
- *probability of survival during transport and storage;*
- *probability of fire blight surviving existing pest management procedures; and*
- *probability of transfer of fire blight to suitable host.*⁴⁰¹

8.280 In light of the above, we conclude that Japan's PRA does not evaluate the likelihood of entry, establishment or spread of fire blight through the importation of apple fruit, as foreseen in Article 5.1 and Annex A, paragraph 4, of the *SPS Agreement*.

³⁹⁹ Exhibit JPN-32, para 1-1.

⁴⁰⁰ Section 2-2-4-1 of the 1999 PRA.

⁴⁰¹ Dr Hale, para. 6.177. See also Dr Smith, para. 6.181-6.181.

(iv) *According to the SPS measures which might be applied*

8.281 As noted above, Article 5.1 and Annex A, paragraph 4 of the *SPS Agreement* require measures to be based on an assessment of risks "according to the SPS measure which might be applied". In this instance, the United States contends that Japan's risk assessment does not comply with this condition because, although it clearly identifies some SPS measures that might apply to US apples, it does not "in any substantial way, evaluate their relative effectiveness in reducing the overall disease risk" as required under Article 5.1.⁴⁰² The United States also notes that Japan failed to consider any alternative measures to those that it was already applying, and in particular did not consider some alternative measures proposed by the United States in 1997.

8.282 Japan notes that the current measures (in particular the limitation of imports of apples from the states of Oregon and Washington) were established on the basis of a proposal by the United States itself. It also notes that the "mature, symptomless" criteria now mentioned by the United States was not proposed at any stage prior to the consultations held in April 2002.

8.283 With regard to the requirement that the evaluation be conducted "according to the sanitary or phytosanitary measures which might be applied", we note that this expression refers to the measures *which might* be applied, not merely to the measures which *are being* applied. This suggests to us that it cannot be assumed that it would be sufficient, under this provision, to simply consider the particular measures that are already in place, to the exclusion of other possible alternatives.

8.284 In this instance, it is apparent from the introductory paragraph of the last chapter of Japan's PRA that it has aimed specifically to assess "whether or not 'plant quarantine measures against *E. amylovora* concerning US fresh apple fruit', which have been taken by Japan based on the proposal by the US government since 1994, are adequate".⁴⁰³

8.285 We note, in this respect, that Japan does not appear to have considered any alternative measures other than these existing measures. We recall that the requirement that the risk assessment be "appropriate to the circumstances", has been considered to leave some flexibility for an assessment of risk, "on a case to case basis, in terms of product, origin and destination, in particular country specific situations".⁴⁰⁴ Arguably, in this instance, part of the circumstances of this particular risk assessment was the fact that the overall Japanese scheme involves an *a priori* prohibition of imports of host plants of fire blight and that this risk assessment was being conducted specifically to verify the viability of a specific set of measures, in order to lift the ban in circumstances suggested and identified by the exporting country itself. The terms of this provision, which refers generally to the measures which "might be applied", suggest to us, however, that consideration should be given not just to those specific measures which are currently in application, but at least to a potential range of relevant measures. Japan has not, in this instance, attempted to identify any other risk-mitigating measures than those actually applied as a result of its discussions with the United States. In this respect, Japan has not, in our view, properly evaluated the likelihood of entry "according to the SPS measures that might be applied".

⁴⁰² US first submission para 83, citing Appellate Body Report in *Australia – Salmon*, para. 133.

⁴⁰³ 1999 PRA, Section 3-1. The United States, however, argues that it accepted the fire blight measures imposed by Japan only reluctantly, recognizing that the scientific evidence did not support the restrictions. See para. 4.29 above.

⁴⁰⁴ Report of the Panel in *Australia – Salmon*, para 8.71.

8.286 With regard to the actual evaluation performed by Japan in relation to those measures which it *has* identified, we recall the Appellate Body's observation in the *Australia – Salmon* case that "some" evaluation of the likelihood of entry [according to the SPS measures which might be applied] is not enough.⁴⁰⁵ We also note that in reaching its conclusion that the Australian risk assessment did not, in that case, meet the third requirement for risk assessments of this type (i.e. an evaluation *according to the SPS measures that might be applied*), the Appellate Body highlighted the following observations of the panel with regard to the quarantine policy options considered to reduce the total risk associated with the disease of concern:

"the ... Report does not substantively evaluate the relative risks associated with these different options. Even though the definition of risk assessment requires an "evaluation ... according to the sanitary ... measures which might be applied", the ... Report identifies such measures but does not, in any substantial way, evaluate or assess their relative effectiveness in reducing the overall disease risk."⁴⁰⁶

8.287 In this instance, each of the measures applied is considered and described in turn in Japan's 1999 PRA, and a brief conclusion is drawn in respect of each of them. While this analysis might be considered to provide "some" evaluation of the risk of entry, establishment or spread and its mitigation through the relevant measure, it seems to suffer from flaws in part linked to the insufficiency of the evaluation of the likelihood itself, and provides only a cursory assessment of some of the proposed measures. The evaluation "according to the measure which might be applied" is considerably less substantial in terms of consideration of the relevant scientific evidence than that found to be insufficient in the *Australia – Salmon* case.

8.288 We also note that a general conclusion is drawn that "so long as [the group of measures under consideration] are adequately obeyed, there is no possibility that fresh apples exported to Japan would be infected with or contaminated by *E. amylovora* through any of cultivation, harvest, selection of fruit, packing or transportation, and *E. amylovora* could never, of course, be introduced via those fruit".⁴⁰⁷ However, no attempt is made to assess the "relative effectiveness" of the various individual requirements applied, and the assessment appears to be based on the assumption from the outset that all these measures would apply cumulatively. In our view, however, an assessment "according to the SPS measures that might be applied" suggests that it would not be sufficient, where a number of distinct measures are considered, to simply draw a general conclusion on their overall combined efficiency, without any analysis of their relative effectiveness and whether and why all of them in combination are required in order to reduce or eliminate the possibility of entry, establishment or spread of the disease.

8.289 We further recall the opinions of Dr Hale and Dr Smith that the 1999 PRA "appeared to prejudge the outcome of its risk assessment"⁴⁰⁸ and that "it was principally concerned to show that each of the measures already in place was effective in some respect, and concluded that all should therefore be applied".⁴⁰⁹ Dr Smith in particular noted that "the question of whether any single measure or combination of fewer measures, could reduce the risk to an acceptable level

⁴⁰⁵ Appellate Body Report in *Australia – Salmon*, para. 134.

⁴⁰⁶ *Ibid.*, para. 133, citing from panel report para 8.90.

⁴⁰⁷ 1999 PRA, section 3-2-3.

⁴⁰⁸ Dr Hale, para. 6.177.

⁴⁰⁹ Dr Smith, para. 6.180.

was not addressed".⁴¹⁰ He further concluded that: "the Japanese PRA had not clearly explained why all the measures it applied were needed".⁴¹¹

8.290 In light of the above, we find that Japan's 1999 PRA concerning fire blight in relation to fresh apples produced in the United States does not meet the requirements of a risk assessment within the meaning of Article 5.1, as defined in Annex A, paragraph 4, of the SPS Agreement.

3. Is the measure "based on" a risk assessment?

8.291 In light of our finding above that Japan's PRA does not amount to a risk assessment within the meaning of Article 5.1, we must also, as a consequence, conclude that Japan's measures are not "based on" a risk assessment. We therefore do not examine this issue further.

4. Conclusion

8.292 In conclusion, we find that the United States has made a prima facie case that Japan has violated Article 5.1 of the SPS Agreement, which Japan has not rebutted. In light of this finding, we do not find it necessary to consider whether the measure at issue is also in violation of Article 5.2 of the Agreement, which identifies further specific factors that Members are required to take into account in their assessment of risks.

G. ARTICLE 5.6 OF THE SPS AGREEMENT

1. Summary of the arguments of the parties⁴¹²

8.293 The United States claims that Japan has acted inconsistently with Article 5.6 of the *SPS Agreement* because Japan's fire blight measures are more trade-restrictive than required to achieve Japan's appropriate level of phytosanitary protection. The United States contends that restricting importation to mature, symptomless apple fruit is an alternative measure that is reasonably available, achieves Japan's appropriate level of protection (ALOP), and is significantly less restrictive to trade than Japan's fire blight measures.

8.294 The United States contends that the fact that Japan's fire blight measures are more trade-restrictive than necessary is also evident from the range of other possible measures that could be envisaged that are less trade-restrictive and that would more than achieve Japan's appropriate level of protection. The United States identified four possible measures:

- (a) Japan could require a phytosanitary certificate that the exported commodity (mature apple fruit) is free from fire blight;
- (b) Japan could require that imported mature, symptomless fruits be harvested in the states of Washington or Oregon;
- (c) Japan could require that imported mature, symptomless fruits be harvested at least 10 meters from a source of inoculum;

⁴¹⁰ Ibid.

⁴¹¹ Ibid.

⁴¹² A detailed account of the arguments of the parties can be found in paras. 4.181-4.200 of this Report.

- (d) Japan could require that imported mature, symptomless fruits be treated with chlorine.

8.295 The United States adds that as the scientific evidence established that apple fruit had never transmitted fire blight and that mature, symptomless fruit are not a pathway for the disease, any of these less trade-restrictive measures would more than achieve Japan's appropriate level of protection. However, for the same reason, the United States argues that, with the exception of the alternative measure in 8.294(a) above, they would also be more trade-restrictive than necessary. Hence, the United States believes that a requirement that exported US apples be mature and symptomless, including through the submission of a phytosanitary certificate, would constitute the only requirement that could be considered as necessary given the scientific evidence.

8.296 The United States argues that its grading standards and law, enforced by federal and/or state inspectors, require exported apples to be mature and symptomless. Apples exported from the United States are inspected for compliance and each fruit passes multiple human and machine-based examinations which categorically exclude immature fruit.

8.297 Japan argues that the exportation of "mature, symptomless" apple fruit to Japan would not achieve Japan's appropriate level of protection. The alternative proposed by the United States is (1) not based on scientific evidence, (2) not supported by real life experience, (3) not practical to implement, and (4) not scientifically sound. Japan claims that the United States has not defined exactly what "mature, symptomless" fruit would mean. Nor has the United States defined specific means to produce, select and export only such apple fruit. Consequently, Japan requests the Panel to consider the "mature, symptomless" criteria as ambiguous and easily manipulated. Japan argues that the "mature, apparently healthy" apple fruit criteria could offer security only when the mechanism by which the bacteria did not exist in such fruit was identified.

8.298 Japan believes that the risk of accidental contamination or erroneous grading is very real. As such, the United States is proposing to replace Japan's current phytosanitary requirements with something: (1) the efficacy of which is questionable; and (2) the quality of which the United States does not guarantee. On this basis, Japan argues that it would be a grave mistake to assume the US proposal would achieve Japan's appropriate level of protection or would provide security at a level comparable to that of the current requirements.

2. Analysis of the Panel

8.299 We have already found above that the phytosanitary measure at issue (i.e. Japan's measure as a whole), breaches Articles 2.2, 5.7 and 5.1 of the *SPS Agreement*. We note that, as stated by the Appellate Body in *Australia – Salmon*,

"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'."⁴¹³

8.300 Therefore, we find it relevant to consider the merits of making a finding in relation to Article 5.6 of the *SPS Agreement*. As recalled by the Appellate Body in *United States – Wool*

⁴¹³ Appellate Body Report in *Australia – Salmon*, para. 223, quoting Article 21.1 of the DSU.

Shirts and Blouses, "a panel need only address those claims which *must be* addressed in order to resolve the matter at issue".⁴¹⁴ Therefore, we must determine whether this additional finding would be necessary for the formulation of sufficiently precise recommendations and rulings so as to allow for prompt compliance by Japan.

8.301 We note that Article 5.6 of the *SPS Agreement* provides 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]

Footnote 3 to Article 5.6 of the *SPS Agreement* 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."

8.302 We recall that what we are reviewing in this case – including with respect to the US claim under Article 5.6 - is the phytosanitary measure at issue *as a whole*, not certain elements of it. In particular, we are not expected to reach a conclusion as to whether some elements of that measure would individually meet the requirements of Article 5.6. Likewise, we are not mandated to find whether some alternative measure would be compatible with the *SPS Agreement* while meeting Japan's phytosanitary objectives.⁴¹⁵

8.303 We have already found that the phytosanitary measure at issue is maintained without sufficient scientific evidence, in contravention of Article 2.2. In other words, this measure cannot be maintained as such by Japan. A finding under Article 5.6 would not add anything in terms of legal implications.⁴¹⁶ In particular, it would not automatically mean that any alternative measure that could be identified would be the only acceptable alternative to Japan's phytosanitary measure in terms of the requirements of Article 5.6. Such a finding would simply establish that Japan's phytosanitary measure *as a whole* is more trade-restrictive than required to achieve Japan's appropriate level of phytosanitary protection. In a context where it has already been established that the phytosanitary measure at issue cannot be maintained, another finding to the same effect that the measure cannot be maintained would be of no practical advantage and thus would be of no assistance to the DSB.

8.304 We therefore decide to exercise judicial economy with regard to the US claim under Article 5.6 and refrain from making any finding.

⁴¹⁴ Appellate Body Report in *United States – Wool Shirts and Blouses*, p. 340.

⁴¹⁵ See para. 8.225.

⁴¹⁶ We recall in this respect that our recommendations are limited, pursuant to Article 19.1 of the DSU, to recommend that the Member concerned bring its measure into conformity with the *SPS Agreement*.

H. ARTICLE 7 AND ANNEX B OF THE *SPS AGREEMENT*1. Summary of the arguments of the parties⁴¹⁷

8.305 The United States claims that Japan has acted in violation of Article 7 and Annex B, paragraphs 5 and 7 of the *SPS Agreement*, in that it has not notified changes introduced to its fire blight measures since the entry into force of the *SPS Agreement* in 1995. More specifically, the United States considers that Japan should have notified to WTO Members the changes effected through Japan's MAFF Notification No. 354, dated 10 March 1997, because it changes Japan's fire blight restrictions and imposes a regulation not based on international standards.

8.306 The United States notes that Japan has substantively changed its fire blight measures since 1995, and has failed to notify these changes. The United States points to four distinct measures by which Japan imposes its requirements regarding fire blight measures: the Plant Protection Law No. 151, Article 7; the Plant Protection Law Enforcement Regulations, Article 9 and Annexed Table 2; the MAFF Notification No. 354; and the MAFF Detailed Rules for US Apples. The United States argues that the latter two of these measures "appear to have been amended or introduced since 1995 without being notified to WTO Members".⁴¹⁸

8.307 Japan considers that, contrary to the US assertions, it did not substantively change its fire blight measures since the entry into force of the *SPS Agreement* in 1995. It further notes that it had notified that it would designate *E. amylovora* as one of the diseases that trigger import prohibition as of 1 April 1997, in accordance with the requirements of Article 7 and Annex B.⁴¹⁹ In Japan's view, the amendments to the notification and the Detailed Rules in 1997 were technical rephrasing of the regulations reflecting the designation of the bacterium, which did not modify in any way the phytosanitary requirements against fire blight.

8.308 In response, the United States observes that this notification "provided notice that Japan's Plant Protection Law Enforcement Regulations would be amended to designate *E. amylovora* as a pest subject to import prohibition"⁴²⁰, but that in its view, a notification of changes to the Plant Protection Act could not be considered as a notification of changes to *other* fire blight measures.

2. Assessment by the Panel

8.309 Article 7 of the *SPS Agreement* provides as follows:

"Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B."

8.310 Annex B to the *SPS Agreement* contains a number of provisions relating to transparency of SPS measures, including notifications. More specifically, paragraph 5 of Annex B foresees the notification of SPS regulations if a number of conditions are cumulatively met, i.e.:

⁴¹⁷ A detailed account of the arguments of the parties can be found in paras. 4.222-4.223 of this Report.

⁴¹⁸ US first submission, para. 114.

⁴¹⁹ Notification contained in G/SPS/N/JPN/19.

⁴²⁰ US answers to additional questions from the Panel, 28 January 2003, para. 42.

- (a) where a relevant international standard does not exist or the content of the proposed measure is not substantially the same as the content of an international standard, guideline or recommendation, *and*
- (b) if the regulation may have a significant effect on trade of other Members.

Paragraph 7 of Annex B, which the United States also argues has been violated by Japan, provides that notifications shall be in French, Spanish or English. The Committee on SPS Measures has adopted recommended guidelines with regard to paragraphs 5 and 6 of Annex B.⁴²¹

8.311 We understand the US claim in respect of Article 7 and Annex B to be limited to two measures only: MAFF Notification No. 354 of March 1997 and the Detailed Rules for US Apples of April 1997, replacing prior similar instruments. In the US view, the notification made by Japan in respect of its Plant Protection Law Enforcement Regulation does not "cover" these separate instruments. Japan, for its part, has indicated in response to a question from the Panel that this notification has no relationship or relevance to the measures at issue, because the change in the regulatory status of *E. amylovora* (i.e. its designation as one of the pests that automatically triggers importation prohibition of host plants) did not in any way affect the measure at issue, which was already in place.

8.312 Both parties thus seem to agree that although Japan made, in 1997, a notification through which it identified fire blight as a pest triggering import prohibition under the Plant Protection Act, this notification is not directly relevant to the measures whose notification is a issue here, i.e. MAFF Notification No. 354 and the 1997 Detailed Rules for US Apples. The question before us is therefore whether these two instruments, which are subsequent to the entry into force of the *SPS Agreement*, should have been notified under Article 7 and Annex B.

8.313 It is not disputed that the present situation is one where "an international standard, guideline or recommendation does not exist [regarding *E. amylovora*] or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation". Therefore, we must determine whether the changes identified above constitute changes which are required to be notified under Article 7 because, *inter alia*, they "may have a significant effect on trade of other Members" in the context of the chapeau to Paragraph 5 of Annex B.

8.314 We consider that the most important factor in this regard is whether the change affects the conditions of market access for the product concerned, that is, would the exported product (apple fruit from the United States in this case) still be permitted to enter Japan if they complied with the prescription contained in the previous regulations.⁴²² If this is not the case, then we must consider whether the change could be considered to potentially have a *significant* effect on trade of other Members. In this regard, it would be relevant to consider whether the change has resulted in any increase in production, packaging and sales costs, such as more onerous treatment requirements or more time-consuming administrative formalities.

8.315 We note that the United States essentially states that Japan "substantially changed its fire blight measures since the entry into force of the *SPS Agreement*". The United States adds that

⁴²¹ G/SPS/7/Rev.2, April 2002, and earlier recommendations.

⁴²² This approach is in line with the discussion of the concept of "significant effect on trade of other Members" in the notification procedures adopted and revised by the SPS Committee G/SPS/7/Rev.2, para. 7).

Japan appeared to have amended or introduced MAFF Notification No. 354 on 10 March 1997, which set the requirements for imports of US apples into Japan, and MAFF "Detailed Rules for US Apples" on 1 April 1997, which implemented Notification No. 354. However, the United States did not specify in what respect Japan had "substantially changed" its fire blight measures. On the other hand, Japan does not admit that it changed its phytosanitary measures for fire blight since 1994.

8.316 We recall that, in *EC – Hormones*, the Appellate Body noted that

"... Panels are inhibited from addressing legal claims falling outside their terms of reference. However, nothing in the DSU limits the faculty of a panel freely to use arguments submitted by any of the parties – or to develop its own legal reasoning – to support its own findings and conclusions on the matter under its consideration."

8.317 However, the Appellate Body clarified in *Korea – Dairy* that "[B]oth 'claims' and 'arguments' are distinct from the 'evidence' which the complainant or respondent presents to support its assertions of facts and arguments".⁴²³ We note in this regard that the party making an allegation must provide sufficient evidence in support of this allegation, and that a panel should not entertain a claim for which a prima facie case has not been made.⁴²⁴ In the present case, the United States has effectively argued that Japan had substantially changed its fire blight measures since the entry into force of the *SPS Agreement*. However, the United States limited its argumentation to mention that new regulations had been implemented and to attach translations of the regulations to its first written submission. It did not specify in what respect these new regulations departed from the previous ones.

8.318 Indeed, either the United States knows in which respect the 1997 texts differ from the ones they replace – in which case it could and should have mentioned it in its submissions – or it does not, in which case it cannot be deemed to have established a prima facie case. In either situation, for the Panel to examine the regulations at issue to identify differences would be equivalent to "making a case" for the United States, something we are not allowed to do. For these reasons we conclude that the United States did not establish a prima facie case in relation to the violation of Article 7 and Annex B of the *SPS Agreement*.

8.319 Even if we were to address that claim, we do not consider that a violation of Article 7 and Annex B has been established. Article 7 of the *SPS Agreement* requires Members to notify "changes" in their SPS measures.⁴²⁵ We note that the MAFF Notification No. 354, dated 10 March 1997, replaced MAFF notification No. 1184, of 22 August 1994.⁴²⁶ Similarly, the Detailed Rules for US Apples, dated 1 April 1997, replaced the MAFF Detailed Rules for US Apples of 22 August 1994.⁴²⁷ We note that both of the preceding instruments predated the entry into force of the *SPS Agreement*. We should therefore consider whether the new instruments adopted in 1997 (subsequent to the entry into force of the Agreement) introduced changes in

⁴²³ Appellate Body in *Korea – Dairy*, para. 139.

⁴²⁴ Appellate Body Report in *Japan – Agricultural Products II*, para.126.

⁴²⁵ In this respect, we do not believe that changes of legal instruments require, in all instances, notification.

⁴²⁶ Exhibit US-11.

⁴²⁷ Exhibit US-12.

Japan's SPS measures such that they should have been notified to WTO Members under Article 7 of the *SPS Agreement*.

8.320 In comparing the MAFF Notification of 1997 with that of 1994, it seems that they both overall follow a very similar structure and contents. Nonetheless, it can be noted that: (1) in the definition of the plants and areas, the 1994 Notification requires that the designation of the area of production as "under intensive pests and diseases control", whereas the 1997 Notification refers to areas "where intensive control for codling moth is conducted and also where the US plant protection authority inspect at proper times" (para. 1); (2) the phytosanitary certificate required under the 1994 Notification refers to codling moth only, whereas the 1997 certificate refers both to codling moth and fire blight; and (3) a requirement for the fruit surface to be sterilized was added in the 1997 Notification, compared with the 1994 Notification.

8.321 We recall that the MAFF Notification of 1997 has included a requirement for the fruit surface to be sterilized which did not appear in the 1994 MAFF Notification as such. Yet, this requirement was already applicable to apples exported from the United States pursuant to another legal instruments: the 1994 MAFF "Detailed Rules for US Apples", at paragraph 6(2).

8.322 We note that a phytosanitary certificate which included only the information required according to the 1994 MAFF Notification would presumably no longer be acceptable since it did not contain the specific information regarding also fire blight required according to the 1997 notification. We note however, on the basis of information submitted by Japan at the interim review stage, that the additional requirements resulting from the 1997 Notification are limited and unlikely to "have a significant effect on trade" in apples from the United States.

8.323 Finally, we note the differences in the definitions of plants and areas in the 1994 and the 1997 Notifications. Since measures were already applied in relation to fire blight before 1997, we do not consider that the change in definitions that we identified would be such as to "have significant effect on trade" in apples from the United States.

8.324 We conclude, therefore, that the MAFF Notification of 1997 may reflect a change in a phytosanitary measure whose content is "not substantially the same as the content of an international standard". However, we do not consider that those changes "may have a significant effect on trade of other Members" and that Japan was required to notify them in accordance with Article 7 and Annex B of the *SPS Agreement*.

8.325 As for the MAFF Detailed Rules for US apples, the 1994 rules already refer to designated areas as areas "with no infection and non-export area or buffer zone in accordance with the following conditions for fire blight" and defines buffer zones and disease-free status for these areas. These appear to be unchanged in the 1997 Detailed Rules. The 1994 Detailed Rules already clearly contain detailed requirements specifically concerning fire blight, and some of these are adjusted in the 1997 Detailed Rules, although it is difficult to judge how substantial such changes actually are.

8.326 We note that most of the changes in the MAFF Detailed Rules for US Apples do not appear to have resulted in any further change which might have affected the access of US apples to Japan. However, when considering the Detailed Rules that have been translated into English from the Japanese language it is difficult to determine whether a change is strictly editorial or whether a more substantial change has been introduced. We are therefore unable to reach any conclusion as to whether Japan was required to notify the changes in the MAFF Detailed Rules for US Apples introduced in 1997.

8.327 For these reasons, we find that the United States failed to make a prima facie case in relation to the violation of Article 7 and Annex B of the SPS Agreement.

I. ARTICLE XI OF GATT 1994

8.328 We have found above that the phytosanitary measure at issue violates Articles 2.2, 5.7 and 5.1 of the *SPS Agreement*. Under those circumstances, we find it appropriate to exercise judicial economy as previous panels did in similar situations in relation to alleged violations of provisions of GATT 1994.⁴²⁸

8.329 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.

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

8.330 We recall that the United States' request for establishment of a panel contains, in addition to the claims already addressed above, the following claims:

"These measures appear to be inconsistent with the commitments and obligations of Japan under ... Article 4.2 of the *Agreement on Agriculture*, and Articles ... , 2.3, ... , ... , 5.3, 5.5, ... , 6.1, 6.2 ... of the *Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)*. Japan's measures also appear to nullify or impair the benefits accruing to the United States directly or indirectly under the cited agreements."⁴²⁹

8.331 Out of these claims, only one – the violation of Article 4.2 of the *Agreement on Agriculture* - was briefly addressed by the United States in its oral submissions before the Panel.

8.332 As mentioned above⁴³⁰, we are mindful that our findings must assist the DSB in making sufficiently precise recommendations and rulings so as to allow for prompt compliance, in order to ensure effective resolution of the dispute. Since we have found that the phytosanitary measure at issue is inconsistent with several provisions of the *SPS Agreement*, we see no particular reason to address the claim of the United States regarding Article 4.2.

8.333 Therefore, we exercise judicial economy and refrain from making any findings with regard to Article 4.2 of the Agreement on Agriculture.

8.334 Regarding the other provisions referred to in the US request for establishment of a panel, namely Articles 2.3, 5.3, 5.5, 6.1 and 6.2 of the *SPS Agreement*, we recall that they were not addressed by the United States in any of its submissions. While they could be considered to be within our terms of reference, we note that, in order for us to make a finding on these claim, the United States should have made a prima facie case for each of them. The United States did not make such a prima facie case for each of these claims.

⁴²⁸ Panel Report in *EC – Hormones (Canada)*, para. 8.275; Panel Report in *Australia – Salmon*, para. 8.185.

⁴²⁹ WT/DS245/2 (emphasis in the original).

⁴³⁰ See, e.g., para. 8.4, referring to the Appellate Body Report in *Australia - Salmon*, para. 223.

8.335 Under these circumstances, we refrain from making any finding regarding the consistency of the phytosanitary measure at issue with Articles 2.3, 5.3, 5.5, 6.1 and 6.2 of the *SPS Agreement*.

8.336 Finally, since we found a violation of the *SPS Agreement*, we see no need to determine whether Japan's measures also nullifies or impairs the benefits accruing to the United States directly or indirectly under the cited agreements in the absence of violation.

IX. CONCLUSIONS

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

- (a) Japan, by maintaining the phytosanitary measure at issue, violated 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) the phytosanitary measure at issue does not comply with the requirement under Article 5.7 of the *SPS Agreement* that relevant scientific evidence be insufficient in order to justify the application of the phytosanitary measure at issue as a provisionally adopted measure; and**
- (c) the phytosanitary measure at issue is not based on a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*.**

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*.