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Japan – Measures Affecting Agricultural Products

Report of the Panel

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I. INTRODUCTION

1.1 In a communication dated 7 April 1997, the United States requested consultations with Japan pursuant to Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU"), Article 11 of the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"), Article XXIII of the General Agreement on Tariffs and Trade 1994 ("GATT 1994"), and Article 19 of the Agreement on Agriculture regarding the prohibition by Japan of imports of certain agricultural products.[1]

1.2 The United States specifically alleged that, for each agricultural product for which Japan required quarantine treatment, Japan prohibited the importation of each variety of that product until the quarantine treatment had been tested for that variety, even though the treatment had proven effective with respect to other varieties of the same product. The United States claimed that Japan's prohibition adversely affected exports of US agricultural products, and, furthermore, that Japan's measure appeared to be inconsistent with the obligations of Japan under the SPS Agreement, the GATT 1994 and the Agreement on Agriculture. The provisions of these agreements with which these measure appeared to be inconsistent included, but were not limited to: (i) SPS Agreement, Articles 2, 4, 5 and 8; (ii) GATT 1994, Article XI; and, (iii) the Agreement on Agriculture, Article 4. The measures also appeared to nullify or impair benefits accruing to the United States directly or indirectly under the cited agreements. Consultations were held on 5 June 1997, but failed to settle the dispute.[2]

1.3 In a communication dated 3 October 1997, the United States requested the Dispute Settlement Body ("DSB") to establish a panel with standard terms of reference as set out in Article 7 of the DSU.[3] 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 an additional claim of inconsistency under Article 7 of the SPS Agreement.

1.4 On 18 November 1997, the DSB established a panel pursuant to the request of the United States, in accordance with Article 6 of the DSU.[4] 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/DS76/2, 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 18 December 1997, the Panel was constituted with the following composition:

Chairman: Mr. Kari Bergholm

Panelists: Mr. Germain Denis
Mr. Eiríkur Einarsson

[1] WT/DS76/1 (Request for Consultations by the United States).

[2] WT/DS76/2 (Request for the Establishment of a Panel by the United States).

[3] WT/DS76/2 (Request for the Establishment of a Panel by the United States).

[4] WT/DS76/3 (Constitution of a Panel Established at the Request of the United States).

1.6 The European Communities, Hungary and Brazil reserved their right to participate in the Panel proceedings as third parties.

1.7 The Panel met with the parties on 2 and 3 April 1998. It met with third parties on 3 April 1998. The Panel consulted scientific and technical experts and met with them on 23 June 1998. The Panel held a second meeting with the parties on 24 June 1998.

1.8 On 3 July 1998 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 stated in document WT/DS76/4.

1.9 The Panel issued its interim report on 6 August 1998. On 21 September 1998, on request by Japan, an interim review meeting was held with the parties. The Final Report was circulated to the parties on 6 October 1998. The report was circulated to Members in all three languages on [27 October 1998].

II. FACTUAL ASPECTS

A. GENERAL

1. Codling moth

2.1 Codling moth (*Cydia pomonella*) is a pest which invades apples, cherries, nectarines and other fruit crops. Newly-hatched larvae of codling moth are known to enter into the fruit. In the United States, the codling moth is a pest of apples and walnuts; it is also known, on occasion, to infest nectarines and cherries. Other hosts of codling moth include apricots, plums, pears and quinces.

2.2 There are four identifiable life stages of the codling moth: egg, larva, pupa and adult. Mated female adults lay their eggs on a suitable substrate such as leaves, nuts or fruit. All life stages are highly dependent upon temperature for development; the higher the temperature, the more rapid the development. After the eggs hatch, newly hatched first stage (instar) larvae find a suitable host to complete their development. They usually burrow into the host. The larvae will molt (shed their skin) four times thereafter inside the fruit, thus producing five larval growth phases called instars. When mature, the fifth instar larvae will exit the host to form a pupae within a silken cocoon. The cocoon is usually formed on the bark of the tree or in the litter at the base of the host plant.

2.3 The next generation of adult moths will exit from the pupae in 1-2 weeks. Depending on temperature, emergence may take longer. Under optimum conditions, developmental time from egg to adult is about 30-40 days. As daylight hours become shorter (10 hours light; 14 hours dark) during the late summer and fall, mature fifth instar larvae will exit the host, but hibernate through the winter as mature larvae within cocoons on bark or litter at the tree base. This larval hibernation (diapause) is a mechanism for survival through the winter. The diapausing larvae will form pupae in the spring when daylight hours and temperature begin to increase toward 14 daylight hours or more. Depending upon temperature, moths will emerge in three to four weeks after the pupae are formed.

2.4 The seasonality of host fruits is important vis-à-vis what life stages of the codling moth might be expected to occur at harvest. In the United States, walnuts are harvested after diapause has been induced in mature larvae. Thus the quarantine treatment for codling moth in walnuts is more severe (using comparatively higher levels of fumigant) than that required for fruits such as cherries and nectarines.

2.5 The fruit development of apples coincides with the time, mid-to-late summer, during which the codling moth is numerous. Severe economic losses can occur if codling moth is not adequately controlled in the field. The quarantine treatment applied to harvested apples is a multiple treatment involving cold temperature and a methyl bromide treatment. The cold treatment destroys most of the codling moth eggs and the fumigation destroys any remaining larvae.

2.6 In contrast to walnuts and apples, cherries are an early spring/early summer crop and only eggs or non-diapausing larvae would be expected to be found. With regard to nectarines, the harvest of nectarines in the United States begins in May and ends in late July to early August, before diapause is induced.

2.7 The Japanese archipelago forms a chain spreading across 3,000 km. from the north to the south between the latitudes 20 to 45 degrees north. Although most of Japan belongs to the temperate monsoon zone, the northern island of Hokkaido lies in a sub-arctic zone and a subtropical climate prevails in the southern edge of the South-western and Ogasawara islands. Ocean currents and prevailing westerly winds contribute to a diversity of climatic conditions. While codling moth is prevalent throughout the temperate zone, the pest has not been discovered in Japan.

2.8 There is no dispute between the parties that Japan is free of codling moth and that it is a pest of quarantine significance to Japan.

2. Methyl bromide

2.9 The Montreal Protocol on Substances that Deplete the Ozone Layer (the "Montreal Protocol") requires developed countries to phase-out the production and importation of methyl bromide beginning in 1999 and ending, with a total phase-out, on 1 January 2005. Developing countries will freeze the production and importation of methyl bromide as of 1 January 2002 and begin a step-down reduction in 2005, with total phase-out by 2015. US law currently calls for a phase-out of methyl bromide production and importation by 1 January 2001.

2.10 Notwithstanding the above, the use of methyl bromide for quarantine and pre-shipment applications is exempted from the phase-out schedule.[5] The US Administration has expressed willingness to consult with the US Congress on changes to US law if alternatives do not exist for control of key pests as the 2001 phase-out date approaches.

3. Technical and scientific terms used in the parties' submissions

CxT value (Concentration times time)

2.11 The CxT value for a fumigation is an expression of the relationship between fumigant gas concentration and time in the fumigation enclosure or chamber. It is an expression of the active gas dosage to which the pest or test organism is exposed during the time of the treatment. Because the concentration decays during the fumigation time, "concentration" is an average value derived from a number of measurements and requires temperature, load and humidity to be specified for proper definition.

Dose-mortality test (DMT)

2.12 The dose-mortality test is an experimental procedure in which the response of an organism is estimated for a series of mortality-inducing doses of a specified treatment. Where possible, individual

[5] Article 2H:6 of the Montreal Protocol.

dose-mortality tests target a specific stage of an organism as the susceptibility to a treatment can vary between life stages. The main purposes of dose-mortality testing are to produce data for analysis used for the determination of parameters categorizing the response of an organism, and the comparisons of efficacies of different treatments. In developing quarantine treatments against codling moth for products exported to Japan, dose-mortality testing is used to produce data for analysis for the determination of the least vulnerable stage of the pest and the prediction of a treatment dose to meet a required level of efficacy. The target organism test unit is usually a sub-sample of 20 – 50 insects; the test is typically replicated three times, at each dose level. For a satisfactory result, five or more dose levels are usually required, evenly spaced between 0 and 100 per cent mortality.

Fumigation

2.13 To kill pathogens or insects by using gas or fumes. A fumigant is a pesticide which acts upon the target pest as a gas. For the purposes of this report, the fumigant is methyl bromide (MB), and "MB treatment" refers to fumigation with methyl bromide.

Probit analysis, LD (lethal dose) and probit 9

2.14 Probit analysis is a biometrical technique for analysis of experimental data in which the quantitative response of an organism, usually expressed as mortality, is subjected to regression analysis with respect to treatment dose. Mathematical transformation of mortality to probability units, termed "probits", assists in conversion of the normal distribution (curve) of the response data to a linear distribution to facilitate analysis. Dose data is frequently, but not invariably, logarithmically transformed for the same purpose of linearity. The outcomes of probit analysis are values such as LD (lethal dose), LC (lethal concentration) or LT (lethal time) for a nominated proportion of the population (for example, 50 per cent or 99.99 per cent), together with nominated confidence or fiducial intervals (for example, 95 per cent).[6] The main purposes of probit analysis are (i) to define susceptibility of a population of target organisms to a treatment in terms of LD, LC or LT values; (ii) subsequent comparisons of susceptibility of populations of target organisms, varying response according to substrates, or treatment; and, (iii) the prediction of the dose required for a specific level of treatment efficacy.

2.15 Probit 9 is equivalent to a target level of mortality, or level of treatment efficacy, of 99.9968 per cent mortality.

Sorption

2.16 The sum of adsorption, absorption and chemisorption. Adsorption is a physical surface effect and results from the attraction of molecules to the surface of products[7] and other materials in the fumigation chamber. Absorption is also a physical process whereby the chemical enters into the product and other materials in the fumigation chamber. Chemisorption is an irreversible reaction in which residues are left in the fumigated products and materials. When the pest takes in the fumigant while in a product, or takes in the fumigant while on the surface of the fruit, it may die.

[6] Dr. Heather referred to: Steel, R.G.D. and Torrie, J.H., *Principles and Procedures of Statistics with Special Reference to the Biological Sciences*, McGraw-Hill (1960) p.22.

[7] In this report the word "product" is used instead of "commodity" or "species".

Variety

2.17 A category within a species, based on some hereditary difference.[8]

B. JAPAN'S PLANT PROTECTION LAW AND THE ENFORCEMENT REGULATION

1. General

2.18 The legislation relevant to this dispute is contained in the Japanese Plant Protection Law, enacted on 4 May 1950, as amended (the "Plant Protection Law").[9] The applicable regulation is the Plant Protection Law Enforcement Regulation (the "Enforcement Regulation"), enacted 30 June 1950, as amended.[10]

2.19 The stated objective of the Plant Protection Law is to ensure the "stabilization and development of agricultural production by inspecting export plants, imported plants and domestic plants, by controlling injurious animals and plants, and by preventing the outbreak or spreading thereof".[11]

2.20 The Plant Protection Law identifies as "quarantine pests" those pests whose existence has not been confirmed in Japan, or those which exist in part of the Japanese territory and are subject to official control (Article 5.2 of the Plant Protection Law). Subsequent to such identification, the Plant Protection Law establishes an inspection mechanism for imported plants and plant products:

(a) all imported plants and plant products have to be accompanied by a phytosanitary certificate, in principle, which states that the plants and plant products are considered free from the quarantine pests (Article 6, paragraph 1 of the Plant Protection Law);

(b) in certain cases, a growing-site inspection by the foreign authorities is mandatory (Article 6, paragraph 2). This mechanism was introduced by the 1996 amendment of the Plant Protection Law, and took effect April 1998;

(c) upon entering the Japanese territory, plants and plant products have to be inspected by plant quarantine officers at one of the 101 major ports (or airports) of entry designated by the Enforcement Regulation (Article 6, paragraph 3; Article 8, paragraph 1); and,

(d) certain plants may be subjected to post-entry inspection at a post-entry quarantine station for viruses and other pests which might not be detected by the visual inspection at the ports of entry (Article 8, paragraph 7) .

[8] Webster's Encyclopaedic Unabridged Dictionary of the English Language, 1996 Random House. The International Convention for the Protection of New Varieties of Plants of 2 December 1961, Article 1, (vi) defines "variety" as: "[A] plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be – defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, - distinguished from any other plant grouping by the expression of at least one of the said characteristics and – considered as a unit with regard to its suitability for being propagated unchanged ….".

[9] Law No. 151 of 1950; most recently amended in 1996. (Japan, Exhibit 6)

[10] MAFF Ordinance No.73 of 1950. (Japan, Exhibit 7)

[11] The Plant Protection Law, Article 1.

2.21 If a plant or a plant product fails to pass the above inspection, it will either be destroyed or disinfected/disinfested under the Plant Protection Law. In order to counter the risk of inadvertent introduction of particularly harmful quarantine pests, the Plant Protection Law delegates to the Ministry of Agriculture, Forestry and Fisheries ("MAFF") the authority to prohibit importation of certain host plants from countries or areas infested by the pests (Article 7, paragraph 1, item 1).[12] This authority is exercised in the form of a list of prohibited products, which is contained in a table annexed to the Enforcement Regulation.[13] This "Annexed Table" identifies the quarantine pest which constitutes the cause of the import prohibition, the countries or areas from which importation is prohibited, and the prohibited host plants and their specific parts.

2.22 In practice, the confirmation process for efficacy of disinfestation treatment consists of two parts: the process applicable to the initial lifting of the import prohibition and the test for the approval of additional varieties. These are contained in two sets of guidelines developed in 1987 and which have, to date, not been published – although they are available to interested parties.[14] The contents of these are summarized below.

2. Initial lifting of prohibition

2.23 The "Experimental Guideline for Lifting Import Ban - Fumigation" ("Guidelines for initial lifting") outline the procedure applicable to the initial lifting of the prohibition. The procedure includes the following:

Basic Tests (small-scale dose-mortality tests)[15]

(a) Determination of the most resistant stage of insects to fumigation (a comparative test of susceptibility between development stages) estimated through small-scale dose-mortality tests.

(b) Estimation of treatment schedule achieving 100 per cent mortality.

Large-Scale Mortality Test

The efficacy of the chosen treatment is tested using 30,000 insects at the most resistant stage on the variety (the representative variety). Japan accepts the efficacy of the treatment if no insect survives, as an approximation of probit 9.

On-site confirmatory test

The results of the test are further confirmed on site by Japanese experts in the on-site test using 10,000 sample insects (on the representative variety).

[12] In addition, the Plant Protection Law prohibits the importation of quarantine pests, soil or plants contaminated by soil and packages containing these articles (Article 7, paragraph 1, items 2 to 4).

[13] List of the Plants Subject to Import Prohibition, Plant Protection Law Enforcement Regulation Annexed Table 2. (Japan, Exhibit 8)

[14] Contained in Japan, Exhibit 10.

[15] A glossary of technical and scientific terms is contained in paragraphs 2.11 to 2.17.

3. Lifting of prohibition for additional varieties

2.24 The guidelines for the approval of additional varieties are set out in "Experimental Guide for Cultivar Comparison Test on Insect Mortality – Fumigation". These include:

Basic test (small-scale dose-mortality test)

As the most resistant development stage of the insect is identified when (part of) the species is approved for the first time, this test targets only the comparative efficacy between the approved varieties and the newly proposed varieties. Response of insects in additional varieties is tested for different levels of treatment (e.g., the amount of fumigant, the length of cold treatment). The results are typically analyzed by comparing LD_{50} by probit analysis. If the new varieties are found to show equivalent or superior effectiveness compared to approved varieties, no large-scale mortality test is necessary. If the result is significantly less effective, however, a new treatment standard has to be developed and tested by a large-scale experiment.

On-site confirmatory test

This test is performed on one representative variety. Japanese experts are sent to confirm the on-site test.

TABLE 1
Test Schedule for Initial and Additional Lifting

Tests (purpose)	Test insects	Subject varieties	Initial lifting of prohibition	Lifting of prohibition for additional varieties
Dose-response (1) identification of the most resistant development stage of the pest; and (2) identification of the representative variety[16]	2,000 in total (200 per one dose bracket times five dose brackets in two replicates)	ALL	YES (for (1) and (2))	YES (for (2))
Large-Scale Confirmation of efficacy	30,000 (10,000 each in three replicates)	ONE	YES	NO*
On-Site Confirmatory Final confirmation	10,000	ONE	YES	YES

* This assumes that the existing treatment would be found by basic tests to be adequate for new varieties. If not, a new treatment would have to be established and confirmed by large-scale tests.

[16] See paragraph 2.23 (under Large-Scale Mortality Test).

C. RELEVANT INTERNATIONAL STANDARDS, GUIDELINES AND RECOMMENDATIONS - THE IPPC

1. General

2.25 The SPS Agreement makes reference, in a number of provisions, to the "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 Secretariat of the International Plant Protection Convention ("IPPC" or "the Convention") in cooperation with regional organizations operating within the framework of the IPPC.

2.26 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 106 contracting parties.

2.27 The purpose of the Convention 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 standard-setting.

2.28 The first text of the international convention 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 Convention, 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. Guidelines for Pest Risk Analysis

2.29 Generally, IPPC standards have their origin in national or regional initiatives, and/or are drafted by expert groups organized by the IPPC Secretariat. The topics and priorities for draft standards are determined by the Secretariat in consultation with Regional Plant Protection Organizations and their members. IPPC standards fall within two categories: reference standards and other standards.

2.30 Among the IPPC's completed standards is the Guidelines for Pest Risk Analysis ("PRA Guidelines"), adopted in 1995.[17] The IPPC describes the PRA Guidelines 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". Finally, based on the information gathered under Stages one and two, Stage three determines the appropriate phytosanitary measure(s) to be adopted. This pest risk management to protect the endangered areas should be proportional to the risk

[17] International Standards for Phytosanitary Measures, Guidelines for Pest Risk Analysis, FAO Publication No.2. (US Exhibit 5)

identified in the pest risk assessment. The three stages are summarized in the PRA Guidelines as: "initiating the process for analysing risk", "assessing pest risk" and "managing pest risk", respectively.

2.31 Pest risk management options include[18]:

(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.

2.32 Pest risk management options may also concern ways of reducing risk of damage. The PRA Guidelines state 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[19]:

(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.

2.33 In sum, the PRA Guidelines define a procedure by which a pest risk analysis should be performed, and lay down relevant factors which should be taken into account by the authorities in the process.

III. CLAIMS OF THE PARTIES

3.1 The **United States** claimed that Japan's varietal testing requirement as it applied to quarantine treatments for codling moth was an unjustified barrier to trade and was inconsistent with the SPS Agreement. As a result of Japan's measure, maintained ostensibly for plant health ("phytosanitary") reasons, Japan effectively blocked access to its market for US varieties that competed with a number

[18] PRA Guidelines, p.20.

[19] PRA Guidelines, p.20.

of Japanese produced varieties of the same product. The United States claimed that Japan's varietal testing measure had failed each of the following obligations under the SPS Agreement in that it:

(a) was maintained without sufficient scientific evidence (Article 2.2);

(b) was not based on scientific principles (Article 2.2);

(c) was not based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health (Article 5.1);

(d) had not taken into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific pests; relevant ecological and environmental conditions; and quarantine or other treatment (Article 5.2);

(e) was more trade-restrictive than required to achieve the appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility (Article 5.6);

(f) was not transparent in that one Enquiry Point was not responsible for the provision of answers to all reasonable questions from interested Members regarding the measure and there was furthermore no published source for the measure itself (Article 7); and,

(g) it was reliant upon control and inspection procedures, and applied to a modified product (i.e. a different variety of a product), was not limited in its information requirements to what was necessary for appropriate control and inspection procedures, and was not limited to what was necessary to determine whether adequate confidence existed that the product still met the regulations concerned (Article 8 and Annex C).

3.2 In its request for consultations, the United States claimed that the fact that Japan's varietal testing requirement was not a legitimate phytosanitary measure meant that it was also inconsistent with Article XI of GATT 1994 and Article 4 of the Agreement on Agriculture. However, the United States did not pursue these claims in its submissions or in its oral statements to the Panel, nor did it request findings with respect to these claims.

3.3 **Japan** claimed that its policy was fully consistent with the relevant articles of the SPS Agreement, Article XI of GATT 1994 and Article 4 of the Agreement on Agriculture. In particular, Japan emphasized that the measure was entirely based on phytosanitary considerations and that the suggestion by the United States to the contrary was false.

IV. ARGUMENTS OF THE PARTIES

A. THE SCOPE OF THE DISPUTE

4.1 The **United States** recalled that following the establishment of the Panel, Japan had raised questions concerning the scope of the dispute.[20] The United States reiterated that the scope of the dispute at issue, consistent with the request of the United States for the establishment of the Panel on 18 November 1997[21], was the prohibition by Japan of the importation of any variety of an agricultural product on which Japan claimed that the pest codling moth might occur until such time as the variety

[20] This was contained in a letter from Japan to the Chairman of the Panel, dated 13 January 1998.

[21] WT/DS76/2.

had been separately tested with respect to the efficacy of treatment with methyl bromide or treatment with methyl bromide and cold storage.

4.2 The United States noted that varietal testing applied to potential US fruit exports largely in instances that involved codling moth. The facts submitted by the United States were therefore limited to varietal testing of quarantine treatment efficacy against codling moth on certain products, using the preferred treatment of MB fumigation or a two-component treatment of MB fumigation and cold storage. The scope of the dispute thus concerned the prohibition by Japan on the importation of *any variety of an agricultural product* on which Japan claimed the pest codling moth could occur until such time as the variety had been separately tested with respect to the efficacy of treatment with methyl bromide or methyl bromide and cold storage.

4.3 In its first submission, **Japan** raised two issues in respect of the scope of the dispute: (1) relevant provisions of the WTO agreements on which the complaining party's claim was based, and (2) the factual scope of the complaint. Japan argued that in its request for bilateral consultations[22], the United States had not clearly identified the relevant provisions and the covered agreements. The United States had stated that relevant provisions "include, but are not limited to" Articles 2, 4, 5 and 8 of the SPS Agreement, Article XI of GATT 1994 and Article 4 of the Agreement on Agriculture. The US request for the establishment of a panel had expanded the legal basis to "include, but are not limited to" Article 7 of the SPS Agreement.[23] Thereafter, the first written submission of the United States (of 19 February 1998) focused only on Articles 2.2, 5.1, 5.2, 5.6, 7 and 8, on Annex B, paragraph 1, and on Annex C, paragraph 1 (c) and (h). Moreover, Japan noted that although the United States referred to Article XI of GATT 1994 and to Article 4 of the Agreement on Agriculture in a footnote, it did not even attempt to offer a *prima facie* case in that regard.

4.4 Japan argued that the Panel should find that the phrase "including but not necessarily limited to" did not constitute part of its terms of reference[24] in light of the recent Appellate Body ruling in *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products* ("*India - Pharmaceuticals*"), which held that the phrase failed to comply with the requirement under Article 6.2 of the DSU.[25]

4.5 Japan argued, furthermore, that the Panel should also eliminate Article 7 of the SPS Agreement from the scope of its investigation, because that article was mentioned by the United States for the first time in its request for establishment of a panel, and no consultation had been held on that particular provision.

4.6 In regard to the description of the scope of the dispute by the United States, Japan requested that the United States clarify if there was any fruit other than "apples, cherries, nectarines and walnuts" which the United States believed was covered by the complaint. Japan noted that for those four products there was no disagreement between the parties as to the efficacy of the current treatment being applied to the approved varieties. Hence, if the scope of the dispute were limited to those fruits, the matter before the Panel was a highly practical question of how effective the same treatment would be for varieties which had not been approved so far. In addition, Japan requested the United States to clarify if the scope of the examination by the Panel was limited to MB treatment or treatment with methyl bromide and cold storage.

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[22]WT/DS76/1.

[23]WT/DS76/2.

[24]WT/DS76/3.

[25] WT/DS50/AB/R, adopted 19 December 1997, paragraph 90.

4.7 The **United States** claimed that Japan had misunderstood the Appellate Body Report on *India – Pharmaceuticals*. In that report, the Appellate Body found that the use of the phrase "including but not necessarily limited to" was "not sufficient to bring a claim relating to Article 63 [of the *TRIPS Agreement*] within the terms of reference of the Panel".[26] Accordingly, the findings of the *India - Pharmaceuticals* Report applied in a situation where a complainant made a claim with respect to a provision of an agreement that was not identified in the request for a panel.[27] The current dispute did not present the Panel with a similar situation. The United States had not made any claim with respect to any provision of an agreement that had not been specifically identified in its request for the Panel at issue. If at some time Japan were to believe that the United States had made such a claim, then Japan could have presented its arguments to the Panel and the United States would have had the opportunity to respond. The United States argued that Japan was seeking a finding in the abstract apparently based on a hypothetical situation, a finding that furthermore would be inconsistent with the practice of judicial economy supported by panels and the Appellate Body.[28]

4.8 In respect of Article 7 of the SPS Agreement, the United States claimed that Japan was in error in stating that no consultation was held on Article 7 of the SPS Agreement. In fact, Article 7 had been specifically mentioned in the US statement at those consultations.[29] In the course of the US discussions with Japan concerning Japan's measures at issue, and also considering Japan's answers to questions before the consultations, it became clear to the United States that these measures were not transparent and were not clearly set forth anywhere. It was only in the consultations, where Japan provided an oral explanation of the way in which some of its measures operated, that the United States had been able to begin to understand the legal basis and scope of Japan's measures.

4.9 The United States noted that a consultation request had to provide an "identification of the measures at issue and an indication of the legal basis for the complaint" (DSU Article 4.4). However, nothing in the DSU required that a Member had to ascertain all of the possible legal claims and relevant provisions of the WTO agreements *before* the Member could even request consultations. In this context, the United States noted that the Panel in *European Communities - Regime for the Importation, Sale and Distribution of Bananas* stated:

> "[as to the argument that] consultations must lead to an adequate explanation of the Complainants' case, we cannot agree. Consultations are the first step in the dispute settlement process. While one function of the consultations may be to clarify what the case is about, there is nothing in the DSU that provides that a complainant cannot request a panel unless its case is adequately explained in the consultations. … Ultimately, the function of providing notice to a respondent of a complainant's claims and arguments is served by the request for establishment of a panel and by the complainant's submissions to that panel."[30]

4.10 The United States stated that one of the purposes of consultations was to foster a better understanding of the relevant measures and concerns of the various Members in order to promote a satisfactory adjustment of the matter. Consultations were often the first time that the Member

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[26] *Ibid*, paragraph 90.

[27] The United States noted that it had been described in the Appellate Body Report on *India - Pharmaceuticals* as "there is a failure to identify a specific provision of an agreement that is alleged to have been violated", WT/DS50/AB/R, paragraph 91.

[28] In this respect, the United States recalled the Appellate Body Report in *United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, adopted 23 May 1995, p.18.

[29] The United States referred to US Exhibit 31, p.5.

[30] WT/DS27/R/USA, adopted 25 September 1997, paragraph 7.20.

maintaining the measure provided a detailed description of the measure and relevant facts and legal documents. Consultations were not a "dress rehearsal" or "moot court" for the panel process requiring Members to have worked out all of their claims and positions in advance and presenting them in the consultations for the other side to practice its prepared responses.

4.11 The United States noted that the DSU reflected the difference between requests for panels and requests for consultations by using different terms for each. With respect to panels, the DSU required that a request for the establishment of a panel provide a "brief summary of the legal basis of the complaint sufficient to present the problem clearly".[31] However, with respect to consultations, the DSU merely required that requests for consultations give "an indication" of the legal basis for the complaint.[32] Moreover, if a matter had indeed been discussed in consultations, as had been the case with respect to the US claim under Article 7 of the SPS Agreement, the responding party had even less basis to claim unfair surprise. For the above reasons, there was no basis for the Panel to find that the US claim under Article 7 of the SPS Agreement fell outside the scope of the panel proceeding.[33]

4.12 The United States reiterated that the dispute covered the prohibition by Japan on the importation of *any variety of an agricultural product* on which Japan claimed that the pest codling moth could occur. In this regard, the United States noted that Japan was best positioned to provide a comprehensive list of products to which its measures applied. Due to the lack of transparency of Japan's measures, the United States had had difficulty in ascertaining the full range of agricultural products involved. According to the "List of Plants Subject to Import Prohibition" submitted by Japan in response to US questions in connection with the consultations, the United States understood that Japan's varietal testing requirements, as they pertained to the pest codling moth, also applied to at least the following products: "apricot, cherry, ... plum, pear, quince and peach, ... and apple, ... and fresh fruits and nuts in shell of walnut".[34] The United States requested further clarification from Japan as to whether there were other products that were or could be subject to this import prohibition. For the purposes of the dispute at issue, the relevant treatments were treatment with methyl bromide or treatment with methyl bromide and cold storage.

4.13 **Japan** explained that the Japanese Government had long since published in the Official Gazette the list of plants subject to import prohibition, namely eight plant products which were host plants of codling moth: apricot, plum, pear, quince, apple, walnut, peach including nectarine and cherry. However, Japan maintained that from a practical point of view, the products to be covered by the current Panel had to be limited to four: apples, cherries, nectarines and walnuts. Japan noted that no data had been provided nor any mention been made of any product other than these four products in the US submissions; hence, the other four products should be excluded from the scope the dispute.

4.14 The **United States** noted that while it had thus far referenced only four products for which it had negotiated entry on some varieties - apples, cherries, walnuts and nectarines - the principles that applied to these products applied equally to the other four products named in the relevant regulation.

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[31] Article 6.2 of the DSU.

[32] Article 4.4 of the DSU.

[33] In this respect, the United States agreed with the findings of the Panel in *European Communities - Regime for the Importation, Sale and Distribution of Bananas*: "Consultations are, however, a matter reserved for the parties. The DSB is not involved; no panel is involved; and the consultations are held in the absence of the Secretariat. In these circumstances, we are not in a position to evaluate the consultation process in order to determine if it functioned in a particular way. While a mutually agreed solution is to be preferred, in some cases it is not possible for parties to agree upon one. In those cases, it is our view that the function of a panel is only to ascertain that consultations, if required, were in fact held or, at least, requested". (WT/DS27/R/USA, paragraph 7.19)

[34] Japan clarified that the term "fresh fruits" related solely to walnuts. Furthermore, nectarine was a variety of peach, this was subsequently confirmed by all three experts advising the panel – therefore the term: "peaches, including nectarines" (Section VI of this report deals with the Panel's consultation with scientific experts).

The United States had an interest in exporting to Japan also plums, pears, quince, peaches and apricots, and had, in fact, requested permission to export to Japan one variety of plums. The omission of the latter products from the debate had only to do with the fact that these had not yet been proposed for export to Japan. Japan's measure was an import prohibition or restriction with respect to these products as well, and the United States had specifically included in its claims all products subject to Japan's measure. Moreover, unlike cherries, nectarines and walnuts, Japan had not pointed to a scientific study regarding any of these other products - presumably because there were no studies that supported its theory of variety affecting efficacy of treatment.

4.15 The Panel made a preliminary ruling on these matters at its first substantive meeting with the parties on 2 April 1998. The ruling is contained in paragraph 8.4.

B. THE MEASURE AT ISSUE

4.16 The **United States** alleged that Japan imposed an absolute ban on all products that Japan asserted were potential hosts to a quarantine pest such as codling moth. The Japanese *legislation* which was applicable imposed an import ban on enumerated "prohibited articles"; this was the Plant Protection Law (described under paragraph 2.18), enacted on 4 May 1950, as amended. The only applicable *regulation* was the Enforcement Regulation, enacted 30 June 1950, as amended. No legislative or regulatory provision specifically described or imposed a requirement of varietal testing to obtain an exemption from such a ban.[35] The *practice* of varietal testing was not formally written in any law or regulation, but stemmed from the implementation of the aforementioned legislation and regulation.

4.17 The United States noted that Article 7 of the Plant Protection Law specified which products were prohibited for importation; these included "quarantine pests". The annex to Article 9 of the Plant Protection Law Enforcement Regulation specified the pest species that were subject to quarantine, the country(ies) or region(s) from which the pest originated, and the plant species that Japan asserted to be potential hosts to the quarantine pest. The annex listed the plants prohibited from entry, and an appendix to the list also indicated which varieties of products from specified regions were permitted entry into Japan. The United States maintained that the regulation was otherwise unclear on the question of *how* a particular variety might be permitted entry.

4.18 As it had evolved through practice, the ban was lifted only for specific varieties of an identified host product upon satisfaction of "quarantine treatment standards established through a regime of basic testing ... to prove complete mortality of the most resistant stage of the relevant pest in the scale of more than 30,000 test insects being used".[36] "The disinfestation test with a scale of 30,000 test insects is to seek for a disinfestation rate equivalent to probit 9 (99.9968 per cent mortality) which was adopted by the United States in its treatment standard."[37] To satisfy this requirement for permission to export a new variety, Japan required elaborate and repetitive testing procedures, and a public hearing process.[38]

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[35] According to the United States, Japan had confirmed this under Question 2 of Japan's Response to US Consultation Questions (US Exhibit 3), in which Japan stated: "Lifiting of import bans by variety is based on the legislation tabulated below. There is no situation where lifting of import bans by variety is based on legislation other than that given below". The table referred to listed the Plant Protection Law and the Enforcement Regulation.

[36] Japan's response to Question 5 of US Consultation Questions. (US Exhibit 3)

[37] Japan's response to Question 8 of US Consultation Questions. (US Exhibit 3)

[38] Japan's responses to Questions 5 and 8 of US Consultation Questions. (US Exhibit 3)

4.19 The United States acknowledged that the SPS Agreement recognized that countries had a sovereign right to implement legitimate restrictions on trade to protect their plant life and health from the introduction of pests that might cause harm. However, the United States stressed that the SPS Agreement did not permit unjustified import prohibitions that did not address legitimate phytosanitary concerns. The Japanese requirement of varietal testing was exactly the kind of unnecessary and unjustified measure that the SPS Agreement was intended to prohibit.

4.20 The history of US efforts to export apples, cherries, walnuts, and nectarines illustrated the way in which the Japanese insistence on varietal testing had served as a significant barrier to trade. Since the early 1970s[39], the United States had been engaged in a rigorous research effort to export various fruit products to Japan. An effective quarantine treatment[40] for cherries had first been developed in the United States in 1976; for US walnuts in 1984; for US nectarines in 1986; and an effective treatment for US apples had first been developed in 1986.

TABLE 2

History of Japanese Approval Process for Varietal Testing on US products

Product	Date Treatment Developed*	Testing Process Began	Confirmatory Test Dates	Public Hearing Date**	Approval Date
APPLES					
Red Delicious	1986	Oct. 1969	17-29 April 1994	7 and 8 July 1994	22 August 1994
Golden Delicious	1986	Oct. 1969	17-29 April 1994	7 and 8 July 1994	22 August 1994
Gala	1986	Oct. 1994	4 Sept. - 26 Nov. 1997	Pending	Pending
Granny Smith	1986	Oct. 1994	4 Sept. - 26 Nov 1997	Pending	Pending
Jonagold	1986	Oct. 1994	4 Sept. - 26 Nov 1997	Pending	Pending
Fuji	1986	Oct. 1994	4 Sept. - 26 Nov 1997	Pending	Pending
Braeburn	1986	Oct. 1994	4 Sept. - 26 Nov 1997	Pending	Pending
CHERRIES					

[39] Moffitt, "Methyl Bromide Fumigation Combined with Storage for Control of Codling Moth in Apples," 64(5) J. Econ. Entomol. pp. 1258-1260, 1971. (US Exhibit 21)

[40] The United States noted that the development of an effective treatment meant that probit 9 security was achieved during large-scale tests of 30,000 codling moths.

TABLE 2

History of Japanese Approval Process for Varietal Testing on US products

Product	Date Treatment Developed*	Testing Process Began	Confirmatory Test Dates	Public Hearing Date**	Approval Date
Bing	1976	1973	1977		10 January 1978
Van	1976	1973	1977		10 January 1978
Lambert	1976	1973	1977		10 January 1978
Rainier	1976	June 1988	July 1991		12 May 1992
Garnett	1976	June 1993	9 May – 10 June 1994		18 January 1995
Brooks	1976	May 1994	13 May 14 June 1994		25 October 1996
Tulare	1976	May 1994	13 May - 14 June 1994		25 October 1996
Sweetheart	1976	August 1995	24 July - 18 Aug 1997	Pending	Pending
Lapin	1976	August 1995	24 July - 18 Aug 1997	Pending	Pending
NECTARINES					
Summer Grand	1986	July 1986	July 1986		17 June 1988
Fantasia	1986	July 1986	July 1986		17 June 1988
May Grand	1986	June 1986	June 1986		17 June 1988
Spring Red	1986	June 1986	June 1986		17 June 1988
Fire Brite	1986	June 1986	June 1986		17 June 1988
Red Diamond	1986	June 1986	June 1986		1 March 1995
May Diamond	1986	June 1988	June 1988		December 1990
May Fire	1986	May 1988	May 1988		December 1990
May Glo	1986	May 1988	May 1988		December 1990
Royal Giant	1986	August 1992	August 1992		1 March 1995
WALNUTS					
Hartley	1984	1982	August 1984		1986
Payne	1984	1982	August 1984		1986
Franquette	1984	1982	August 1984		1986
Eureka	1984	1982	August 1984		

* Development of an effective treatment means that probit 9 security was achieved during large-scale tests of 30,000 codling moths.
** Absence of public hearing date denotes only that the information is not available.

Source: USDA Agricultural Research Service, USDA Animal and Plant Health Inspection Service (US Exhibit 1)

4.21 The United States noted that Japan was a major producer and consumer of apples - the twelfth largest producer in the world. In 1995-1996, Japan had produced for commercial use 879,100 metric

tons of apples, and consumed 796,883 metric tons of apples. Imports accounted for less than one percent of that consumption (1,089 metric tons).[41]

4.22 The United States claimed that as a consequence of Japan's unjustified trade restrictions, exports to Japan of cherries, nectarines, apples and walnuts currently represented only a small part of US exports world-wide. In 1996, US apple exports totalled US$409.49 million. Only 0.14 per cent of those exports (US$570,000) went to Japan. Of the total US$78.85 million nectarine (and peach) exports in 1996, only 0.26 per cent (US$185,000) were exported to Japan. In respect of walnuts, 18.91 per cent of US exports went to Japan. While a significant amount of US cherry exports were sent to Japan (61.91 per cent of US exports), this number was not as significant when compared to the number of cherry varieties that were not even considered for export to Japan because the testing of quarantine treatment for each variety would be overly burdensome.

4.23 It was common practice, according to the United States, to produce new varieties of agricultural products and enhance existing ones to capture a particular preference in the market place, or to modify harvesting time to coincide with demand trends for that fruit. These changes and enhancements could be as benign and subtle as a variation in the color of the product. The modifications of the product represented the sort of variability that did not affect how effective the quarantine treatment would be at killing the plant pests of concern. Yet Japan required *complete testing* and review of each variety, no matter how similar the variety might be to already accepted varieties. The entire testing and approval process for a given variety took anywhere from 2 to 4 years to complete, and was expensive to perform.[42] As a result, the United States claimed that Japan's measures served to restrict or altogether block access to Japan's market for new varieties.

4.24 The United States claimed that efficacy of MB treatment for apples, cherries, walnuts and nectarines had been conclusively established. Japan was obliged to allow importation of all US varieties of these products without delay, subject only to application of the respective protocol of treatment for the product.[43]

4.25 **Japan** noted that the importance of phytosanitary measures to protect plants against foreign pests had long been recognized under the IPPC (paragraphs 2.25 to 2.33), to which Japan had been a party since 1952. While codling moth was prevalent throughout the temperate zone, the pest had not been discovered in Japan (paragraph 2.6). It was Japan's opinion that, to a considerable extent, this was attributable to Japan's plant quarantine policy. For Japan, (i) the diverse and mild climatic conditions surrounding Japanese agriculture, which allowed for a high risk of the establishment of exotic pests once they were introduced into the country; (ii) the highly concentrated, intensive cultivation, which would be seriously damaged once pests were established; and, (iii) the recent increase in the volume and diversity of plant/agricultural imports, made international plant quarantine essential to Japan. Hence, in order to prevent the entry of quarantine pests, the Plant Protection Law and the Enforcement Regulation identified quarantine pests, and prescribed inspection, disinfestation and other quarantine measures.

4.26 Japan contended that the exercise of the authority of import prohibition was kept to the minimum necessary on the basis of available scientific evidence. Specifically, the import prohibition applied only to host plants of the quarantine pests which were found to pose a particularly significant risk, as a result of the risk assessment conducted in compliance with the PRA Guidelines of the FAO

[41] USDA, Economic Research Service.

[42] US Exhibit 1.

[43] The United States referred to the work plans for cherries, nectarines, and apples. These indicated a thoroughness in testing procedures that would be applied consistently to any product that was subject to quarantine. (US Exhibit 22)

(paragraph 2.30), and against which no inspection would be effective. Currently these high-risk quarantine pests were 12 species of insects[44], three diseases[45] and pests of rice not found in Japan.

4.27 Japan stated that prohibited plants, countries or areas of origin and the quarantine pests concerned were subject to continuous review whenever additional information became available in respect of the introduction of a pest into a new area, its eradication, new discoveries on pests and hosts, or development of a risk analysis method. Most recently, Japan had reviewed the regulations in April 1997[46], on the basis of the PRA Guidelines, and, as a result, the sweet potato vine borer had been deleted from - and fire blight had been added to - the quarantine pests whose host plants were subject to import prohibition.[47]

4.28 Japan recalled that the MAFF had the authority to lift the import prohibition. This was done by the de-listing of the product from the Annexed Table to the Enforcement Regulation (an amendment of the Enforcement Regulation). This was, according to Japan, the subject matter at issue in the current dispute (characterized by the United States as "varietal testing"). Japan claimed that contrary to the arguments of the United States, the import prohibition was not absolute (paragraph 4.16). The Japanese Government had accommodated foreign governments' requests for lifting of the prohibition. The number of products de-listed from the ban was evidence of this. The criteria established through past practice for de-listing were the following:

(a) lifting was subject to a proposal of an alternative measure by the foreign government;

(b) the level of protection required of the measure was that equivalent to import prohibition; and,

(c) the exporting government bore the burden of proving that the proposed measure achieved the required level of protection.

4.29 In respect of the first criteria, Japan claimed that an active measure was necessary to counter the quarantine pest, because inspection did not work effectively against the pest. Such a measure could be: complete eradication of the pest from the territory, establishment of a pest-free area, or disinfection/disinfestation treatment prior to shipment. The purpose of involvement of the foreign government was to ensure implementation of the measure in the foreign jurisdiction. In respect of the second criteria, the requirement of equivalency was self-explanatory; Japan noted that the parties to the dispute at issue were not in conflict over the level of protection. Third, for practical reasons, the importing country was at a disadvantage in respect of the gathering of sufficient information on exotic pests (which did not exist domestically), for varieties that often were not produced in Japan, hence, the exporting government had the burden of proving that the proposed measure achieved the required level of protection.

4.30 Japan claimed that these criteria had been designed as part of the policy for the implementation of domestic law through *past practice*. They represented fundamental policy orientation and were not published as a document. However, for the key process of demonstration of

[44] (i) Codling moth; (ii) Mediterranean fruit fly; (iii) *Bactrocera dorsalis* species complex: (iv) Queensland fruit fly; (v) melon fly; (vi) sweet potato weevil; (vii) West Indian sweet potato weevil; (viii) Colorado potato beetle; (ix) potato cyst nematode; (x) white potato cyst nematode; (xi) citrus burrowing nematode and (xii) Hessian fly.

[45] Potato wart, tobacco blue mold and fire blight.

[46] Japan noted at the first substantive meeting that amended regulations were effective as of 1 April 1998.

[47] Japan noted, in addition, that in light of the latest information on the insect classification, the Oriental fruit fly was reclassified as the *Bactrocera dorsalis* species complex, and the white potato cyst nematode was separated from the potato cyst nematode.

efficacy of quarantine treatment, MAFF had developed test guidelines in order to enhance transparency and these were made available for exporting countries.

4.31 The description of the Japanese practice by the United States was misleading (paragraphs 2.18 to 2.24). Japan did not demand "complete testing and review of each variety" (paragraph 4.23), the requirement depended on the US export strategy. If the United States proposed to export more than one variety, complete testing including a large-scale test (30,000 test insects in three replicates) would be required on only one *representative variety*. That is, if the United States were to apply for approval of 100 varieties of the same product, complete testing would be required only of the one variety which demonstrated the lowest degree of sensitivity to the proposed treatment in dose-mortality tests and a probit analysis. The concept of a representative variety applied equally to approval of additional varieties. As long as efficacy of the treatment in use was confirmed with respect to additional varieties by dose-mortality tests, what was required was an on-site confirmatory test (10,000 test insects) for one representative variety alone. Even if the results of dose-mortality tests were unsatisfactory, a large-scale test was necessary for only one representative variety of the additional varieties.

4.32 Japan maintained that the essence of the requirement was a demonstration that a proposed treatment would be effective on all varieties which the exporting government proposed to ship to Japan. The exporting government was free to propose any method for the purpose of this demonstration.

4.33 Japan pointed out that what the United States had referred to as the testing procedure (in paragraph 4.18) were the contents of the "Experimental Guidelines for the Lifting Import Ban" and the "Experimental Guide for Cultivar Comparison Test on Insect Mortality"[48] which the MAFF had provided as a model confirmation process for a proposed disinfestation treatment of insects. Japan stressed that these were *model* guidelines, they did not have the force of law, and were not imposed by the MAFF. Exporting governments were free to propose their own confirmation method.

4.34 Japan stated that the US data cited in paragraph 4.22 showed that Japan was the largest importer of American cherries, and was a major (the largest, if members of the European Communities were treated separately) importer of US walnuts.

4.35 According to the **United States**, to have the ban lifted on a new variety, the testing procedure included: (i) an initial test to estimate the basic dose-response of the pest in question, in or on the variety in question; (ii) data review by a MAFF official; and, (iii) a large-scale test consisting of a total of 30,000 insects at 10,000 insects in each of three successive individual trials. If successful, only then was an on-site confirmatory test conducted in the presence of MAFF staff. Resulting data was again reviewed by a MAFF official, and following confirmation of efficacy, a public hearing in Japan was required on lifting the ban for the particular variety. The United States noted that where there was an accepted quarantine treatment for another variety of the same product, Japan allowed for a comparison dose-mortality test. The same treatment was tested simultaneously on the new and old variety and the results were compared to ascertain whether there were differences in response of the insects. The results of this test were reviewed by Japanese officials. If there were no differences, then an on-site confirmatory test was required with 10,000 insects generally divided into three replications, in the presence of a MAFF official. This process was rarely employed, however, because it was possible that the old variety was no longer cultivated or the harvest time for one variety did not coincide with another.

4.36 In respect of the concept of representative variety, the United States noted that as a matter of practical application of these tests, there were occasions where the United States would seek to introduce more than one variety at the same time. Japan was correct in asserting that in some

[48]Contained in Japan, Exhibit 10.

circumstances, because of the varietal testing requirement, a representative variety could be chosen to perform the confirmatory tests. But that did not mean that significant time and resources had not already been devoted to dose-mortality testing on all of the proposed varieties. Dose-mortality testing could take as long as a month or more to perform on a given set of varieties. It was also important to bear in mind that the benefit of allowing for a representative variety was not always realized. This was because it was difficult to test certain varieties simultaneously due to the fact that they were harvested at different times. Moreover, with some fruit products, new varieties were developed so rapidly and there were so many varieties that it was not practical to conduct this type of intensive varietal testing. Thus, while not all of the varieties that had been tested by the United States had undergone confirmatory testing, a large proportion of the varieties had; and more importantly, *all* varieties had been subjected to some form of detailed testing.

4.37 In this respect, the United States noted that it had tested seven varieties of apples, nine varieties of cherries, four varieties of walnuts and ten varieties of nectarines. There had never been a difference in results from one variety to another. Every confirmatory test had uniformly achieved Japan's level of quarantine protection against the codling moth at the same exact treatment level for a product.[49] Moreover, Japan was not able to point to a single example in which any agricultural exporting country in the world had had to modify a treatment for killing codling moth among varieties of the same product. Japan had *approved* the treatments for ten varieties of nectarines, two varieties of apples, seven varieties of cherries and three varieties of walnuts. This was despite differences in dose-mortality tests and despite differing CxT values. Japan had approved these varieties because of the ability of the United States to demonstrate that the quarantine treatment provided the desired level of mortality. Every article published on the efficacy of MB and/or MB and cold storage for disinfestation of codling moth had demonstrated that there were no differences among varieties that affected efficacy of a quarantine treatment.

4.38 **Japan** countered that large-scale demonstration (i.e., the large-scale confirmatory test or the on-site confirmatory test) applied to *one* representative variety which was found, in dose-mortality testing and the probit analysis, to be the most resistant to a treatment. Thus, contrary to what had been suggested by the United States, the number of varieties which had been subject to either form of large-scale demonstration had been: **two** varieties of apples (as opposed to seven as the United States had claimed), **seven** varieties of cherries (as opposed to nine), **one** variety of walnuts (as opposed to four) and **three** varieties of nectarines (as opposed to ten) (Table 3). Japan's policy was not such that would require unnecessary testing on *all* varieties.

[49] US Exhibit 2.

TABLE 3
History of Lifting and Large-Scale Demonstration of US Fruits
(i.e. either large-scale confirmatory test or on-site confirmatory test)

	Approved Year	Varieties	Large-Scale Test	On-site Confirmatory Test
Apples	1994	Red Delicious Golden Delicious	Red Delicious	Red Delicious
	(under way)	Gala Braeburn Jonagold Fuji Granny Smith		Fuji
Cherries	1978*	Bing Van Lambert	Bing Van Lambert	Bing Van Lambert
	1992	Rainier		Rainier
	1995	Garnet		Garnet
	1996	Brooks Tulare		Tulare
	(under way)	Sweetheart Lapin		Sweetheart
Nectarines	1988	Summer Grand May Grand Fantasia Spring Red Firebrite Red Diamond	May Grand	May Grand
	1993	May Diamond Mayfire May Glo		May Diamond
	1995**	Royal Giant	Royal Giant	Royal Giant
Walnuts	1986***	Franquette Payne Hartley	Hartley	Hartley

* At that time, each of the varieties was subjected to large-scale demonstration.
** The large-scale test was necessary because the element of the treatment was modified (fruit containers were changed from wooden bins to export carton boxes).
*** The representative variety was selected by the CxT value.

4.39 Conversely, five varieties of apples (out of seven), seven varieties of nectarines (out of ten), two varieties of cherries (out of nine) and two varieties of walnuts (out of three) had been, or were being, approved by the small-scale laboratory experiment alone. It was therefore not correct to state that "all varieties have been subjected to some form of detailed testing". On the contrary, the present confirmation mechanism used the dose-mortality test to screen so that not all varieties needed to be subjected to large-scale demonstration, either by the large-scale confirmatory test or the on-site confirmatory test.

C. APPLICATION OF THE SPS AGREEMENT

4.40 The **United States** argued that the SPS Agreement applied to "all sanitary and phytosanitary measures which might, directly or indirectly, affect international trade" (Article 1.1). In this sense, Japan's measures were phytosanitary measures[50], as defined by the SPS Agreement in Annex A, and directly or indirectly affected international trade.

4.41 According to the United States, the definition demonstrated that whether a measure was a sanitary or phytosanitary measure depended on the *purpose* of the measure. Japan had stated that the purpose of varietal testing was to protect plant life or health within Japan from the establishment and spread of certain pests that could cause harm to its agriculture.[51] In order to export varieties to Japan, the exporting country had to obtain certification that it had met Japanese requirements.

4.42 As the definition of a "sanitary or phytosanitary measure" in Annex A of the SPS Agreement specifically listed "testing procedures" as being included in sanitary and phytosanitary measures, Japan's measure at issue was a phytosanitary measure. The United States further argued that Japan's measure was a "procedure to check and ensure the fulfilment of sanitary or phytosanitary measures" (chapeau to Annex C of the SPS Agreement). In addition, the United States was of the view that as a phytosanitary measure, it was subject to all of the requirements of Articles 2, 5, and 7 of the SPS Agreement. As an Annex C measure, it was also subject to all of the requirements of Article 8 and Annex C of the SPS Agreement.

4.43 Japan's measure applied to imports of certain agricultural products such as apples, cherries, walnuts, and nectarines. It prohibited the importation of any agricultural product that had been identified by Japan as a host to a quarantine pest. The ban was only lifted upon a showing that a quarantine treatment for a pest achieved Japan's level of protection for each variety of the agricultural product, irrespective of the fact that an effective quarantine treatment had been accepted for another variety of the same product. Therefore, the Japanese requirement of varietal testing adversely affected international trade.

4.44 **Japan** did not dispute that the measure at issue was covered by the SPS Agreement. Japan argued that the requirement of demonstration of efficacy was consistent with international practice. There was nothing in the SPS Agreement which prevented enforcement of that requirement.

D. BURDEN OF PROOF

4.45 The **United States** claimed that Japan had failed to present "minimally sufficient evidence" as to why variety mattered in regard to MB quarantine treatment. Instead, Japan insisted that the exporting country had to provide evidence as to why variety did not matter. This was clearly contrary to the obligations of the SPS Agreement. The United States accepted that it had the burden to establish a *prima facie* case that the measure of varietal testing was inconsistent with the SPS Agreement In this dispute, the United States maintained that it had shown that Japan's measure was not based on scientific evidence and a risk assessment, that all available scientific and empirical evidence indicated that differences among varieties did not affect efficacy of treatment against codling moth; that the testing of efficacy of quarantine treatment by product alone achieved Japan’s level of protection against the risk of entry, establishment and spread of codling moth; and that testing and treatment by product was a significantly less trade restrictive measure available to Japan. The United States had

[50] Relating to the protection of the life or health of plants.

[51] In the Government of Japan's response to Question 2 of US Consultation Questions, Japan had stated that "GOJ designates pests and diseases, which do not exist in Japan but which could conceivably cause serious damage to agriculture if outbreak were to occur, and prohibits imports of their host plants". (US Exhibit 3)

met its burden of proof. As the Appellate Body in *EC Measures Concerning Meat and Meat Products ("EC - Hormones")* stated, "when the prima facie case is made, the burden of proof moves to the defending party, which must in turn counter or refute the claimed inconsistency".[52]

4.46 **Japan** contended that the United States had not submitted any demonstration that the proposed product-by-product approach would be effective for all varieties. The requirement of demonstration, which was the exercise of domestic authority under the Plant Protection Law, was not only reasonable in light of the disparity of information but was consistent with established international practice. Furthermore, Japan noted that there was no disagreement between the parties in this respect; the United States had accepted this principle in that it had stated that it was reasonable for the importing country to require the exporting country to propose and substantiate the efficacy of an approach that achieved the importing country's level of phytosanitary protection (paragraph 4.50). There was nothing in the SPS Agreement which prevented enforcement of the requirement of demonstration as such; it was not per se inconsistent with the SPS Agreement. It was the responsibility of an applicant to prove safety (or absence of harm) of a medicinal product, for example; it was not the obligation of Member governments under the SPS Agreement to disprove safety. No Member government of the WTO allowed the applicant the luxury of obtaining governmental approval of a drug, food additive or phytosanitary treatment simply because inefficacy and/or danger thereof had not been proven. Nor was it Japan's obligation to scientifically demonstrate that varieties resulted in different degrees of efficacy of a treatment by, for example, conducting large-scale tests at Japan's expense. Such interpretation of the provisions of the SPS Agreement was tantamount to denial of the requirement of demonstration by the exporting government. The issue was rather whether or not the importing authorities had acted in conformity with the Agreement in perceiving the risk presented by the eventual importation of a different variety. Japan claimed that there *was* data which suggested the possible presence of varietal difference in efficacy of a treatment which gave rise to the concern. Hence, the requirement under the SPS Agreement of scientific evidence or a risk assessment was fully met. Insofar as the requirement of demonstration was thus consistent with the SPS Agreement, the exporting government had to show, with scientific evidence, that a given treatment would be effective for the proposed varieties.

4.47 Japan noted that it did not impose a particular measure, as long as a proposed alternative method demonstrated efficacy equivalent to the import prohibition.[53] For instance, for lemons, grapefruits and ponkan oranges, Japan had approved importation on a product-by-product basis (although the relevant pest, fruit fly, and the relevant treatment, cold treatment, were not covered by the terms of reference of the current dispute). This was because most of these citrus varieties had been developed by somatic mutation, such as bud mutation, and their varietal differences were not known to be significant.

4.48 Japan argued that the United States had not submitted any relevant evidence in this regard. Nor had any convincing argument to support the absence of varietal differences been made. In order for the United States position to prevail under Articles 2.2 and 5.1, it had to prove that the varietal risk was either non-existent or insignificant in light of scientific evidence and/or a risk assessment. It was not sufficient for the United States to prove that there were risks other than those resulting from varietal differences including "natural variation". The United States had repeated arguments that (i) laboratory test results were unreliable and that (ii) the existing treatment had been effective so far. In doing so, the United States had failed to show that Japan was not abiding by the requirement of scientific basis or evidence. Hence, Japan urged the Panel to apply the burden of proof principle which was stated in the *EC - Hormones* case correctly. The United States had failed to make a *prima facie* case.

[52] WT/DS/26/AB/R, adopted 13 February 1998, paragraph 98.

[53] MB fumigation, cold treatment, vapor heat treatment, dry heat treatment, phosphine fumigation and a combination of these alternatives were an example of specific disinfestation measures which Japan had already approved.

4.49 The **United States** stressed that it was important not to confuse the fact that the exporter would typically assume the burden of meeting the importing country's concerns with the question of the burden of proof for dispute settlement purposes. The United States had always accepted that in the current proceeding it bore the burden of presenting facts and arguments sufficient to establish a presumption that Japan's measure was inconsistent with the cited WTO Agreements. However, this did not alter the fact that *Japan* was required to have sufficient scientific evidence to *maintain* its measure and to base its measure on a risk assessment. The United States had proven that Japan did not have sufficient scientific evidence or a risk assessment to justify its *assumption* that variety mattered. The United States did *not need to prove* that there were no varietal differences that mattered for purposes of treatment efficacy. This was a fundamental issue of burden of proof under the SPS Agreement; in *EC – Hormones*, the European Communities claimed that it could ban meat because it was not proven that there was no risk. This approach had not been accepted by the Appellate Body.

4.50 The United States noted that as a general proposition, assuming that a product proposed for export was indeed a potential host for a pest appropriately determined to be a pest of quarantine significance, it was reasonable for the importing country to require the exporting country to propose and substantiate the efficacy of an approach that achieved the importing country's level of phytosanitary protection. As Japan acknowledged, such a proposal could involve eradication of the pest from the territory, establishment of a pest-free area, or a disinfestation treatment (paragraph 4.29). The United States maintained, however, that such an approach could also involve integrated pest-management practices and a systems approach, which did not necessarily involve a disinfestation treatment. Indeed, the United States had long proposed integrated pest-management practices for codling moth in conjunction with MB fumigation and, in the case of apples, cold treatment. The United States believed it had established the efficacy of this approach for apples, cherries, nectarines, and walnuts.

4.51 In the absence of a recognized pest-free area, it was the experience of the United States that Japan did not permit importation of any varieties of the relevant products without demonstration of the efficacy of the applicable MB quarantine treatment for codling moth on each and every variety. This rigid criterion for demonstration of efficacy was not a reasonable procedural requirement.

4.52 The United States noted that in connection with Japan's claims regarding lemons, grapefruits and ponkan oranges, Dr. Ducom (an expert advising the Panel[54]) had stated that there was no scientific basis for distinguishing these products from the products at issue in considering whether product-based testing was feasible. Further, the United States pointed out that the treatments developed for each product had been uniformly effective for the entire commodity.

4.53 **Japan** noted in respect of integrated pest management or other techniques, that while they were effective to reduce the level of infestation, they did not eliminate the risk of the pest to the level equivalent to an import prohibition. Disinfestation had been chosen in the light of these considerations, and not because pre- or post-harvest techniques were irrelevant.

E. ARTICLES 2.2, 5.1 AND 5.2

1. General

4.54 The **United States** argued that the Japanese varietal testing requirement was maintained without sufficient evidence in contravention of Article 2.2. Furthermore, it was not based on an assessment of risk in contravention of Articles 5.1 and 5.2. The SPS Agreement indicated in Article 2.2 that a Member was not allowed to maintain a phytosanitary measure "without sufficient

[54] See Section VI of this report in respect of the Panel's consultation with scientific experts. The experts advising the Panel are listed under paragraph 6.4.

scientific evidence" and a measure had to be "based on scientific principles". Article 5.1 stated that a Member had to ensure that its phytosanitary measure was based on an assessment, "as appropriate to the circumstances, of the risks to ... plant life or health".

4.55 In relation to risk assessment, the United States recalled that the Appellate Body Report on *EC - Hormones* had made it clear that Article 5.1 could "be viewed as a specific application of the basic obligations contained in Article 2.2 of the SPS Agreement".[55] Thus, the United States argued, Article 2.2 and Article 5.1 of the SPS Agreement were necessarily linked together. Under Articles 5.1 and 5.2 of the SPS Agreement, Japan was required to base its SPS measure, in this instance variety-by-variety testing for quarantine efficacy, on a risk assessment. Such an assessment was important in establishing whether the measure was "based on scientific principles", and was not "maintained without scientific evidence" (Article 2.2).

4.56 The United States stressed its request that the Panel make findings with respect to both Article 2.2 and Article 5.1 of the SPS Agreement. In the view of the United States, the heart of the dispute was the fact that Japan's measure did not merely lack an assessment of risk, it lacked sufficient scientific evidence to support the measure. This had also been stressed by the Appellate Body's statement in *EC - Hormones* 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".[56] Furthermore, in that dispute, where the Panel made a finding under Article 5.1 but not Article 2.2, the Appellate Body expressed that it was "surprised by the fact that the Panel had not begun its analysis of this whole case by focusing on Article 2 that is captioned 'Basic Rights and Obligations,' an approach that appears logically attractive". [57]

4.57 The United States stressed that a failure to make a finding with respect to Article 2.2 could lead to confusion rather than furthering the objective of "providing security and predictability to the multilateral trading system".[58] If the Panel were to make a finding on all of the elements necessary to make a determination with respect to Article 2.2 (which in this dispute would be inherent in a finding with respect to Article 5.1), and yet not actually make that determination, it could be perceived by some as implying that Japan's ban was *not* maintained without sufficient scientific evidence. This negative implication would be inaccurate. Japan's measure did not merely lack a risk assessment, it was not supported by scientific evidence. In that regard, the lack of sufficient scientific evidence was a more fundamental and fatal flaw than the lack of a risk assessment, and thus was a more important finding than a finding under Article 5.1.

2. Article 2.2

(a) General

4.58 The **United States** recalled that Article 2.2 of the SPS Agreement required a Member to base its phytosanitary measures on scientific principles and prohibited a Member from maintaining sanitary and phytosanitary measures "without sufficient scientific evidence". The SPS Agreement did not define "based on scientific principles". However, at a minimum, to base a measure on scientific principles required that a WTO Member had *identified a particular risk* that the measure was designed to protect against, and conducted some review of scientific evidence or other relevant scientific information to demonstrate that the measure in fact protected against that risk. The risk that

[55] *Op. cit.*, p.72, paragraph 180.

[56] *Ibid.*

[57] *Ibid.*, paragraph 250.

[58] Article 3.2 of the DSU.

had to be addressed was whether there was a possibility of the inadvertent entry of codling moth from US products, on a variety-by-variety basis, in light of pre- and post-harvest practices and quarantine treatment. In other words, the risk of introduction of codling moth *in the absence* of the varietal testing requirement. The United States noted that the strongest wording Japan had been able to employ was that "it is *possible* there *may* be variation in the efficacy of disinfestation even if the same quarantine treatment is applied to different varieties" [emphasis added].[59] Yet the Appellate Body Report on *EC - Hormones* had noted that a theoretical risk would always remain because "science can *never* provide *absolute* certainty that a given substance will not ever have adverse health effects. We agree with the Panel that this theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed".[60]

4.59 The United States claimed that Japan had never been able to provide an explanation as to why it was necessary to test each variety of a product. There was no scientific reason why the types of differences that distinguished one apple, nectarine, walnut or cherry from another would be relevant to the effectiveness of the quarantine treatment. Empirical evidence supported the fact that with quarantine treatment for codling moth using the preferred treatment of MB and/or a two component treatment of MB and cold storage, the particular *variety* of the product did not matter for purposes of the quarantine treatment needed.[61] In other words, the quarantine treatment had always been equally effective irrespective of variety. The additional and redundant testing required by Japan had never been proven necessary.

4.60 **Japan** noted that the main thrust of the US argument appeared to be that there was no scientific basis for varietal testing. Japan maintained that its position was based on a sufficient amount of available literature and scientific data which indicated the possible presence of a statistically significant difference in the efficacy of known disinfestation measures across varieties of the same products, differences which could require application of a different treatment.

4.61 Japan claimed that the import prohibition fully met the criteria, developed by the Appellate Body in *EC - Hormones*, of being "based on" scientific evidence, or a risk assessment:

> "... Article 5.1, when contextually read as it should be, in conjunction with and as informed by Article 2.2 of the SPS Agreement, requires that the results of the risk assessment must sufficiently warrant – that is to say, reasonably support – the SPS measure."[62]

4.62 Japan had relied on the following available evidence which had led to the conclusion that the import prohibition was warranted against codling moth:

(a) Honma, K. (1976) *Plant Protection* 30: 237-244. (in Japanese)

(b) Proverbs, M.D. *et al.*, (1982) *Can. Entomol.* 114: 363-376.

(c) Moffitt, H.R. *et al.*, (1988) *J. Econ. Entomol.* 81: 1511-1515.

(d) Beers, E.H. *et al.*, (1988) In *Orchard Pest Management*, pp. 63-68.

(e) MAFF (1995) In *Handbook of Agricultural Statistics*, pp. 225-238. (in Japanese)

(f) IIE (1995) *Distribution Maps of Pests*, Series A. No. 9, CAB International.

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[59] Japan's response to Question 4 of US Consultation Questions (US Exhibit 3).

[60] *Op. cit.*, paragraph 186 (italics in original).

[61] US Exhibit 2.

[62] *Op. cit.*, paragraph 193.

(g) Tokyo Astronomical Observatory (1995) In *Chronological Scientific Tables*, pp.198-199. (in Japanese)

(h) Yamaguchi, A. & A. Otake eds. (1986) In *Disease and Invertebrate Pests of Fruits Trees*, pp. 226-230. (in Japanese)

(i) Japan Tariff Association (1993, 1994, 1995) In *Japan Exports & Imports* No. 12, p. 94. (1993), p. 93. (1994), p. 93. (1995).

4.63 These pieces of literature contained or lead to the following findings:

(a) Codling moth could survive in areas where the effective cumulative temperature (the yearly sum of the daily temperature figures which are 10 degrees or above) was 600 day-degrees and the lowest monthly temperature of the coldest month fell below 10 degrees centigrade. Most Japanese regions met this criteria.

(b) The insect was able to establish itself in Japan in light of the amount of host plants.

(c) When codling moth larvae diapaused through the winter in cocoons, and, after the pupal stage in early spring, the moth emerged during the blooming season of apples.

(d) In contrast to a sedentary pest such as scale, codling moth was able to spread by flight. There was a report that the moth could move within a range of 300 to 500 feet, and records that they had flown 1,000 to 2,000 feet. Moreover, a Canadian study on control by sterile insect releases found that male moths released from a point were recaptured in traps 3.5 kilometres to 7.2 kilometres away.

(e) The larvae entered into the apple fruits at every growing stage, and it severely damaged commercial value.

(f) In an area not subject to pest control, the infestation rate in pears was 57.3 per cent to 100 per cent.

(g) Newly hatched larvae entered into the fruits from the calyx end or from cracks, and were very difficult to detect.

(h) Export markets could be lost.

(i) Control costs could increase.

4.64 From the above findings, Japan drew the following conclusions and decided that import prohibition was the appropriate phytosanitary measure:

(a) codling moth had a high potential (grade a) of entry and establishment, while its spread potential was medium (grade b);

(b) the pest was highly likely to cause grave damage (grade a) to agricultural production once it was introduced into the country; and,

(c) there was no practical, effective inspection method to detect the presence of the moth inside fruits, and the level of management difficulty was the highest (A1).

4.65 The **United States** claimed that Japan was mischaracterizing the dispute. The issue was not whether codling moth was of quarantine significance. That was not in dispute. What was in dispute was whether there was any scientific basis for Japan's assumption that variety affected efficacy of treatment against codling moth. Japan had asserted that variety presented a risk in relation to quarantine treatments with methyl bromide, and yet it could not support this theoretical uncertainty with scientific evidence. In fact, Japan had instituted this requirement *before* any of the scientific studies on which it

claimed to rely had been conducted.[63] Japan had yet to explain why varieties needed to be tested separately. If each variety needed to be tested separately because varietal differences "could" matter, then why not separately test by a whole series of other arbitrary factors, such as by color, by ripeness, or by length of time in shipment? In essence, Japan had *assumed* variety mattered, and then challenged exporting countries to prove it did not. According to the United States, this was not the way the SPS Agreement was structured.

4.66 The United States noted that addressing the risk at issue came down to an exporting Member's ability to kill the pest in question, codling moth, in each variety of a product. This was the fundamental question that had to be analyzed under Articles 2.2 and 5.1 of the SPS Agreement. Japan had established a particular level of mortality that it wanted any quarantine treatment to achieve. This was, however, not the same as an appropriate level of protection. There was no dispute over that mortality level. The United States wished to clarify the mortality level did not relate to: sorptive patterns, CxT findings, preliminary dose-mortality testing or the other information and procedures that scientists used to identify a treatment that would kill codling moth on a given product. The significance of those data and techniques was in the contributions that they made to scientists' conclusions about the fumigant dosage needed to *achieve the required level of pest mortality*.

4.67 Japan had suggested that the existence of risks could be inferred from the studies it had submitted. Yet none of the these studies were structured in such a way that they answered the basic questions of fact which might serve as scientific evidence for the risk at issue. Even if Japan had been accurate with respect to the significance of every piece of data it had cited, and the conclusions of each and every study, the question would remain whether Japan's varietal testing requirement was supported by sufficient scientific evidence, and whether the risk at issue was more than hypothetical. The United States maintained that responses by the experts advising the Panel had been very helpful in clarifying that it was not possible to attribute the data variations cited in these studies to varietal differences, let alone to differences of a magnitude that could affect treatment efficacy. The United States stressed that all of the experts had confirmed that the existence of varietal differences affecting treatment efficacy could *not be determined on the basis of the evidence before the Panel*.

4.68 **Japan** claimed that the risk it faced was not the "theoretical uncertainty" the Appellate Body had referred to in *EC - Hormones*. The present case was substantially different from *EC – Hormones*; while the safety of the substances was internationally established in the *EC – Hormones* case, no one doubted the risk posed by codling moth to Japan. While the European Communities only asserted that safety of hormones was not proven beyond doubt, Japan's concern was based on available data. This data was the basis for Japan's scientific concern over the efficacy of the treatment across varieties.

4.69 Hence, Japan disagreed with the US argument that Japan referred only to theoretical uncertainty as the basis for "varietal testing" for MB fumigation, and, therefore, that Japanese policy was not based on a risk assessment. First, Japan recalled that there was *no* requirement of "complete testing and review of each variety" under the Japanese policy (paragraph 4.23). All that was required of *each* variety was the demonstration of efficacy in small-scale laboratory experiments to compare dose-response with other varieties (at the time of initial lifting), or with the approved treatment level (at the time of additional lifting). Large-scale demonstration was only required of a representative variety. Second, Japan noted that there was nothing inherently wrong about Japan's concern in respect of varietal differences. Japan claimed that the United States had itself established different treatment standards for different varieties of mangoes (paragraph 4.136 and following paragraphs).

4.70 Japan noted that in the case of MB fumigation to counter codling moth, data was available in the form of varietal dose-response results which suggested the possible presence of differences in

[63] The United States noted that the earliest reference wherein Japan identified any basis for its assumption that variety affects efficacy of quarantine treatment was in the Wearing *et al.*,1980 Study on New Zealand Cherries (contained in Japan, Exhibit 13).

efficacy of fumigation treatment between varieties. Japan's hypothesis was that characteristics of a particular variety could affect fumigation efficacy, possibly by their impact on the CxT value (explained in further detail in paragraph 4.109 and after). In light of available data and present knowledge of the fumigation process, this was a reasonable argument. Japan's policy was thus based on a scientific hypothesis which was in turn supported by empirical data, in full conformity with the obligations contained in Article 2.2 and Article 5.1.

4.71 Japan noted that the United States apparently found rationale for the product-by-product testing in the fact that the efficacy of the treatment applied for one variety of a product had never varied from that of the treatment applied to another variety of the same product. The United States repeatedly emphasized the fact that an MB fumigation standard had not been modified in the past. Japan acknowledged that it was true that existing treatment levels of host plants of codling moth had been found effective for additional varieties. However, as a matter of science, all this proved was the efficacy of the treatment on the *tested* varieties; it fell short of showing absence of varietal difference within a product altogether. Possibly, the US argument could be founded on an intuitive judgement, based on past experience. However, out of 100 varieties of nectarines in commercial production, only three varieties had been tested by a large-scale (10,000 to 30,000 insects) test. Similarly, out of 44 varieties of apples, only two had been tested by the large-scale test.

4.72 Japan further noted that, according to the US argument, if there were 100 varieties in one product category, a treatment based on a selective test of any variety would have to be presumed to be effective for the other 99 varieties. Far more scientific evidence than provided by the United States in the current proceedings was needed before Japan could reach such a conclusion. The implications of the US arguments were: (i) that the present quarantine treatment would be effective for unapproved varieties (including varieties yet to be developed) of apples, cherries, nectarines and walnuts; and, (ii) for other products which the United States claimed to be within the terms of reference, they would seek to apply a single treatment for all varieties (including varieties yet to be developed).

4.73 The United States had not provided any information on disinfestation of unapproved varieties or unapproved products. Obviously, there was no information on products yet to be developed, possibly through rapidly advancing biotechnology. Nor had the United States presented a theoretical argument regarding the absence of varietal difference in the disinfestation effects of these products. Japan had to conclude that the United States had not performed the required demonstration of efficacy of treatment across varieties.

4.74 The **United States** stated that it found unremarkable Japan's conclusion that the United States had not proven, with scientific certainty, the absence of varietal differences. This conclusion did not more than state, as the Appellate Body Report in *EC – Hormones* recognized, that science could never, with absolute certainty, prove the negative. This did not excuse Japan from its obligations to base its requirement on a risk assessment and sufficient evidence, obligations which Japan had failed to fulfill.

(b) Probit 9, dose-mortality tests and confirmatory tests

4.75 The **United States** noted that dose-mortality tests were a critical tool to determine what commercial treatment might be effective. The dose-mortality test result established a range of treatments for varieties from which scientists could compare and estimate a final treatment for the product as a whole. The highest minimum dose observed in the dose-mortality tests that scientists believe would achieve the level of protection required by Japan (probit 9) was supplemented by 10-20 per cent in the second stage of testing, the confirmatory tests, to account for all sources of variation in the dose-mortality tests. Thus it was the confirmatory test that was the relevant indicator of efficacy of treatment.

4.76 The primary reason for the 10-20 per cent (buffer) increase of dose in confirmatory tests, as well as the reason why scientists did not rely on dose-response results to establish a commercial quarantine treatment, was that not every replicate of a dose-mortality test would exactly mirror

another. Such factors as experimental error, physical condition of the fruit, sorption of the fumigant by packing material, and load of fruit in the chamber could account for differences in results. Phytotoxic[64] effects and effects on residue levels would ordinarily establish the upper bound for a proposed buffer.

4.77 The United States noted that dose-response data could vary from test to test with the same species of insect in the same variety. It was well established that insect susceptibility to insecticidal treatment differed greatly among individual insects, and that the response of insect populations varied. Since each test necessarily required new insects, the response of test insects would differ naturally among tests and that accounted in part for the observed variability in dose-mortality test results.[65] With small scale dose-mortality tests, using limited numbers of pests, it was unlikely that variability of insects relative to susceptibility to the fumigant would be fully represented. Confirmatory tests, however, contained sufficient numbers of insects (10,000 to 30,000) to ensure representation of insects at all levels of MB susceptibility.

4.78 Thus, because of natural variation of the test insect population, as well as other factors that ensured that no *one* dose-mortality test would be exactly the same as another, it was impossible to conclude that differences in variety were the explanation for variations in dose-response results. The United States argued that Japan's own acceptance of varieties that exhibited differences in dose-response results established that Japan recognized effective quarantine treatment always accommodated some differences in dose-mortality testing.

4.79 Confirmatory tests established the efficacy of treatment for a product because they took into consideration *all of the sources of variation that could be attributed to the smaller scale tests* - most notably the variation in a pest population, and the experimental error that was bound to occur from one small-scale test to the next. A confirmatory test would show if a treatment were too low because there would be an unacceptable rate of survival of the pest. However, confirmatory tests would not indicate if a treatment were too high.

4.80 The United States noted that although confirmatory tests were necessary in the initial development of a quarantine treatment, they were unnecessary for every new variety of the same product. The confirmatory test administered to the initial variety, with a target pest population of 30,000 insects, was of such a design and order of magnitude to include a "real world" range of the pest population (and therefore relative levels of tolerance to methyl bromide) to detect an inadequate treatment; in other words, such a large-scale test would capture the range of susceptibility of insect population. The United States noted that 30,000 codling moths was a substantially larger number of insects than had ever been encountered in either dose-mortality tests or the actual conditions of US products proposed as candidates for export to Japan.[66] The United States noted that the experts advising the Panel had affirmed that the incidence of codling moth on commercially marketable US products was low. Pest population levels for US products were measured, at most, in extremely low numbers, not

[64] Toxic or injurious to plants.

[65] Finney, D.J., (1964) "Statistical Methods in Biological Assay," Griffin, London, pp. 91-92, *Cited in* Robertson, Preisler, Hickle and Gelernter, "Natural Variation: A Complicating Factor in Bioassays with Chemical and Microbial Pesticides", 88(1) J. Econ. Entomol. 1-10, 4-6. (1995). Finney states, "In general the assumption that a response curve once determined can be used in future assays is inadmissible. Because of natural variation, responses of a group of insects tested at any one time will therefore never be exactly the same as responses of another group tested at either the same time or at a different time, regardless of the extent to which bioassay techniques are standardized". In examining responses of Colorado potato beetle, diamondback moth, and western spruce budworm to three chemical and one microbial pesticides, Robertson *et al.*, concluded that , "Studies of resistance, control of product quality, and tests of treatment efficacy are complicated by variation in response to a pesticide (whether chemical or microbial) that occurs within generations of a particular strain or within cohorts of a population: such variation is a natural phenomenon when any bioassay is repeated". (US Exhibit 11)

[66] The United States referred, in general, to US Exhibits 7, 8, 9, 10, 16 and 30 as well as US Exhibit 22: Work Plans already in place for the export to Japan of certain varieties of US products.

hundreds per fruit, as encountered in the confirmatory test. Any treatment that could kill 30,000 codling moths in one application would not have difficulty killing the rare individual codling moth that might appear in a particular commercial shipment. Dr. Heather had further emphasized the robustness of methyl bromide treatment. The United States further claimed that no literature or scientific data supported an inherent variability in the products to indicate that a successful confirmatory test on 30,000 insects would not be uniformly successful for all varieties of the host product. The buffer of treatment used by scientists accounted for the natural variability of the pest and the experimental variability seen in small scale dose-mortality tests. Due to these factors, a confirmatory test would account for the variability in small scale tests and establish a treatment that was appropriate for all varieties of a product.

4.81 **Japan** claimed that empirical dose-response results confirmed the proposition that varietal differences could affect the mortality effect of MB fumigation. Data which indicated the presence of such statistically significant differences was contained in:

(a) a 1987 study on American nectarines, in which Summer Grand was found significantly more susceptible to MB fumigation[67],

TABLE 4
Susceptibility of Codling Moth Eggs to MB Fumigation
(2 hours, 21 °C) in 6 Nectarine Varieties (American Nectarines)

Variety	No. of Sample Insects	LD_{50}(95%CL) (g/m^3)
Summer Grand	**2,210**	**6.3 (2.2 - 9.1)**
May Grand	2,458	14.2 (11.1 - 17.0)
Firebrite	1,880	18.8 (14.7 - 22.8)
Spring Red	1,019	17.7 (14.0 - 20.9)
Fantasia	1,548	17.6 (14.0 - 20.0)
Red Diamond	1,445	18.4 (17.1 - 19.8)

[67] Yokoyama, Miller and Hartsell, "Methyl Bromide Fumigation for Quarantine Control of Codling Moth (Lepidoptera: Tortricidae) on Nectarines,"80 J. Econ. Entomol. 840-842, 1987. (US Exhibit 14)

(b) a 1987/88 test on New Zealand cherries in which LD_{50} showed a significantly lower value for Bing than for Rainer and Sam[68], and

TABLE 5
Susceptibility of 1-day-old Codling Moth Eggs to MB Fumigation (2 hours, 12°C) in 5 Cherry Varieties (New Zealand Cherries)

Variety	LD_{50} (95%FL) (g/m^3)	LD_{99} (95%FL) (g/m^3)
Dawson	33.6 (31.8 - 35.1)	61.1 (55.9 - 69.8)
Bing	**30.0 (28.9 - 30.9)**	**46.8 (44.7 - 49.6)**
Rainier	33.8 (32.1 - 35.3)	62.2 (57.2 - 70.3)
Sam	35.4 (33.8 - 36.6)	52.9 (49.6 - 58.6)
Lambert	32.3 (29.9 - 34.0)	52.9 (48.4 - 61.7)

(c) a 1983/84 study on disinfestation of New Zealand nectarines in which Fantasia showed a significantly lower LD_{50} than Redgold.[69]

TABLE 6
Susceptibility of 1-day-old Codling Moth Larvae to MB Fumigation (2 hours at 12°C) (New Zealand Nectarines)

Variety	LD_{50} (95%FL) (g/m^3)	LD_{99} (95%FL) (g/m^3)
Fantasia	**10.96 (10.56 – 11.33)**	**21.15 (19.82 - 22.93)**
Redgold	12.09 (11.54 – 12.59)	32.86 (29.83 - 37.12)

4.82 Japan reaffirmed that it used the results of the dose-mortality test (which was part of the "basic test" paragraph 2.23) in the screening process to select a representative variety.[70]

4.83 Probit analysis[71] typically estimated LD_{50} by measurement of the mortality rate in different doses and regression analysis of the statistically processed data (e.g., probit-conversion). The use of LD_{50} value was justified on the basis of relative accuracy of estimation; the confidence level diminished as the value departed from the 50 per cent. A leading textbook of the analysis stated:

[68] Waddell, Birtlex, Dentener and Wearing, "Disinfestation of New Zealand Cherries Cultivar Comparison Test 1987/88", New Zealand. Department of Scientific and Industrial Research, Entomology Division, 1988. (Japan, Exhibit 17)

[69] Batchelor, Wearing, O'Donnel, "Disinfestation of New Zealand Nectarines 1983/1984", 1984. (Japan, Exhibit 18)

[70] Japan claimed that the estimation of LD_{50} by probit analysis was commonly used for evaluation of toxicity of agricultural chemicals or for comparison of tolerance of pests to disinfestation treatment. Japan referred to e.g., OECD Guidelines for Testing of Chemicals, adopted 17 July 1992 (Japan, Exhibit 19) for the use of LD_{50} value to assess toxicity of industrial chemicals; Knowles, C. (1988) J. Econ. Entomol.81;1586-1591 for comparison of LD_{50} values between different insect groups. (Japan, Exhibit 20).

[71] Definition in paragraph 2.14.

> "As will become apparent in later chapters, by experiment with a fixed total number of subjects effective doses in the neighbourhood of ED_{50} [effective dose 50%] can usually be estimated more precisely than those for more extreme percentage levels, and this is characteristic of the stimulus; its chief disadvantage is that, especially in toxicological work, much greater interest may attach to doses producing nearly 100% responses than to those producing only 50%, in spite of the difficulty of estimating the former."[72]

4.84 The use of the LD_{50} value (estimated on the basis of the dose-mortality test results) in comparing efficacy of insecticide agents was a generally accepted scientific method of analysis. While the United States claimed that the dose-mortality test was effective only for estimating the ultimate quarantine treatment, it was typically utilized for the comparison of susceptibility of developmental stages of the treatment, in developing treatment schedules.[73]

4.85 Japan noted that the United States had pointed to "experimental error, physical condition of the fruit, sorption of the fumigant by packing material, and load of fruit in the chamber", as well as "natural variation of the test insect population", and claimed that "[t]he condition of any particular fruit could affect dose-response results". The conclusion drawn was that small scale dose-mortality tests were unable to correct for these variations. Of these other exogenous variables, "experimental error, physical condition of the fruit, sorption of the fumigant by packing material, and load of fruit in the chamber" were the factors which scientists who conducted these tests were responsible for controlling and consciously made equal.[74] Indeed Japan noted that scientists endeavoured to set conditions that resembled each other as closely as possible and test insects were taken from artificially reared groups. For example, Yokoyama and other authors of the 1987 experiment on nectarines described in detail conditions of the fumigation chamber, wrapping of fruits, the load factor, time of fumigation, conditions of the codling moth and their rearing, and, from these descriptions, one could recognize that the scientists exerted efforts to ensure as much similarity between test samples. What would *not* be acceptable - if these factors affected the results - was the *data* they generated, and not Japan's hypothesis. In Japan's view, any responsible scientist would have to ensure that such exogenous factors did not falsify the results. It was not scientifically correct to reject a statistical conclusion on the grounds of experimental errors. If there were such exogenous factors as the United States claimed, their presence would mean that it was dangerous to draw any kind of conclusion from the results of such an experiment. None of the experts advising the Panel had concluded that experimental errors explained all of observed differences in the LD_{50} values across varieties.

4.86 Japan claimed that another possible explanation for these factors was that they resulted from inevitable sampling error. If this was the case, the US position that confirmatory tests were the relevant indicator would be justifiable. However, Japan noted again that finding ways to alleviate, if not eliminate, problems of this kind belonged to the scientists of the government of exporting countries. Japan claimed that while there were always variables other than varietal differences, this was a statement of truth for any natural phenomenon. It was the responsibility of the exporting government to identify the variables and establish a treatment which would satisfactorily incorporate them so that Japan's level of protection would be achieved despite natural variation. The reason Japan chose to address the issue of varietal difference was because one could reasonably assume the presence of a route by which fruit characteristics of a particular variety might affect the outcome of a disinfestation treatment through their impact on CxT values. On the other hand, it was an established

[72] Probit Analysis (3rd ed.) Finney, D.J. (1971).

[73] Japan referred to a letter of 9 May 1997 from Robert G. Spade, Assistant Deputy Administrator, PPQ, which stated that: "During the development of quarantine treatment schedules, does-response data is used only to identify the least susceptible life stage of a target insect and to estimate effective treatment dosages". (Japan, Exhibit 34).

[74] Japan noted that statistical analysis, significance testing in particular, was precisely the tool to correct for experiment error.

practice to ignore crop-to-crop or other natural variations in fruits or insects. The issue was the level of protection which an importing Member had the authority to choose.

4.87 In respect of the issue of the "buffer", Japan noted that while the United States claimed that the buffer was likely to cover conceivable varietal differences, the experts advising the Panel had not made any definitive arguments in this regard, nor had the United States explained the scientific grounds for their conviction. The United States seemed to rely intuitively on the past record of the efficacy of the treatment for additional varieties. However, as Dr. Heather had pointed out, this was a question of "risk management". In other words, the risk of inefficacy existed, and the rest was to be determined by the policy of the importing country.

4.88 Further, in regard to the buffer dose, Japan could not share the view of Dr. Heather and Mr. Taylor who had stated that the 10-20 per cent additional buffer dose might possibly cover the presupposed varietal differences. Japan argued that the buffer dose proposed by the United States had been established on the basis of *laboratory scale* dose-mortality tests. However, conditions for *large-scale commercial application* were different and the effect of gas sorption far from negligible. The amount of gas equivalent to the buffer dose would be sorbed to warehouses and containers. This coupled with inevitable gas leakage could mean the CxT values might be lowered to risky levels. Japan maintained that according to US data, as much as 20 per cent of the methyl bromide dose could be sorbed by picking bins, warehouses and possible leakage. On that basis, Japan could hardly assume that the 10-20 per cent buffer dose would cover possible differences of the magnitude of varietal variations.

(i) Nectarines

4.89 According to the **United States**, in the consultations Japan had suggested that a scientific basis for requiring testing for each variety arose from USDA data for the development of an MB quarantine treatment for codling moth in nectarines for export to Japan. The research alluded to by Japan was presented in two articles by American scientists, one in 1987 and the second in 1990. In the first study (1987), dose-mortality tests were conducted on six early- to mid-season varieties of nectarines: May Grand, Fire Brite, Red Diamond, Spring Red, Summer Grand and Fantasia. The test results had shown that the level of methyl bromide estimated to produce 50 per cent mortality in codling moth on Summer Grand was significantly lower than for the remaining five varieties.[75] In 1990, three additional varieties of nectarines were tested (May Diamond, Mayfire and May Glo). The dose-response of these suggested that a lower amount of methyl bromide was necessary to achieve 100 per cent mortality.[76] Nevertheless, the higher dose established in 1987 was used for the confirmatory tests. The United States argued that the principal reason a higher dose had been established in 1987, was because the Summer Grand variety that had "stuck out" in dose-mortality tests in 1987, had also required the highest minimum dose to achieve 100 per cent mortality.

4.90 In the 1990 study on nectarines, the authors had looked at different insect and fruit interactions to evaluate the necessity for varietal testing. Dose-response data had been obtained for eggs fumigated on different fruit substrates (i.e., different species: nectarines, plums, peaches, apples) as well as eggs on waxed paper inserted into the fumigation chamber with a load of fruit. The authors compared LD_{50} and LD_{95} for codling moth eggs. The scientists found that while there might have been slight apparent numerical differences in codling moth susceptibility to methyl bromide (dose-response) on various substrates, this *did not affect the efficacy* of the quarantine treatment, nor had these differences been anything but natural variations in the response of the test insects. The highest minimum doses tested that caused 100 per cent mortality of codling moth on nectarines, peaches,

[75] *Op. cit.,* pp. 840-842. (US Exhibit 14)

[76] Yokoyama, Miller and Hartsell, "Evaluation of a Methyl Bromide Quarantine Treatment to Codling Moth (Lepidoptera: Tortricidae) on Nectarine Cultivars Proposed for Export to Japan," 83 J. Econ. Entomol. 466-471, 1990. (US Exhibit 12)

plums and apples, and waxed paper during dose-mortality tests were well below the 48 g/m^3 methyl bromide that was used in the ultimate quarantine treatment for nectarines established through confirmatory tests. Based on these results, the authors of the study had concluded that testing for efficacy of methyl bromide against codling moth eggs on *every* nectarine cultivar proposed for export to Japan was unnecessary to show the efficacy of the quarantine treatment.[77]

4.91 The United States claimed that, in consultations, Japan had pointed to the relative susceptibility to methyl bromide of codling moth eggs on Summer Grand and noted differences in the physical characteristics of the fruit as an indicator of significant differences among varieties of the same agricultural product which warranted varietal testing. Yet the United States was of the view that the authors' comment regarding flaws in Summer Grand did not state or imply that these flaws were characteristic of the variety. Because varieties ripen at different times, scientists had only a small window of opportunity to test the quarantine treatment simultaneously on several varieties. Thus idiosyncratic aspects of the physical condition of the specific fruit due to harvest practices, weather conditions, the amount of time one variety may have been stored while waiting for other varieties to be harvested for testing, and other external factors were reflected in the dose-mortality tests. The condition of any particular fruit could affect dose-response results.

4.92 Moreover, although Summer Grand required less methyl bromide than the other varieties to achieve 50 per cent mortality of the test insects, it required more methyl bromide to achieve 100 per cent mortality of the test insects than the other five varieties tested. This apparently contradictory information indicated that the natural variation of the insect, and factors such as experimental error, fruit condition, and factors that could affect the amount of fumigant to which insects are exposed, such as sorption by the packing material and load in the chamber, all played a role in differing dose-response results.[78]

4.93 It was also significant to note that over the summer of 1997, Vail and Yokoyama had re-tested two varieties of nectarines - May Grand and Summer Grand. In the dose-mortality tests, the level of methyl bromide required to achieve a lethal dose for 50 per cent and 95 per cent of codling moth eggs *did not* differ significantly.[79] This was in contrast to the initial 1987 nectarine study results. The United States argued that these 1997 results confirmed that the differences noted in 1987 were due to natural variation of the insects and other experimental variables. The authors of the 1997 study had stated the "extremely high numbers of insects killed in large-scale confirmatory tests and the virtual non-host status of nectarines attest to the high level of security afforded to this treatment to prevent introduction of codling moth to Japan via nectarine cultivars". In re-testing this variety in 1997, however, results of dose-mortality testing had indicated that the highest minimum dose for Summer Grand was now a dose closer to the six varieties tested in 1990. This indicated that a dose closer to that seen with dose-mortality tests for the 1990 batch might be the more appropriate level of treatment for nectarines.

4.94 More significantly, the confirmatory test applied in 1987 had established the efficacy of the treatment on *all* nectarines tested. A dose that was 20 per cent greater than the highest minimum dose required for 100 per cent mortality during the dose-mortality testing had been proposed as a quarantine dose for these six varieties.[80] This treatment had proven successful to achieve Japan's level

[77] *Ibid.*, pp. 466, 468, 470. (US Exhibit 12)

[78] The United States noted that probit model of analysis looked only at the linear relationship between dose and mortality (as stated in US Exhibit 28). There were other, more sophisticated statistical models which included consideration of natural variation of the test insect population. Such a model had been used to re-analyze all varieties in the 1987 and 1990 studies by Yokoyama *et al.*, Taking natural variation into consideration, it had been shown that the LD_{50}s among varieties were not significantly different (in Robertson and Yokoyama, "Effect of Nectarine Cultivar on Response of Codling Moth (Lepidoptera: Tortricidae) to Methyl Bromide Fumigation," Unpublished, 1998. (US Exhibit 15)).

[79] Vail and Yokoyama, "Nectarines: The Issue of Varietal Testing", unpublished. (US Exhibit 16)

[80] MB fumigation at 48 g/m^3 for 2 hours at 21° C or above and 50 per cent or less load.

of protection and had been accepted by Japan for all six varieties. As it was the large-scale confirmatory tests at a lower dose had not been done in 1990, because the 1987 results indicated that a higher dose was necessary. Thus confirmatory tests at 48 g/m^3 were completed (which was the dose established in 1987 that was derived from the highest minimum dose believed to achieve Japan's level of protection in the dose-mortality tests with 10-20 per cent added) and showed that this dose was effective for all nectarine varieties. Hence, the United States reaffirmed that confirmatory tests were the only relevant indicator of efficacy of a quarantine treatment. The United States maintained that Japan's claim that variations in dose-mortality tests obtained from two groups of varieties tested three years apart were the result of inherent varietal differences was scientifically invalid. Such a position ignored natural variation in responses of insects, and lack of a common control among tests (i.e., no one variety was tested in both years). Dose-mortality testing would inevitably show natural variability among dose-response results. This did not justify re-establishment of confirmed quarantine treatments for codling moth on a given product.

4.95 The United States noted that similar findings on different host fruit species and other insect species had been published in Japan; Misumi had investigated quarantine control through MB fumigation of the Japanese mealybug and the citrus mealybug naturally infesting Satsuma mandarins.[81] All stages of the two species of pests were reared on fresh pumpkins as an alternative to Satsuma mandarins because of difficulty in rearing mealybugs on the Satsuma mandarin. The physical and chemical differences between Satsuma mandarins and pumpkin were considerable. Yet despite the use of different host plants, the authors concluded this was of no significance to the efficacy of the fumigation process. Hence, Japanese scientists were willing to accept efficacy of quarantine treatment for a pest as it related to two radically different *products*, pumpkins and mandarins. This experiment supported the position of the United States that requiring exhaustive data on individual varieties of a product was not necessary. The study demonstrated that methyl bromide, when applied at specified concentrations over specified periods of time, killed codling moth in the same way, regardless of variety, and even regardless of substrate.

4.96 **Japan** recalled that at the time of the *additional* lifting of the ban for the 1990 varieties, even though a dose of 20 g/m^3 had been proven effective to ensure 100 per cent mortality, the United States had chosen to propose 48 g/m^3 as the treatment level.[82] The United States did have the option to propose 20 g/m^3 or 24 g/m^3, adding a "buffer", as the treatment for the additional three varieties. Japan accepted the application of the existing treatment[83] as the on-site confirmatory test had demonstrated its efficacy. This did, however, raise a practical question as to what level of treatment the United States would have proposed had the six varieties (tested in 1987) not been approved initially. It was reasonable to assume that they would *not* have proposed 48 g/m^3, but would have chosen a level around 24 g/m^3 instead. The United States could not argue that "confirmatory tests … showed that this dose (of 48 g/m^3) was effective for all nectarine varieties" (paragraph 4.94). At the most, the United States could argue that this dose was effective for the six varieties tested in 1987, and might be effective for the same varieties in the future.[84] A similar problem arose with respect to New Zealand cherries of the Bing variety (from paragraph 4.103).

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[81] Misumi, Kawakami, Mizobuchi and Tao. No. 30 Res. Bull. PL. Prot. Japan 30: 57-68, 1994. (US Exhibit 13, in Japanese)

[82] Japan noted that the scientists had determined the treatment level of 48 g/m^3 by multiplying the complete mortality dose of 40 g/m^3 by 1.2 times (buffer).

[83] Paragraph 4.94.

[84] Japan noted that Robertson (*Op. cit.*, US Exhibit 15) re-analyzed the data on American nectarines (1987 and 1990) by a statistical method developed by the author and concluded that no statistical difference was observed. However, the analysis failed to reject even a 190-times difference of confidence level. Such a wide degree of ambiguity was not acceptable to Japan.

TABLE 7
Doses which Achieved 100 per cent Mortality of One-day-old Eggs

Year	Varieties	Dose (g/m^3)
1987	**Summer Grand**	40
	May Grand	35
	Firebrite	35
	Spring Red	35
	Fantasia	30
	Red Diamond	30
1990	May Diamond	15.0
	Mayfire	17.5
	May Glo	20.0

4.97 Japan acknowledged that the issues of natural variation within the same insect group or year-to-year variation of the fruits were scientifically genuine. There would always be variables *other* than varietal differences. The existence of various exogenous variables did not by itself prove that observed differences were *not* attributable to varieties. The task of a scientific demonstration began, not ended, with the discovery of variables. Therefore, Japan had no reason to doubt the 1997 data on two cultivars of nectarines (May Grand and Summer Grand) which indicated, contrary to the 1987 test data, absence of a statistically significant difference between LD values. Explanatory variables other than varietal differences could include natural variation in insects or crops. However, Japan pointed out, once it was assumed that populations were different year-to-year, or case-by-case, any increase in the sample number was pointless, and large-scale confirmatory tests could not predict efficacy of a treatment either, because the confidence in the tests would end at the termination of that particular crop year (for the particular crop population), or with the last individual of that particular group of codling moth (for the particular insect population). This also belied the US claim that "the confirmatory test applied in 1987 established the efficacy of the treatment of *all* nectarines tested" (paragraph 4.94) The United States should have argued that the test did not confirm efficacy of the treatment for any variety in any year except 1987. Alternatively, the United States meant to say that there were unknown exogenous variables which *significantly* affected the results of these studies. However, from a practical point of view, this argument was equally empty; efficacy of a treatment could never be established.

4.98 Japan noted, in respect of the US reference to the 1987 nectarine study (paragraph 4.89), that the authors had stated that "no differences in egg susceptibility to MB were found among five infested cultivars". Hence, the conclusion had applied only with respect to the *five* varieties out of total of *six* varieties tested. In fact, a difference in efficacy had been found between the last variety (Summer Grand) and the others tested. The authors acknowledged that "[a] comparison of the LD_{50}'s showed that eggs on Summer Grand were significantly (non-overlap of 95 per cent CL) more susceptible to MB fumigation than eggs on other cultivars".[85]

4.99 In respect of the US reference to the 1990 nectarine study (paragraph 4.90), Japan noted that the authors had stated, "[w]e propose that a c x t product of 68.0±3.0 gh/m^3 methyl bromide ... would be a useful measurement to help maintain treatment security for control of codling moth on all

[85] *Supra* note 67, p.841. (US Exhibit 14)

nectarine cultivars".[86] The proposed measurement of the CxT product was the basis for the cited conclusion. However, the present treatment of nectarines did not control the CxT value during the fumigation process. Consequently, its efficacy across all cultivars could not be assumed from the authors' statement.

4.100 In respect of the US reference to the Vail *et al.*, 1997 re-test of Summer Grand and May Grand nectarines (paragraph 4.93), Japan pointed out that the authors had not demonstrated that a "high level of security" was equivalent of Japan's level of protection. Furthermore, the authors had not denied contribution of varietal differences; they had stated "the source of variation cannot be attributed *solely* to cultivar differences". (emphasis added).

4.101 The **United States** refuted Japan's claim that the order in which dose-mortality tests were conducted could result in the establishment of a treatment for one variety that would fail on additional varieties. As it had not been shown that variations in dose-mortality test data reflected underlying varietal differences affecting treatment efficacy, there was no evidence to support this assertion. The 1997 retest of the 1987 Summer Grand nectarine data indicated that the 1987 test results were anomalous. Had the results been in reverse order, there would have been no reason to believe that a treatment based on the lower dosage levels would not have been effective. And had the anomalous 1987 data been too low rather than too high, this would not have resulted in an ineffective quarantine treatment since the confirmatory test on the same variety would have failed. The United States stressed that an ineffective treatment would not be established in the first place, let alone be permitted to remain in place for future varieties. In addition, the United States noted that a confirmatory test could never indicate whether a dose was too high, only if was too low.

4.102 **Japan** noted, in this respect, that the results which the United States now described as "anomalous" were the United States' own test results which had formed the basis for lifting the ban on the importation of the products at issue.

(ii) Cherries

4.103 **Japan** recalled the conclusion of the authors of a 1987/1988 New Zealand study on cherries:

> "For the range of mortalities that we considered, the relationship between the c x t sum and the injected dose is close to linear, with a non zero constant term that varies between cultivars and between season. Thus, the injected dose that is required to achieve a given mortality will vary between cultivars. Factors that may affect the sorption pattern of any one cultivar require further investigation."[87]

4.104 In the case of New Zealand cherries, Japan noted that the same treatment level had been initially established for the Dawson and Bing varieties. When Rainier, Sam and Lambert varieties were additionally approved, test results showed a significantly higher level of efficacy for the Bing variety in comparison to Dawson, Rainier and Sam in terms of non-overlap of 95 per cent confidence intervals of LD_{50} and LD_{99}. As it was, since the treatment level had been set at a level which would ensure effective treatment of Dawson, the less susceptible variety, its efficacy was confirmed for the additional three varieties as well. Similar to the case of nectarines, the data implied a possibility, however, that, had Bing alone been approved initially, the treatment could have been established at a level which would have been found ineffective for Dawson, Rainier or Sam (Table 5, above).

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[86] *Supra* note 76, p.470. (US Exhibit 12)

[87] Maindonald, Waddell and Birtles, "Response to Methyl Bromide Fumigation of Codling Moth (Lipidoptera: Tortricidae) Eggs on Cherries", New Zealand. J. Econ. Entomol. 85(4): 1220-1230, 1992. (Japan, Exhibit 21 and US Exhibit 4)

4.105 Hence, Japan argued there were cases where, while the actual treatment levels were not modified, variations did exist to such a degree that different treatment levels could have been proposed depending on the sequence in which the varieties were tested. By no means did this imply that varietal difference did not exist because the same treatment of the pest had been found effective for all approved varieties of the respective products.

4.106 The **United States** pointed out that the authors of the New Zealand study on cherries had concluded that "although the results indicated a higher injected dose when 'Rainier' had been fumigated compared to 'Bing', the large change between seasons in the results for 'Sam' indicated that seasonal differences (perhaps associated with differences in maturity) may have been more important than cultivar".[88] Many factors could have contributed to a variation in Bing in 1987. The authors had noted that "sources of variation that may affect results include the insect material, cherry sorption, and measurement and circulation of methyl bromide within the chambers". [89] For example, Sam cherries had different sorption patterns between 1987 and 1989. Again, the Japanese overlooked the existence of natural variation of the test insects, whether it occurred in the United States or another exporting nation.

4.107 Most significantly, the United States claimed that Japan had also ignored the stated conclusion of the authors that the developed quarantine treatment for cherries was applicable to all cherry varieties. "Where complete kill is the objective, the commercial rate used by cherry exporters is 64 g/m^3, 12º C, 2 hours, and 40% load. *This treatment controls codling moth eggs potentially infesting any of the cultivars considered".*[90] [emphasis added]. For all season-cultivar combinations, in both years, the highest lethal dose levels of methyl bromide at the LD_{95} had still been at least 10 g/m^3 below the "complete kill" commercial dose used to do the confirmatory test. As the authors further noted in the article abstract: "The commercial treatment thus affords a high level of security". Japan had incorrectly interpreted the significance of these studies and erroneously concluded that the efficacy of treatment could vary within a product.

4.108 The United States argued that there was always a degree of variability in any dose-mortality test from variety to variety and even *within the same fruit variety*. Such variations were the inevitable result of differences in natural conditions and testing environments, from crop to crop and year to year. Japan had already accepted a certain dose-response variability in allowing imports of the varieties that it had already approved. This normal variability in testing results could not constitute a legitimate basis for denying approval for other varieties of the same products. **Japan** maintained that the existence of various exogenous variables did not in itself prove that the observed differences were *not* attributable to varieties.

(c) CxT Values

4.109 **Japan** claimed that in the specific case of MB fumigation, the link between varietal differences and divergent efficacy of the fumigation treatment could manifest itself by way of the difference in the CxT value.[91] The process could take the following sequence: When MB gas was injected into the fumigation chamber, it would be absorbed by the surface or the pulp of the fruits. If the sorption varied depending on the variety of the fruits, the amount of fumigant remaining in the chamber air would vary in an inverse relationship to the sorption. Then the CxT value, a known

[88] *Ibid.,* p.1227. (Japan, Exhibit 21 and US Exhibit 4)

[89] *Ibid.,* p.1224. (Japan, Exhibit 21 and US Exhibit 4)

[90] *Ibid.,* p.1229. (Japan, Exhibit 21 and US Exhibit 4)

[91] Japan noted that in fact, the mode of action of MB treatment on insects was not fully known, and there could be other mechanisms by which varietal differences could affect the efficacy and referred to by Bell *et al.*, (Price and Chakrabarti, "The Methyl Bromide Issue", 1996. (Japan, Exhibit 11))

indicator to control the degree of efficacy of the treatment[92], would vary as well depending on the variety of the fruit. Japan claimed that it could reasonably be assumed, by ways of the CxT values, that there was a route by which the characteristics of a fruit of particular variety could affect the outcome of disinfestation efficacy.

4.110 Japan claimed that there were three empirical cases which demonstrated a statistically significant difference in the CxT value between tested variety samples, including the case of three cultivars of walnuts the United States referred to in their submission[93]:

[92] Japan noted that E. J. Bond had stated that "[t]he use of integrated c x t products is particularly useful in routine fumigations when the reaction of a particular species or groups of species has been carefully worked out under the range of conditions likely to be encountered. It has been used successfully in large-scale eradication campaign" (Bond, E.J., "Manual of Fumigation for Insect Control", 1984. (Japan, Exhibit 12)).

[93] Japan noted that in addition, in a test on New Zealand cherries, it had been found that "[g]as chromatograph readings during the fumigations suggested that 'Bing' cherries absorbed less methyl bromide than 'Dawson' cherries", Wearing, Batcholor, Maindonald, "Disinfestation of New Zealand Cherries", Department of Scientific and Industrial Research, 1981. (Japan, Exhibit 13).

(a) 1985 tests on three varieties (Hartley, Payne and Franquett) of American walnuts (1985 Walnut Test Report): CxT values had been significantly different between Franquett (75.7 gh/m^3 at the first replicate; 71.5 gh/ m^3 at the second replicate) and Payne (109.4 gh/m^3, and 99.9 gh/m^3, respectively). [94]

TABLE 8
Fumigant Concentration and CxT Values for 3 Varieties of American Walnuts

Variety	Replicates	Fumigant Concentration (g/m^3)		CxT Value (gh/m^3)
		Immediately after Injection of Fumigant	4 hours after Injection	
Hartley	1 2	54.0 54.1	16.2 15.0	101.0 87.4
Payne	1 2	51.2 50.8	18.9 17.5	109.4 99.9
Franquett	**1** **2**	**51.3** **33.7**	**12.7** **12.9**	**75.7** **71.5**

(b) 1988 tests on three varieties (May Glo, Mayfire and May Diamond) of American nectarines: CxT values of May Diamond had showed a statistically significant difference with the other two cultivars for most of the doses. [95]

TABLE 9
CxT Values of American Nectarine Varieties and Doses (2 hours, 21°C, 50% Load Factor)

Variety	CxT Values (gh/m^3±SD) for Fumigant Doses			
	48 g/m^3	64 g/m^3	96 g/m^3	128 g/m^3
May Glo	64.8±0.8	86.6±1.8	132.7±5.1	173.8±7.3
Mayfire	63.8±1.2	86.4±3.4	135.0±4.9	182.4±10.2
May Diamond	**72.4±4.4**	**98.2±8.4**	**158.2±7.5**	**208.2±9.7**

[94] Vail, Hartsell and Tebbets, "Walnut On-Site Operational (Demonstration) Test Report to Japanese Ministry of Agriculture, Forestry and Fisheries", USDA/ARS, 1985. (Japan, Exhibit 14)

[95] Vail, "Efficacy of Methyl Bromide for Codling Moth on Nectarines – Consideration of Nectarines as a Product Group", USDA, 1988. (Japan, Exhibit 15)

(c) 1997 tests on three varieties (Fantasia, Flavortop and Shuhou) of Japanese nectarines: There had been a statistically significant difference in CxT values between Shuhou and Fantasia.[96]

TABLE 10
Residual Gas Rate of Fumigant, CxT Value and Fumigant Sorption of Fantasia, Shuhou and Flavortop Nectarine Varieties in MB Fumigation
(48g/m^3, 20^{o}C, 2 hours, 0.143t/m^3 Load Factor)

Variety	Replicates	Weight (kg)	No. of Fruits (Unit)	Residual Gas Rate (%)	CxT values		Sorption (mg/kg)
					gh/m^3	Mean ± SD	
Fantasia	1	4.218	32	68.2	71.1	71.0	133.1
	2	4.213	32	67.1	69.9	±1.1	139.8
	3	4.218	32	68.4	72.0		134.2
Shuhou	**1**	**4.217**	**30**	**69.7**	**66.1**	**66.0**	**146.7**
	2	**4.212**	**30**	**70.3**	**65.9**	**±0.2**	**144.9**
Flavortop	1	4.213	26	69.7	69.8	68.8	136.2
	2	4.216	26	68.4	67.8	±1.4	141.9

4.111 Japan noted that these significant differences were attributable to varieties as the CxT value was affected by physical and chemical properties of the fruits, which were attributable to varietal characteristics. For example, in the case of walnuts, Japan suspected that the differences in the oil content of the walnuts, a qualitative feature of the particular variety, affected the sorption of fumigant and the resulting CxT values. Similarly, the CxT value variation in the 1997 nectarine experiment (third table under paragraph 4.110) was considered attributable to Shuhou's rougher surface, another feature characteristic of the variety, compared to other varieties.

4.112 Japan noted that despite test-to-test variation, statistical analysis using Tukey's multiple range test had found a *statistically significant* difference in the CxT values between Payne and Franquett varieties of walnuts. Statistically speaking, Franquette's CxT value was lower than that of Payne at the confidence level of 95 per cent. Similarly, the same statistical tool had found a significant difference among the nectarine varieties in the second and third experiments set out in paragraph 4.110 上の.

4.113 Japan claimed that the study on Satsuma mandarins and pumpkins which the United States had cited (paragraph 4.95) was in fact fully consistent with the present Japanese practice. Japan recalled that the hypothesis underlying the Japanese policy was that varietal differences could be such as would affect sorption of fumigant by the fruits, resulting in different CxT values and hence efficacy of MB fumigation treatment. In the cited experiment, faced with the difficulty of rearing and placing mealybugs on Satsuma mandarins[97], scientists had chosen to use pumpkins as a proxy for Satsuma mandarins because the CxT values between the two plants were remarkably close. It was incorrect to

[96] Research Division, Yokoyama Plant Protection Station, "Methyl Bromide Sorption in Nectarine Varieties", unpublished, 1997. (Japan, Exhibit 16)

[97] Japan noted that it was difficult to rear mealybugs on Satsuma mandarins because, under conditions suitable to the insects, the fruits easily decayed and/or the peel hardened. If one tried to place mealybugs on Satsuma mandarins after rearing them on other fruits, on the other hand, their natural mortality would be very high because of possible damage the insects would suffer upon such placement.

state that "Japanese scientists were willing to accept efficacy of quarantine treatment for a pest as it related to two radically different products". Quite the contrary, these products were almost identical as far as the crucial factor – the CxT value – was concerned. This experiment by no means undermined the hypothesis relating to the varietal differences.

TABLE 11
CxT Values for Satsuma Mandarins and Pumpkins[98]

Subject	Replicates	Load (kg)	CxT Value (mgh/l)
Satsuma Mandarins	1	1.45	92
	2	1.50	92
	3	4.10	98
Pumpkins	1	1.45	94
	2	1.50	93
	3	4.10	95

4.114 The **United States** claimed that minor differences in CxT values between varieties did not indicate differences in varieties of a single product. While CxT values could assist in developing a commercial treatment to kill codling moth, they did not in and of themselves indicate differences in varieties. The difference in CxT could be just as pronounced within the same variety. The experts advising the Panel had not accepted the notion that these differences could be attributed to varietal differences and had furthermore pointed out that, whatever the cause of CxT variation between varieties, these differences had not been observed to affect treatment efficacy.

4.115 Reasons for CxT value variations included (i) minor differences in leakiness of fumigation chambers; (ii) the amount of toxicant taken up by the product or the packaging material; (iii) the amount of product being fumigated (the load); (iv) the accuracy of the various measurements used to calculate the CxT; and, (v) the times at which the concentrations in the chambers were sampled. The United States stressed that CxT values were used by researchers only as a control mechanism for fumigation trials. They were not useful for concluding that there were differences in varieties. In addition, the United States pointed out that the experts advising the Panel had confirmed that test-to-test variation was inevitable in small-scale tests because of natural variations in pest populations, testing equipment and conditions, and product samples. Also, variations within a product were likewise inevitable from season to season, tree to tree and fruit-to-fruit within a variety. The experts had, according to the United States, in this regard noted that fruit-to-fruit variation could greatly exceed variety-to-variety variation, if any. Variation could also occur because of the difficulty of having different varieties in the same physiological state because of ripening times.

4.116 Importantly, the United States stressed that the experts advising the Panel had made very clear that it was not possible to conclude that that test-to-test variation in CxT values were attributable to varietal differences rather than any of the other sources of variation described.

4.117 In the 1992 New Zealand study on cherries, the CxT values for the Sam variety of cherry varied from one season to the next (paragraph 4.106). Moreover, from the Summer Grand and May Grand varieties of nectarines tested in the Vail *et al.*, 1997 nectarine re-test (paragraph 4.93), it was possible to see that CxT values differed within the same varieties compared to the 1987 nectarine study results. In large-scale US tests of nectarines, it was again evident that there could be as much difference in CxT values within a single variety as among varieties. The difference in CxT value ranges

[98] *Supra* note 81, pp.57-68. (US Exhibit 13).

within May Grand nectarines, in 1991, was comparable to the difference between May Grand and Royal Giant nectarines in 1989 and 1991[99] (Table 12 below). The United States noted that in respect of walnuts, the Hartley variety referred to by Japan exhibited a difference in CxT values from one test to the next; this difference was greater than the difference in CxT values between the varieties Hartley and Payne.[100] Hence, in the view of the United States, these results illustrated that there could be any number of reasons why CxT values varied and their variations were not indicative of any varietal characteristics.

TABLE 12
CxT Values From Large-scale Tests on
U.S. Nectarine Varieties in Carton Containers

	1989	**1991**	**1992**
Royal Giant	69.6 72.1		67.8
May Grand		70.8 79.4	
Fantasia		73	

4.118 In respect of walnuts, the United States noted that Japan had pointed to the results of the 1985 Walnut Research Report[101] to assert that a difference in CxT values in dose-mortality tests applied to varieties of fruits supported the need for varietal testing. Again, the United States claimed that test-to-test variation of *one variety* had been as great as that found among all three tested varieties of walnuts.[102] CxT values were an indication of how much toxicant was available to the target insect. Regardless of the observed differences in the CxT values, there was no difference in the efficacy of the quarantine treatment for the three varieties of walnuts. Japan approved the methods and data generated during these studies and had not requested different quarantine schedules for the three varieties.[103] In this respect, the United States noted that in bilateral talks in March 1997, the parties had discussed the Japanese decision not to allow import of the walnut variety Eureka due to perceived differences in sorption of methyl bromide. In fact, Japan had refused importation because, although its de-sorption rate had not been significantly different, Eureka had consistently higher residues, likely attributable to higher natural oil content (that would retain the methyl bromide), as compared with other varieties of walnuts.[104] Concerns over methyl bromide residues were exclusively related to food safety and had nothing to do with the efficacy of the quarantine treatment. The United States insisted

[99] Yokoyama, Miller, and Hartsell, "Methyl bromide efficacy and residues in large-scale quarantine tests to control Codling moth (Lepidoptera: Tortricidae) on nectarines in field bins and shipping containers for export to Japan". 87 J. Econ. Entomol. 730-735, 1994. (US Exhibit 36)

[100] US Exhibit 31.

[101] Vail, Nelson, Hartsell and Tebbetts. "Development of a Quarantine Treatment for the Codling Moth in Walnuts for Export to Japan. (Not published in a scientific journal). Walnut Research Report 1985. Walnut Marketing Board, Sacramento, CA., pp.149-154. (US Exhibit 17)

[102] *Ibid*., p.150. (US Exhibit 17)

[103] The United States recalled that the uniform treatment for walnuts was 56g/m^3 methyl bromide fumigation for 4 hours at 15.6º C at 100mm HG, and a load factor of less than 50 per cent.

[104] Hartsell, Tebbets, and Vail, "Methyl Bromide Residues and Desorption Rates from Unshelled Walnuts Fumigated with a Quarantine Treatment for Codling Moth (Lepidoptera: Tortricidae)" 84 J. Econ. Entomol. pp. 1294-1297, 1991. (US Exhibit 18)

that perceived differences in de-sorption rates (rate at which fumigant leaves a product) did not indicate varietal differences with respect to quarantine protection. Although Eureka had consistently higher residues than the other three varieties tested, these differences had not been statistically significant and had not affected treatment efficacy. In fact, preliminary tests showed that there was no survival of test larvae in any of the varieties treated. The authors of the 1991 report on the 1985 tests on walnuts, had stated that "no significant differences were found in mortality of larvae among the four walnut cultivars tested, nor was variation in the size of walnuts of each cultivar a significant factor".[105] At the second substantive meeting of the Panel, the United States submitted an article which clarified that oil content in walnuts did not vary by variety.[106] Hence, even if sorption was affected by oil content, there was no basis for concluding that this varied by variety.

4.119 The United States pointed at the Japanese admission that for apples, cherries, nectarines and walnuts, there was no disagreement as to the efficacy of the treatment as applied to the approved varieties (paragraph 4.6). The United States claimed that implicit in this acknowledgement was a recognition that there would be variations in the preliminary dose-mortality testing and these differences did not alter the final quarantine treatment. These variations were evident in the test results of these approved varieties. Japan's recognition acknowledged that CxT values could vary, but that they were not relevant in reaching efficacy (in killing the required amount of codling moth). To suggest that the variations of data in dose-mortality testing on its own represented differences in varieties was inconsistent with this concession on the part of Japan.

4.120 Moreover, the United States claimed that CxT was not an indicator of *likeness* among varieties or products. In reference to Satsuma mandarins and pumpkins Japan had asserted that it was within reason to accept treatment for a pest on two different products so long as the two products had identical CxT values (paragraph 4.113). This ignored all other physical aspects of the product such as size, as well as what biological stage of the pest would interact with a product. The United States recalled that the CxT value measured the amount of fumigant outside of a product in a fumigant chamber. Yet codling moth was not only on the outside of nectarines. The pest actually burrowed into apples, cherries and walnuts. CxT was silent on the way the fumigant interacted with the pest *inside* the product. If CxT were the standard of efficacy, then treatments would be developed that were ineffective in addressing the stage of pest, where the pest was located on the product, and the obvious differences among products that necessitate different treatments. Irrespective of what accounted for differences in CxT values, it had to be remembered that these values were merely tools in estimating and establishing a treatment level that resulted in mortality. Treatment efficacy did not rely on CxT values. It relied on the ability to kill the required level of pests.

4.121 Finally, the United States claimed that Japan had, in attempting to justify its theory, mischaracterized the meaning of the article by E.J. Bond that it cited (footnote 92 to paragraph 4.109). While Japan seemed to be suggesting that Bond linked CxT values to variety of the product and differences among those varieties, he was in fact discussing CxT values as they related to the pest, and specifically the role of CxT values as a tool to observe the interaction of the fumigant and the pest. The Bond article did not suggest that differences in CxT indicated differences in variety.[107]

4.122 In addition, the United States noted that Japan had stated that the method it used to test the statistical significance of walnut data was "Tukey's multiple range test". However, tests such as Tukey's were based on an analysis of variance. In order to be used correctly, several assumptions had to be met,

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[105] Hartsell, Vail, Tebbets and Nelson. "Methyl Bromide Quarantine Treatment for Codling Moth (Lepidoptera: Tortricidae) in Unshelled Walnuts", 84 J. Econ. Entomol. pp. 1289-1293, 1991. (US Exhibit 19)

[106] Greve, McGranahan, Hasey, Soder, Kelly, Glodhammer and Labavitch, "Variation in Polyunsaturated Fatty Acids Composition of Persian Walnut", Department of Pomology, University of California, USA , J. Amer. Soc. Hort. Sci 117(3):518-522, 1992. (US Exbibit 40)

[107] Bond 1994, p.25. (Japan, Exhibit 12)

among them the requirement that samples used in replicates had to be randomly and independently selected and the requirement that the variances of the different samples were homogeneous. Tukey's test was not relevant to an analysis of the walnut data Japan examined[108] because this data failed to meet both assumptions. For each of the varieties listed in Table 8 (page 41), the walnuts used in each "replicate" were taken from the same batch of walnuts. The samples were thus not independently selected, and it was inaccurate to describe the test on each variety as "replicates". Second, the variances of the data for each variety were not homogeneous.[109] Finally, the United States pointed to the observation of the experts advising the panel that even if Japan had demonstrated "statistically significant" differences in CxT, such differences would not necessarily have been a reflection of significant biological differences which could affect efficacy.

4.123 In sum, CxT values did not indicate differences among varieties. Those differences were just as pronounced *within* varieties. The United States claimed that Japan implicitly had to have understood this conclusion since it did not require different quarantine treatments or testing for the same variety despite differences in CxT values within varieties.

4.124 **Japan** contended that among the exogenous factors to which the United States attributed the differences in varieties (as set out in paragraph 4.115), the load factor had been controlled in the second and third of the three empirical cases described in paragraph 4.110 上の. Other factors, such as leakiness of fumigation chambers or the measurement error, called for further empirical confirmation. They by no means vindicated the US position that varietal differences were irrelevant to the statistically significant differences in CxT values. In addition, the factor of "the amount of toxicant taken up by the product", which the United States admitted affected the variation in CxT values, was exactly what Japan believed was a key determinant of the values which could be attributable to varietal differences. Japan contended that even though codling moth larvae burrowed into the pulp from the exterior of the fruit, it respired the surrounding, fumigated air. It was therefore reasonable to assume that that CxT was indicative of some interaction with the fumigant.

4.125 In respect of the US argument in paragraph 4.117, regarding the 1992 New Zealand study on cherries, Japan noted that the cited results indicated possible interaction of variables, and by no means proved the absence of a link between a significant difference of CxT values and varietal differences. Japan reiterated that it was the scientists' responsibility to identify variables, account for them and devise ways to alleviate statistical problems, unless one were to discard the CxT value in phytosanitary experiments.[110] After all the efforts to discredit the statistical significance of variation of the CxT values, the United States had nevertheless admitted that they had value as "tools in estimating and establishing a treatment level that results in mortality" (paragraph 4.120). If the values could vary for "any number of reasons", and if scientists were incapable of controlling these reasons, Japan failed to understand how the values could "estimate" or "establish" any parameter.

4.126 Furthermore, in respect of the same study, Japan noted that the authors' conclusion applied only to the *five* varieties tested for efficacy confirmation: "[b]ecause the five cultivars of cherry that we considered have different sorption patterns, different injected doses are required to achieve a given level of mortality. ... Where complete kill is the objective, the commercial rate used by cherry exporters is 64 g/m^3, 12 C, 2 hours, and 40 per cent load. This treatment controls codling moth eggs potentially infesting any of the cultivars considered".[111] Japan stressed that the authors had, in fact, acknowledged the presence of varietal difference; for they had stated: "We found differences in

[108] In paragraph 81 of Japan's first submission.

[109] US Exhibit 39.

[110] In this respect, Japan noted that it was puzzled by the small number of samples in the 1997 retest (30 individuals compared to 160 in 1987).

[111] *Op. cit.*, p.1229. (Japan, Exhibit 21 and US Exhibit 4)

sorption of methyl bromide between cultivars and between seasons"[112] and, "For the range of mortalities that we considered, the relationship between the c x t sum and the injected dose is close to linear, with a non zero constant term that varies between cultivars and between season. Factors that may affect the sorption pattern of any one cultivar require further investigation."[113] Japan reiterated that with regard to nectarines, the same authors had suggested that the CxT value "would be a useful measurement to help maintain treatment security for control of codling moth on all nectarine cultivars".[114]

4.127 With regard to walnuts, the reason why Japan did not request different quarantine schedules for the three varieties was because, under the concept of a representative variety discussed before, Japan had accepted the large-scale efficacy data on Hartley and found that the proposed treatment would disinfest codling moth to the satisfactory level. It was not because varietal differences were irrelevant.

4.128 Japan noted, in respect of the US citation of the Hartsell *et al.*, 1991 walnut study on MB treatment (paragraph 4.118), that the study did not include comparative tests of varieties and the cited conclusion was drawn from the result of 100 per cent mortality which was achieved for all varieties stored in the same fumigation chamber at the same time. Absence of varietal differences could not be proved under such conditions. In fact, in a preliminary study it was stated the "[t]here were no significant differences due to cultivar except Eureka, which had higher residue at all three temperatures tested and is indicative of the higher oil content found in this cultivar", and that "[a]ll cultivars desorb MB at about the same rate with the exception of Eureka which due to its higher oil content has a slightly longer retention time".[115] Japan had concluded from these results that the Eureka variety tended to retain MB at a higher level due to its oil content and could show differences in efficacy, and that further comparative tests would be needed on the variety. In the end, the United States had dropped the Eureka variety from the request for approval, and import prohibition was lifted for the other three varieties in 1986. Japan stressed that the issue of MB residue in Eureka was not related to concern over food safety.

4.129 With regard to Bond's study (paragraph 4.121), Japan had cited an authoritative view on the utility of the CxT value as an indicator of efficacy of fumigation. The Japanese argument was simply that if CxT value varied depending on the variety, efficacy of a treatment might vary according to varieties.

4.130 The **United States** maintained that Japan had misinterpreted the scientific data. Japan was alleging that the primary basis for its assumption (that variety mattered) was that differences in CxT values meant that there were differences in sorption between varieties that affected efficacy of treatment. The fact that CxT values had been observed to be different in tests involving different varieties appeared to be the sole basis of Japan's theory that variety mattered. Yet the experts advising the Panel had stated that there was no evidence to support Japan's suggestion that sorption differences had been shown to be large enough to affect treatment efficacy. Such differences, would, in their expert opinion, have to be "significant" or "large" in order to create sorption differences of sufficient magnitude to affect treatment efficacy. Furthermore, Dr. Ducom had emphasized that there was a lack of precise studies on factors contributing to differences in sorption levels and that the "notion of CxT has not been studied enough". In respect of sorption and apples, the United States pointed out that Dr. Heather had explained that while sorption might have an impact on MB treatment, it would have no impact on cold treatment.

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[112] *Ibid.*, Abstract, p.1222. (Japan, Exhibit 21 and US Exhibit 4)

[113] *Ibid.*, Discussion, p.1228. (Japan, Exhibit 21 and US Exhibit 4)

[114] *Supra* note 76, p.470. (US Exhibit 12)

[115] *Supra* note 101, p.107. (US Exhibit 17)

Thus, there were no grounds to even speculate that sorption differences among apples could affect treatment efficacy.

4.131 Moreover, the United States noted that, according to Dr. Ducom, if Japan were serious about developing sufficient scientific evidence to support its theory that CxT variations might be related to varietal differences affecting treatment efficacy, Japan could conduct specific studies on the matter. Yet no effort had been undertaken in this respect. In fact, Japan had not put its own theory into practice. In regard to those products that Japan indicated exhibited differences in CxT values (nectarines and walnuts), the fact remained that Japan had never attempted to confirm its hypothesis, to explore *why* CxT values varied, or to link differences in CxT values with differences in products. In regard to other products subject to this measure (apples, apricots, cherries, pears, peaches, plums and quince) Japan had not made any such observations or assertions regarding variations in CxT. Therefore, presumably there was no basis for applying its measure *a priori* to these products.

4.132 The United States reiterated that the measure of efficacy was not CxT values, but whether the exporting country could eliminate the pest of concern at a sufficient rate to achieve Japan's level of phytosanitary protection. Differences in CxT values were the result of "real world" variables typically seen in testing procedures and did not indicate that varietal differences affected the efficacy of quarantine treatment. Under the SPS Agreement, Japan was required to have a scientific basis for its assumption that variety did matter, but its embrace of CxT values as the basis of such a theory fell short of that responsibility.

4.133 The United States claimed that if Japan truly believed that CxT values were the indicator of efficacy, there would be no need to show that the dose of fumigant resulted in a particular level of mortality of the pest. Yet the ability of the United States to gain access for a variety of fruit into Japan depended upon its ability to show that the requisite amount of codling moth had been killed. CxT values could vary from Payne walnuts to Franquette walnuts, but the MB treatment was the same because that treatment killed codling moth uniformly in both varieties. There could be differences in CxT values between May Glo and May Diamond nectarines, but the MB treatment was identical for these two varieties because that treatment killed the codling moth uniformly. It was evident that CxT was not a direct indicator of efficacy of treatment. The indicator of efficacy of quarantine treatment was the ability to uniformly achieve the required level of mortality of codling moth. In every instance, regardless of CxT values, and regardless of variety, the level of phytosanitary protection required by Japan had been achieved with a treatment that was uniform for all varieties of a product.

4.134 The United States also noted that the arbitrary manner in which the measure was applied further called into question its scientific basis. As Japan had explained it, if an exporting country had ten varieties of a commodity available for export, a so-called representative variety could be used in a confirmatory test. Yet if those same ten varieties were proposed in sets of five over two different years, a confirmatory test that previously would have sufficed for all ten varieties had now to be applied twice. There was no logic to this application. Moreover, the United States noted that Dr. Heather had pointed out that if one were to accept that dose-response tests could be used to establish varietal differences, why then would it be necessary to follow-up these tests on newly tested varieties with a confirmatory test?

4.135 **Japan** noted that it had never claimed that varietal differences *always* resulted in differences in CxT values. What was argued was that there existed studies which detected a statistically significant difference of CxT values between varieties. Furthermore, replication-to-replication variation was in itself irrelevant; testing in replicates was exactly for the purpose of eliminating experimental bias. Presence of replication-to-replication variation by no means impaired the utility of the CxT value as an indicator of varietal difference. Japan pointed out that Dr. Ducom had endorsed the presence of the link between varietal differences and differences in the CxT value. In any event, it was the United States' responsibility to identify relevant variables which they claimed existed and establish a treatment which would satisfactorily incorporate them so that Japan's level of protection would be achieved despite such variations.

(d) Comparison with other products

4.136 **Japan** noted that while the main focus of the dispute at issue related to fumigation, there were cases where certain differences in efficacy of thermal treatment between different varieties were observed. Japan recalled that the United States had established standards which treated mango varieties differently for hot water treatments.[116] The immersion time was set differently according to varieties with physical differences (the size and shape) of the mango. The treatment time was shorter for fruits with a flat and long shape, or for smaller fruits.

4.137 Japan did not doubt that the United States had a genuine reason to differentiate the varieties as they related to physical characteristics of the fruits, in light of their impact on the efficacy of the treatment. Under the same logic, Japan's policy of differentiating varieties was justifiable as they related to physical/chemical characteristics of the fruits, which might impact on efficacy of treatment. Moreover, in 1993, when additional varieties of Thai mangoes (Nam Dokmai, Rad and Pimsen Daeng) were investigated, Japan had found by a mortality comparison that the existing vapor heat treatment (46.5° Celsius for 10 minutes, developed for the Nang Klamguan variety) was not sufficient. This resulted in a new vapour heat treatment (the temperature to be raised by a fixed rate to 43 degrees Celsius and held at over 47 degrees for 20 minutes).[117]

4.138 Japan noted that other countries also considered varietal differences in their design of quarantine treatment. According to a Japanese survey, in addition to the Republic of Korea, both Canada and Australia considered relevant issues surrounding varietal differences. Japan noted that Australia had indicated in a communication to Japan that when new varieties were proposed for approval into Australia, their "likely procedure would involve re-evaluation of the relevant pest risk analysis (PRA)," and that "[t]he PRA process would consider any relevant technical information on varietal differences". Hence, contrary to the United States' assertion, Australia would perceive the risk of varietal differences and act accordingly.[118] In the case of New Zealand, the authorities' manual for development of fruit fly disinfestation treatment stated:

> "A disinfestation treatment may need to be developed for each variety of fruit separately. While a variety may be described formally in the procurement of proprietary rights, where a variety is not formally described or where varieties can be shown to be morphologically and physiologically similar, definition of the distinctive fruit types must be provided (for example, ovoid eggplant as opposed to oblong eggplant, or long green chilli as opposed to small yellow chilli)."[119]

4.139 The **United States** noted that Japan, in referring to thermal treatments as used on mangoes from Thailand, was attempting to infer that the US practice of treatment for mangoes made distinctions based on variety; this was distorting the scope of the dispute by introducing alternative treatments which were not within its scope. It was clear to the United States that the scope of the dispute related to products that could be host to codling moth and for which the quarantine treatment of methyl bromide or methyl bromide and cold storage was used.

4.140 Nevertheless, the United States was compelled to rebut the assertion made by Japan that the United States differentiated quarantine treatment for pests on a variety-by-variety basis. US scientists were aware that such objective morphological characteristics as fruit size and shape, irrespective of variety, were important parameters in determining the schedule for heat treatments. The treatment

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[116] PPQ Treatment Manual. (Japan, Exhibit 22)

[117] Unahawutti, U. *et al.*, Unpublished, 1991. (Japan, Exhibit 23)

[118] Japan, Exhibit 38.

[119] MAF, Regulatory Authority Standard., paragraph 3.2.1. (Japan, Exhibit 24)

schedule for mangoes in the United States was not by variety but by size and shape, which could vary within the same variety. As Dr. Heather had noted, size and shape of the fruit "are a varietal characteristic but not exclusively so". The larger or rounder the fruit, the longer it took to heat the fruit to the centre. Thus the heating rate for fruit that was small or flat was much faster than for fruit that was large or round. This was evident from the heat treatment schedules for mangoes found in the APHIS Plant Protection and Quarantine Treatment Manual.[120] Moreover, the United States did not require testing of new mango varieties, but assigned a treatment based on the size and shape of the proposed import variety. Furthermore, the United States noted that the experts advising the Panel had stated that reactions of different products to different treatments "have nothing to do with each other" and that fumigation bore little relationship to other treatments.[121] It was therefore not relevant to compare thermal treatment on mangoes with fumigation on the products at issue.

4.141 The United States also noted that Japan had indicated that Canada, Australia and New Zealand all took into account varietal differences in quarantine treatments. Recent communications with these countries clearly refuted this assertion:

(a) Australia had indicated in a communication with the United States, that it did not require assessments by variety for fumigation quarantine treatments.[122] In respect of the letter from Australia referred to in paragraph 4.138 above[123], the United States emphasized that Australia did not require varietal testing nor did Australia apply different quarantine treatments based on variety. The letter in fact indicated that Australia had not prejudged the need for a varietal testing requirement, that it would examine "any relevant scientific or technical information on varietal differences" in deciding whether to extend existing treatments to additional varieties. The United States maintained that the experts had confirmed that there was no scientific evidence that varietal differences affected efficacy.

(b) The Government of New Zealand had similarly confirmed that it did not differentiate between varieties of a product[124]; moreover, the "MAF Regulatory Authority Standard 155.02.03 Specification for the Determination of Fruit Fly Disinfestation Treatment Efficacy" addressed the possibility of a statement of varieties for dimethoate dip treatments for fruit fly in tomatoes.[125] All other fruit fly treatments were determined on a species basis.

(c) The Government of Canada, in a communication dated 17 April 1998, had confirmed that it did not require testing by variety for quarantine treatments.[126]

Hence, in sum, none of these countries required varietal testing for quarantine treatments.

4.142 In respect of Australia ((a) above), **Japan** restated that contrary to the United States' assertion, Australia also considered varietal differences in their design of quarantine treatment and would act accordingly (paragraph 4.138). Japan refuted the US statement that the treatment schedule for

[120] United States Department of Agriculture, Animal and Plant Inspection Service, Treatment Manual, V.2, pp. 5.45 - 5.58. (US Exhibit 32)

[121] See Section VI of this report, Question 15.

[122] Letter to Ms. Audrae Erickson from Mr. Paul Morris, dated 20 April 1998. (US Exhibit 33)

[123] Letter to Mr. Takeo Kocha from Mr. Christopher W. Wood, dated 18 June 1998. (Japan, Exhibit 38)

[124] Letter to Ms. Audrae Erickson from Mr. Tony Pautua, dated 9 April 1998. (US Exhibit 34)

[125] Dated 22 November 1994. (Japan, Exhibit 24)

[126] Letter to Ms. Audrae Erickson from Dr. J.E. Hollebone, dated 17 April 1998. (US Exhibit 35)

mangoes was not by variety. Clearly the US schedule referred to varieties. If, as the United States implied, a "flat, elongated" variety such as Frances was sometimes treated as a "rounded" variety, an almost insurmountable administrative problem would arise. It appeared impractical to implement the schedule without a predetermination of the treatment on a varietal basis. Although this schedule was for hot water treatment and not MB fumigation, it did show that concern over varietal difference was quite common.

3. Article 5.1

4.143 The **United States** recalled that Article 5.1 of the SPS Agreement required WTO Members to "ensure that their sanitary or phytosanitary measures were 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".

4.144 The United States noted that in bilateral consultations, Japan had asserted that it had conducted a risk assessment according to the procedures set out in the FAO PRA Guidelines (these procedures are described in paragraphs 2.29 and below).[127] The document provided to the United States subsequent to the consultations, however, did not support this assertion. In the view of the United States, Japan had not followed the FAO guidelines.[128] The document which Japan described as a "risk assessment" merely asserted that codling moth was a pest of quarantine significance.[129] This was not in dispute. What was in dispute was whether *the measure* taken by Japan to ensure its level of protection was based on scientific principles, maintained with sufficient scientific evidence, and *based on an assessment of risk*. On this point, the Japanese document was silent. In other words, Japan's consideration of factors such as the ability of the pest to survive in Japan's climate, the biology of the moth as it related to crop seasons in Japan, the ability of the pest, once it had entered Japan, to infest and harm crops, or, the costs of such harm - were *only* relevant to the determination that codling moth was a quarantine pest. It was the practice of lifting the import ban only upon a showing that the same quarantine treatment was effective for every variety of a product that was the phytosanitary measure at issue. The United States had seen no assessment of that measure.

4.145 **Japan** argued that it had conducted a full-scale risk assessment in 1996 to ensure that current plant quarantine measures, and import prohibition in particular, were scientifically justified. This risk assessment was fully consistent with the PRA Guidelines established by the FAO. In this process, Japan had evaluated the "likelihood or entry, establishment or spread of a pest … within the territory … according to the … phytosanitary measures which might be applied, and of the associated potential biological and economic consequences…" (SPS Agreement, Annex A, paragraph 4) Furthermore, Japan stressed that an individual risk assessment of a particular plant was performed whenever an exporting government requested the lifting of an import prohibition of the product, or other modification of quarantine measures.

4.146 The immediate impetus for the full-scale risk assessment had come in 1995, when the FAO adopted the PRA Guidelines. In this risk analysis, Japan's objective had been to identify particularly dangerous pests which might not be countered by the normal screening process and which were likely to cause serious damage, and to effectively prevent their introduction by means of import prohibition or otherwise. In order to ensure objectivity of the analysis, Japan had sought advice on the selection of relevant factors and the pest risk assessment procedure from 28 researchers belonging to various

[127] Japan's response to Question 3 of US Consultation Questions. (US Exhibit 3)

[128] The United States noted that reference to the FAO Guidelines was not intended to establish a particular risk assessment framework, nor did it imply that failure to comply with the FAO guidelines necessarily constituted a violation of the SPS Agreement.

[129] Japan, Exhibit 9.

national laboratories. Further professional input to the draft procedure was given by an Expert Committee in June and September 1996. The committee advised on the standards by which phytosanitary measures were chosen according to the level of the risk. This advice and internal review resulted in a numerical evaluation standard. The 12 members of the expert committee were those recommended by the Japanese Society of Applied Entomology[130] and Zoology and the Phytopathological Society of Japan (six experts in entomology and nematology and six experts in plant pathology).

4.147 Following the procedure developed with academic input, Japan identified 117 species of agricultural/forestry pests on the basis of documentary evidence as those which could cause a serious damage once they were introduced into the Japanese territory, and analyzed the risk of each of them. Through this process, the 15 quarantine pests, including codling moth, were found not to be adequately detectable by the normal inspection procedure. Japan therefore decided to maintain an import prohibition on host plants of these pests. Furthermore, Japan concluded that ten quarantine pests were detectable by growing-site inspection of the government by the exporting country.[131] While their risk of introduction and damage was comparable to that of the 15 species, as from April 1998, host plants of these pests were allowed to be imported into Japan subject to completion of the growing-site inspection.

4.148 With regard to codling moth, Japan described the 3-stage process as follows: **Stage 1** of the analysis consisted of the re-evaluation of 117 specific pests, initiated in 1996. In terms of the PRA Guidelines, the initiation was justified as the result of "[a] policy decision … to revise phytosanitary regulations or requirements concerning specific pests".[132]

4.149 In **Stage 2**, Japan developed a relative, numerical evaluation standard which graded pests from "a" (high) to "c" (low), and assessed each factor of the analysis according to the standard. Valuation was objectively based on Japanese and foreign literature.

4.150 First, the guidelines required an assessment of the pest's establishment potential in light of biological suitability of the PRA area and a pest's survival capability. In light of the Japanese environmental conditions and the abundance of host plants, as well as known characteristics of the codling moth, Japan's analysis found that codling moth had a grade "a" establishment potential.

4.151 Second, in respect of the spread potential, the Guidelines required an assessment of possible spread in light of biological factors such as suitability of the natural and/or managed environment for natural spread of the pest, movement with products or conveyances, or potential natural enemies of the pest in the PRA. In the present case, codling moth showed a relatively low reproductive capacity and was graded "b" in terms of spread potential.

4.152 Third, the PRA Guidelines required consideration of factors affecting economic consequences of the pest introduction and spread. In this analysis, type of damage, crop losses, loss of export markets, increases in control costs, environmental damage, or perceived social costs such as unemployment were incorporated in the Japanese analysis of pests. Host plants (apples, cherries and other fruits) of the insect were produced in great quantity in Japan. The potential substantial damages led Japan to conclude that the insect was graded "a" in terms of economic importance.

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[130] Entomology: the study of insects.

[131] (i) Sugar beet nematode; (ii) false root-knot nematode; (iii) banana burrowing nematode; (iv) Fusarium wilt of pea; (v) bacterial wilt of beans; (vi) watermelon bacterial fruit blotch; (vii) Stewart's wilt; (viii) Goss's bacterial wilt and blight; (ix) broad bean stain virus and (x) broad bean true mosaic virus.

[132] PRA Guidelines, Item 8, paragraph 1.2 .

4.153 Factors which affected the introduction potential were enumerated in the "partial checklist" in paragraph 2.3 of the PRA Guidelines.[133] Codling moth was capable of surviving the transportation stage, hidden inside the fruits which would be imported in large quantities. Factors affecting establishment (e.g., number and frequency of consignments of the product, intended use of the product) had to also be considered.[134] In respect of these factors, codling moth ranked high, and grade "a" was given to the insect.

TABLE 13
Overall Risk Grading of Pests Based on the Score of Grades

Score of Grades in Stage 2 Analysis	Overall Risk Grading
a for "potential economic importance" and at least two **a**'s for the other potentials	**A** (very high risk)
At least one **a**	**B** (high risk)
No **a**	**C** (low risk)
All **c**'s	**D** (very low risk)

4.154 In summary, as outlined above in respect of the Stage 2 analysis, codling moth was graded "b" in terms of spread potential after establishment, but was given grade "a" in the rest of the Stage 2 analysis. Subsequently, Japan performed overall grading of the risk the pest posed and found that the insect's overall risk was grade "A" (very high risk). It thus met the requirement of a quarantine pest under this stage of the analysis, and Japan decided to proceed to Stage 3.

4.155 Under **Stage 3** of the PRA Guidelines, pest risk management entailed the task of choosing appropriate phytosanitary measures against quarantine pests identified through the Stage 2 analysis. Possible phytosanitary measures were enumerated in paragraph 3.1 of the Guidelines. Notably, the Japanese inspection process, disinfection/disinfestation or import prohibition defined under the Plant Protection Law all appeared in the menu of options under the PRA Guidelines (paragraph 2.30).

4.156 The choice of an appropriate phytosanitary measure (or measures) was based on efficacy and impact of these options, and, for this purpose, paragraph 3.2 of the PRA Guidelines identified 9 factors which were relevant to the efficacy and impact, and required that these be considered in the policy choice (paragraph 2.32). In order to incorporate these factors in an operational model, Japan first developed a standard decision tree of five questions to evaluate the degree of difficulty (or ease) in managing the risk of the pest, with the results expressed in five levels from A1 to C.

4.157 These assigned levels reflecting the degree of difficulty (or ease) in managing the risk of the pest were then combined with the grades of overall risk (A to D) determined by Stage 2. Resulting combinations, which appeared in the left two columns of the Table 14 below were linked to specific risk management measures in the right column, in order to prevent the pest's introduction into the Japanese territory.

[133] The factors are: (i) opportunity for contamination of products or conveyances by the pest; (ii) survival of the pest under the environmental conditions of transport; (iii) ease or difficulty of detecting the pest at entry inspection; (iv) frequency and quantity of pest movement into the PRA area by natural means, and (v) frequency and number of persons entering from another country at any given port of entry.

[134] The checklist further enumerated: (i) number of individuals of a given pest associated with the means of conveyance; (ii) intended use of the product and (iii) environmental conditions and availability of hosts at the destination and during transport in the PRA area.

4.158 In the case of codling moth, Japan recalled that newly hatched larvae were known to enter into fruits, and it was virtually impossible to detect these larvae by normal visual means. Growing-site inspection was equally ineffective because the insect penetrated the products in the post-harvest stage. Finally, post-entry inspection was impractical because it would destroy the product's commercial value. Thus the insect was classified in "LEVEL A1" according to the decision tree.

4.159 Under the PRA (Stage 2) and the study of management options (Stage 3), the overall risk of the codling moth was evaluated to be A (very high risk), and the level of difficulty of management was in the highest bracket, A1. Japan found it to be impossible to properly manage the risk of the pest by means other than import prohibition, and decided to maintain the measure.

TABLE 14
Choice of Appropriate Phytosanitary Measures Based on Overall Risk Grading and Levels of Management Difficulty

Overall Risk Grading	Levels of Management Difficulty	Quarantine Measures
A	**A1**	Import prohibition of host plants
	A2	Growing site inspection
	B1	Post-entry quarantine inspection
	B2	Import inspection by specific techniques
B	**B1**	Post-entry quarantine inspection
	B2	Import inspection by specific techniques
	C	Normal import inspection
C	**B2**	Import inspection by specific techniques
	C	Normal import inspection
D	**-**	(Non-quarantine pests)

Note: Even though other combinations of risk evaluation and difficulty may exist theoretically, Japan noted that there were no known examples. Therefore, the above combinations exhausted all practical possibilities.

4.160 The **United States** restated that the document which Japan asserted was its assessment of risk under Article 5.1 of the SPS Agreement, merely addressed whether the codling moth was a pest of quarantine significance. That was not in dispute. However, the Appellate Body Report in *EC - Hormones* made it clear that Article 5.1, relating to assessment of risk, "may be viewed as a specific application of the basic obligations contained in Article 2.2 of the SPS Agreement". Japan had been unable to provide a risk assessment relating to the varietal testing measure because there was no scientific basis warranting the measure.

4.161 In other words, Japan had been unable to provide a risk assessment because there was no scientific evidence that warranted testing by variety to achieve effective quarantine treatment against codling moth. In particular, there was no scientific evidence supporting the necessity of varietal testing (as opposed to testing by product) for quarantine treatment efficacy against codling moth with MB and/or MB fumigation and cold storage. Japan contended that it was *possible* that varietal

differences within the same agricultural product *might* affect the efficacy of the treatment.[135] Faced with the uniformly lethal efficacy of the quarantine treatment in all confirmatory tests and the dearth of scientific evidence in support of varietal testing, Japan had offered descriptions of dose-response variation in support of the measure. However, these descriptions ignored the conclusions of the scientific studies done on quarantine treatments for codling moth, and abundant US empirical evidence that there were no differences among varieties that affected efficacy of quarantine treatment. The uniform success of treatments accepted by Japan also belied this notion.[136] The United States noted that none of the small-scale dose-mortality studies and studies relating to CxT cited by Japan constituted a risk assessment. Japan had never claimed otherwise. At most, these studies were designed to provide data relevant to a risk assessment.

4.162 The United States noted that in its submission Japan had indicated that it performed an individual risk assessment each time a country requested that the import ban be lifted for the product (paragraph 4.145). Yet, for years the United States had sought the lifting of the ban for certain products only to be thwarted by the varietal testing requirements of Japan. While Japan had indicated that it was open to proposals other than varietal testing, experience had shown that there was little flexibility to accept an equally effective alternative. The United States was unaware of any individual risk assessment that had been done for apples, cherries, nectarines, or walnuts.

4.163 **Japan** maintained that an *overall* risk assessment relating to varietal testing had been conducted. Japan held that the efficacy of any proposed *alternative* disinfestation treatment of host plants had to be demonstrated by the exporting country. In fact, Japan stressed that the element which needed to be based on a risk assessment was the substantive requirement that efficacy of disinfestation treatment be demonstrated. The United States had not challenged the necessity of confirmation. Falling short of such proof, Japan assumed that the initial risk assessment continued to govern in respect of the pest and its host plants, and varietal testing would continue to apply. In other words, the "risk assessment" relating to varietal testing was performed as part of the overall risk assessment of the pest.

4.164 In terms of the PRA Guidelines, lifting of import prohibition could be understood as an alteration of the quarantine measure (which constituted part of the "risk management" to be performed in Stage 3 under the terminology of the PRA Guidelines, see paragraph 4.155).[137] It was the element of "biological effectiveness" (paragraph 4.156) of the proposed treatment that Japan considered in requiring demonstration of the absence of varietal difference of treatment efficacy.

4.165 Moreover, the "risk assessment" relating to varietal testing was made each time Japan determined if a proposed treatment would ensure the required level of protection against the risk of codling moth:

(a) when an exporting government sought approval of additional varieties (of apples, for example), Japan investigated what alternative measure would achieve the required level of protection;

(b) it was the responsibility of the exporting government to demonstrate that a treatment (e.g., the existing treatment for other varieties) would achieve the level of protection;

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[135] In response to US Question 4 in consultations, Japan had stated: "It is *possible* there *may* be variation in the efficacy of disinfestation even if the same quarantine treatment is applied to different varieties. For that reason GOJ requires that the efficacy of quarantine standards be confirmed". [emphasis added]. (US Exhibit 3)

[136] US Exhibit 2.

[137] Japan noted that a conditional lifting of the import prohibition corresponded to an alteration of the measure from "prohibition of entry of specific commodities from specific origins" to "definition of requirements to be satisfied before export".

(c) available data suggested that efficacy of a treatment could vary depending on the varieties;

(d) other factors listed in Article 5.2 were also considered to verify if any new information was available; and,

(e) unless new discoveries in the above process had lead to a different conclusion, the exporting government had to positively demonstrate either that varietal differences would not affect the efficacy of a treatment, or that the treatment they proposed would achieve the level of protection for other varieties by tests ("varietal testing").

4.166 Japan further argued that the Appellate Body in *EC – Hormones*, had discarded the notion of a "minimum procedural requirement" from Article 5.1. Accordingly, all that was required was that an SPS measure be based on a risk assessment which might be carried out by anyone. The fact that the risk assessment had taken into account all relevant scientific factors and was consistent with FAO PRA guidelines had been affirmed by Mr. Taylor.

4.167 The **United States** noted that Dr. Heather had explained that an assessment of the risk associated with varietal differences, if any, would focus on two elements: (i) the interaction between the physical and physiological characteristics of the product and the fumigant which resulted in higher sorption in one variety than another; and, (ii) higher susceptibility of the product to pest which resulted in consistently higher levels of infestation risk on one variety than another. There was no indication in the document submitted by Japan (Japan, Exhibit 9) that either of these factors had been considered. Furthermore, the United States recalled that Mr. Taylor had stated that the risk assessment was sufficient to justify a measure to ensure that the *pest* was kept out of Japan, and not the *product*. In other words, if an efficacious treatment had been established, Japan would not be justified to continue to ban the product.

4.168 The United States also noted that, while compliance with the FAO Guidelines was not dispositive in the case at issue, Japan itself had admitted in its submission that the risk assessment it submitted related only to Stage 2 of the FAO Guidelines. Consideration of the need for quarantine requirements such as Japan's varietal testing requirement would fall under Stage 3. The United States noted that section 3.3 of the FAO Guidelines emphasized that "it is not justified to complete only Stages 1 and 2 and then take phytosanitary measures without [completion of Phase 3]." However, Japan had done precisely this.

4.169 The United States concluded that no risk assessment existed with respect to the question of whether differences in varietal characteristics could affect treatment efficacy. The varietal testing requirement was thus not based on a risk assessment as required by Article 5.1. This was valid even if Japan's Exhibit 9 was considered a risk assessment as that exhibit was not rationally related to the varietal testing measure and did not reasonably support it since it contained no assessment of risks attributable to varietal differences affecting treatment efficacy. Hence, as Japan had not assessed the risk, consistent with Articles 5.1 and 5.2 of the SPS Agreement, it had no basis to make a scientific determination about the potential for entry and establishment of codling moth in Japan. Because the varietal testing requirement was not based on a risk assessment under Article 5.1, it necessarily was not based on sufficient scientific evidence under Article 2.2 and was inconsistent with that obligation as well.

4. Article 5.2

4.170 Serving as a guideline for evaluation of risk, the **United States** pointed out that Article 5.2 suggested that Members take into consideration "available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases and pests; existence of pest- or disease-free areas; relevant ecological and environmental

conditions; and quarantine or other treatment". There was no evidence that Japan had complied with this obligation. Japan had not taken into consideration the relevant risk factors for contamination by the pest, which would necessarily include: an understanding of the growth patterns of the pest[138], which products were considered to be preferred host of the pest, and what pre- and post-harvest techniques were implemented to reduce levels of infestation.[139] Although there was a significant body of published information on these topics, the United States maintained that Japan had not factored any of these considerations into their pest risk analysis. Neither had Japan given consideration to the intended use of the product - which in the case of exported fruit was for consumption and not for propagation.

4.171 Furthermore, contrary to Article 5.2, Japan had not examined relevant process and production methods; prevalence of codling moth; or relevant environmental and ecological conditions as these factors related to US apples, cherries, walnuts, and nectarines.[140] Had Japan engaged in such an assessment of risk of introduction of codling moth to Japan, it might have examined the biology of the codling moth to discern what stage was most tolerant to MB fumigation, what stage of tolerance of the pest would be expected at harvest, and when if at all the codling moth would be most abundant on a particular fruit product. Such technical issues were of value in developing the appropriate quarantine treatment.[141]

4.172 An assessment of risk might also have examined, as required under Article 5.2, the prevalence of codling moth on US products. Codling moth was rarely found in exported US fruit mainly due to the combination of integrated pest management (IPM) and production and post-harvest practices. IPM practices included monitoring of moth activity to determine when generations appeared and in order to predict when egg laying would occur. Use of moth-trap catch data, combined with historical and environmental data, permitted relatively accurate predictions of moth activity. These predictions, plus field observations, dictated when and what type of control was necessary.[142] There were studies that demonstrated that the presence of codling moth on US apples[143] and on walnuts[144] was relatively limited; and that US cherries[145] and nectarines[146] were not preferred hosts of the codling moth.[147]

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[138] US Exhibit 29.

[139] US Exhibit 30.

[140] Article 5.2 of the SPS Agreement indicated that when carrying out a risk assessment, "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 or other treatment".

[141] US Exhibit 29.

[142] Jang and Moffitt, "Systems Approaches to Achieving Quarantine Security" in Sharp and Hallman, Quarantine Treatments for Pests of Food Plants, West View Press, Boulder, San Francisco, Oxford, 1994, pp.225-237. (US Exhibit 7)

[143] Moffitt, "A Systems Approach to Meeting Quarantine Requirements for Insect Pests of Deciduous Fruits," 85 Proceedings, Washington State Hortic. Association, 1989. pp.223-225. (US Exhibit 8)

[144] Vail, Tebbets, Mackey and Curtis, "Quarantine Treatments: A Biological Approach to Decision-Making for Selected Hosts of Codling Moth (Lepidoptera: Tortricidae)", 86(1) J. Econ. Entomol, 1993, pp.70-75, 72. (US Exhibit 9)

[145] *Ibid.* (US Exhibit 9)

[146] Curtis, Clark and Tebbets, "Incidence of Codling Moth (Lepidoptera: Torticidae) in Packed Nectarines," 84(6) J. Econ. Entomol., 1991, pp.1686-1690. (US Exhibit 10)

[147] US Exhibit 30.

Moreover, Japan had not taken into consideration the existence of uniform and effective US quarantine treatments for the pest in the relevant fruit product. [148]

4.173 The United States claimed, thus, that the document which Japan had asserted was its risk assessment did not take into account the factors listed in Article 5.2. It did not, and could not, demonstrate any objective or rational relationship between Japan's varietal testing requirement, on the one hand, and scientific evidence of a phytosanitary risk on the other.

4.174 **Japan** noted that on this question of law, the United States seemed to argue that Japan's entire pest risk analysis had not taken into account the factors listed in Article 5.2. In respect of available scientific evidence, Japan claimed that the 1996 pest risk analysis had relied on the data set out under Article 2.2, as they were available in 1996. In respect of relevant process and production methods, Japan claimed that there were no known processes or methods of cultivation which could avoid codling moth completely. In respect of relevant inspection, sampling and testing methods, Japan noted that there were no known inspection, sampling and testing methods, either by exporting countries or by Japan, which would effectively detect and prevent introduction of the insect into Japan. Japan had taken into account that the host fruits were for consumption. In respect of the prevalence of specific diseases or pests, Japan had identified areas infested by pests, including the United States, by available literature and other surveys. In respect of existence of pest- or disease-free areas, Japan had not been able to obtain information regarding the presence of a pest-free area within a country or area infested by the moth. Furthermore, relevant ecological and environmental conditions – the biological characteristics of codling moth and the Japanese environmental conditions had been examined, and it had been found that the insect could be successfully introduced and established in Japan. Finally, in respect of quarantine treatment or other treatment, Japan recalled that codling moth eggs or young larvae which entered into the fruits at the calyx were very difficult to detect. Although no comprehensive quarantine treatment of host plants had been developed so far, effective treatments had been established for certain varieties of American cherries, nectarines, in-shell walnuts and apples, Canadian cherries, New Zealand cherries, nectarines and apples.

4.175 Japan further rebutted the US claims set out in paragraph 4.171: (i) Japan had considered the biology of the codling moth in order to discern what stage was the most tolerant to MB fumigation – this factor constituted the core of the "basic test"; (ii) in respect of the stage of tolerance of the pest that could be expected at harvest, Japan noted that the test guidelines required exporting governments to investigate development stages of the insect which could be encountered at harvest, and that the most resistant of possible development stages found on harvested fruits be tested for a treatment; (iii) in respect of when the codling moth would be most abundant on a particular fruit product, Japan noted that as the harvest season would not vary for a variety, variation in the number of individuals would not affect the kinds of tests required.

4.176 In respect of the US claim that Japan had not taken into account the fact that codling moth was rarely found in exported US fruit (paragraph 4.172), Japan noted that the concept of IPM was to manage the insect population so that harmful populations be diminished and maintained at a level lower than an economic injury level. By definition, it did not achieve the level of protection equivalent to import prohibition. This risk would not be eliminated by import procedures alone, for there was no inspection technique which would effectively discover the pest. Disinfestation had been chosen in light of these considerations, and not because pre- and post-harvest techniques were irrelevant. Furthermore, although the United States had pointed out that there were studies that demonstrated that the presence of codling moth on US apples and walnuts was relatively low; and that US cherries and nectarines were not preferred hosts to the codling moth (also in paragraph 4.172), Japan noted that available literature confirmed the presence of codling moth in apples, walnuts,

[148] US Exhibit 2.

cherries and nectarines.[149] In a previous case, dead larvae because of fumigation were found upon inspection of exported cherries.[150]

4.177 The **United States** noted that the approach taken by Japan was to evaluate each factor on its own to achieve Japan's level of protection was a peculiar approach to risk assessment. The United States claimed factors such as the biology of the codling moth, the prevalence of codling moth on various US products, the scientific evidence and the empirical data, had to be viewed as complementary factors and cumulative in effect to assess the risk of codling moth from US products for export to Japan. This differed significantly from the position of Japan, which examined each aspect of risk as a "zero sum" matter. In other words, if, as they had asserted, there was no inspection process that completely accounted for the presence (or lack) of codling moth on exported products then there was risk irrespective of the fact that the United States engaged in rigorous pre- and post-harvest techniques to reduce the prevalence of codling moth in the first place.

F. ARTICLE 5.6

4.178 The **United States** argued that the Japanese varietal testing requirement was inconsistent with Article 5.6 in that it was significantly more trade-restrictive than required to achieve the appropriate level of phytosanitary protection. Article 5.6 required that:

> "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."[151]

4.179 The United States noted that the "appropriate level of sanitary or phytosanitary protection" was defined in paragraph 5 of Annex A of the SPS Agreement as: "The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory." For the purpose of the dispute at issue, the level of protection could be achieved by a certain rate of mortality of the pest (probit 9 level of mortality).

4.180 The United States noted that in order to fulfil the requirements of Japan, the United States had conducted the testing procedure on seven varieties of apples, nine varieties of cherries, ten varieties of nectarines, and four varieties of walnuts. The efficacy of the quarantine treatment had always been shown in the confirmatory tests, in which the exact same treatment for the product uniformly achieved Japan's level of quarantine protection irrespective of variety. The United States had never had to modify a quarantine treatment for codling moth for varieties of the same product. Hence, according to the United States, these results conclusively demonstrated that Japan's varietal testing requirements had no value in providing additional quarantine protection.

4.181 The United States further claimed that the uniform experience of efficacy of treatment for varieties against codling moth was not limited to the United States. Japan had yet to identify any

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[149] Chapman, P.J. & S.E. Lienk, 1971. (Japan, Exhibit 25)

[150] Japan noted that during the export inspection of 1997 cherries, four dead larvae had been found. Because the sampling was conducted only on 1 per cent and it was difficult to fully discover the pest by inspection, Japan had assumed that a fair number of fruits were infested.

[151] The footnote to Article 5.6 of the SPS Agreement reads: "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".

instance where a quarantine treatment developed by any country (New Zealand, Australia, Chile, South Africa, Spain, Israel, and others) for codling moth on fruit to be imported into Japan had been changed for subsequent varieties. The United States maintained that no other country had ever had to modify a treatment among varieties to achieve Japan's level of protection for codling moth. Additionally, the accepted international practice in the area of pest quarantine treatment by virtually every other country in the world was to require testing by product, not by variety. In this respect, the United States noted that as an example, with respect to quarantine practices for all arthropods (pests), the United States had for decades cleared fruit by pest and plant species, not by variety. In the operation of these quarantine approvals by species, there had never been any indication of varietal differences that required modification of the established treatment for the product. Therefore, it was evident that testing by product (in which a treatment was established with one variety, or group of varieties, and then applied to all other varieties of that product subsequently sought for export), provided an equal level of quarantine protection and was significantly less trade restrictive.

4.182 Article 5.6 was violated if there was a reasonably available alternative, taking into account technical and economic feasibility, which achieved Japan's level of quarantine protection and was significantly less trade restrictive. Because there were no varietal differences that affected the efficacy of quarantine treatment, the same established treatment would achieve the appropriate level of protection for all varieties of a product. The United States noted that testing by variety took a minimum of 2-4 years to complete per variety, was resource intensive and costly to perform, and, furthermore, seriously delayed market access of US products. On the other hand, testing by product was significantly less trade restrictive. The Japanese requirement of varietal testing was significantly more trade-restrictive than required, and testing by product was a reasonably available alternative which achieved Japan's level of phytosanitary protection.

4.183 **Japan** stated that its lifting of import prohibition was indeed a result of the discharge of its obligation under Article 5.6. Whenever Japan found a measure which achieved the appropriate level of protection and was significantly less restrictive, the import prohibition was replaced with such a measure. In this particular case, however, Japan had found data which suggested presence of varietal differences in efficacy of MB fumigation, and a hypothesis which explained such a variation.

4.184 The United States had challenged Japan under the assumption that "[b]ecause there are no varietal differences that affect the efficacy of quarantine treatment, the same established treatment will achieve for all varieties of a product the appropriate level of protection". However, the US evidence did not support their position; the United States had simply submitted a hypothesis which not only cast doubt on laboratory results but on large-scale tests as well. Japan claimed that prior to the lifting of the import prohibition on certain products subject to implementation of an alternative measure, efficacy of the measure had to be demonstrated by the exporting government, and this was a reasonable requirement in light of the asymmetric presence of information on exotic pests and goods. As the United States had not proven species-wide efficacy, Japan was not obliged to accept their alternative at this stage.

4.185 Japan pointed out that it had nevertheless made efforts to alleviate the burden of exporting governments. Japan had accepted the concept of a representative variety. This was why there was no requirement of a full-scale testing of each variety. In additions, for approval of additional varieties, the size of samples in large-scale demonstrations had been reduced from 30,000 to 10,000 insects.

4.186 The **United States** noted that other than recognition of pest-free zones or eradication of a pest from a region or country, Japan had never accepted an alternative to its varietal testing regime with respect to codling moth or other pests of similar significance to Japan. The United States stressed that it considered testing by product as the *only acceptable quarantine measure in the context of the dispute at issue*. It was acceptable that the first variety of a particular product from any source should be subject to the full range of testing. Japan's required procedures for the development of a quarantine treatment included a large-scale test with sufficient numbers of insects to validate that treatment for the product. After such validation, *no further testing was necessary for additional*

varieties. The United States claimed that to be required to treat 10,000 insects and to use the necessary quantity of fruit for each additional variety would be virtually as time-consuming and burdensome as the current requirement to do dose-mortality tests for each variety and confirmatory testing on representative varieties. Hence, to accept the requirement of confirmatory tests on each subsequent variety would be tantamount to acknowledging that varieties made a difference in the ultimate efficacy of MB quarantine treatment for codling moth, a notion unsupported by scientific evidence, data, or principle.

G. ARTICLE 5.7

4.187 **Japan** claimed that varietal testing could be considered a provisional measure. The rationale of the present policy to require efficacy confirmation on a variety basis was that available evidence suggested a possible presence of varietal differences in the efficacy of disinfestation treatment. This policy was based on a scientific hypothesis, it did not presume, *a priori*, varietal differences in all circumstances. Import prohibition could be lifted on a product basis subject to sufficient demonstration. As an example, in respect of fruits whose varietal difference was attributed to bud mutation (e.g., lemons), and no major differences were anticipated, a single treatment would ensure an appropriate level of protection for all varieties of the product.

4.188 Once the import prohibition had been lifted on a particular variety subject to a disinfestation treatment, new data would be accumulated on the effects of a treatment or on the characteristics of prohibited items, and it would then be possible to reach a level of confidence on broader applicability of the existing treatment. This was a reasonable assumption; however, until that had been achieved, Japan insisted on its right to maintain the prohibition, on a provisional basis, on importation of the other varieties. Japan based its measure on available pertinent information as set out in its risk assessment and recognized that the importing government was required to "seek to obtain the additional information necessary for a more objective assessment of risk and review the … phytosanitary measure accordingly within a reasonable period of time" (Article 5.7).

4.189 The **United States** noted that it had been engaged in detailed negotiations with Japan for over two decades. Although Japan had chosen to present a risk assessment on an undisputed matter, Japan was intimately aware of the evidence that had been discussed in the US submissions and what the evidence signified. That evidence was relevant and sufficient, and specifically addressed the specific mortality level of codling moth required by Japan. The United States had firmly established that efficacy of treatment by product achieved Japan’s required level of mortality. The varietal testing requirement could not be characterized as a provisional measure - invocation of Article 5.7 was not a supportable claim.

4.190 The United States pointed out that although Japan claimed it believed it had presented sufficient scientific evidence to meet the obligations of Articles 2.2 and 5.1, Japan also claimed that the measure nonetheless was a provisional measure. These two positions were diametrically opposed. Indeed, Article 2.2 listed Article 5.7 as an *exception* to its requirements, because it was considered that Article 5.7 would permit a measure to be applied even where the "sufficient scientific evidence" requirement of Article 2.2 was not met. Similarly, Article 5.7 applied *only* where the relevant scientific evidence was insufficient to permit a risk assessment. Consequently, the United States argued that Japan’s claim that it had enough evidence to satisfy the requirements of Articles 2.2 and 5.1 with respect to its ban meant that Japan’s ban failed to meet the threshold requirement of Article 5.7. Moreover, the United States claimed that this was not a situation in which there was insufficient scientific evidence, because there was no evidence supporting Japan's claim that variety mattered, and because all evidence in the case at issue, including the success of uniform treatments of different varieties exported to Japan and the absence of failures by product-based testing regimes in other countries, indicated that varietal differences did not affect treatment efficacy.

4.191 The United States noted that the measure had gone into effect 48 years ago. Therefore, the measure could hardly be called "provisional". Moreover, there was no evidence that Japan had undertaken a process to yield "within a reasonable period of time" a more objective assessment of risk so that it could review whether the "provisional measure" should be continued. Japan had therefore failed to meet the requirement of Article 5.7 that an objective risk assessment be done within a reasonable time.

H. ARTICLE 7 (ANNEX B)

4.192 The **United States** argued that the Japanese measure lacked transparency, and was thus inconsistent with Article 7. Article 7 and Annex B set out a number of requirements that Members had to follow in regard to transparency of an SPS measure. Specifically, Annex B, paragraph 1 required that "Members shall ensure that all sanitary and phytosanitary regulations which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them". The United States had made a specific request to the Enquiry Point for Japan which had admitted that there was no published source for varietal testing.[152] The measure had been developed over time through a series of protocols and practice.

4.193 The United States noted that the lack of transparency was made more evident by the lack of a risk assessment on the varietal testing measure. Had the measure been based on scientific principles, maintained with sufficient scientific evidence, based on an assessment of the risks, and not significantly more trade-restrictive than required to achieve the appropriate level of protection, it would have been possible to justify in a transparent fashion the legitimacy of the measure. As the requirement of varietal testing could not fulfil any of these WTO requirements, it was not surprising to find that the measure lacked transparency.

4.194 **Japan** noted that the claim of the United States related to the guidelines developed by the MAFF concerning confirmation of efficacy of disinfestation treatment.[153] These had been distributed to foreign plant quarantine authorities for the purpose of transparency. The contents of the guidelines were not mandatory and exporting governments could choose to demonstrate efficacy of treatment by other means. Consequently, these guidelines did not fall under the concept of "regulations" under paragraph 1 of Annex B. In other words, they did not constitute enforceable regulations covered by Article 7. Nevertheless, these guidelines were available to any interested foreign government through Japan's Enquiry Point, consistent with paragraph 3(b) of Annex B.

4.195 The Annexed Table to the Enforcement Regulation identified the quarantine pest which constituted the cause of the import prohibition, the countries or areas from which importation was prohibited, and the prohibited host plants and their specific parts. Japan pointed out that this allowed any exporter of agricultural products to know in advance which items were prohibited, as well as the quarantine pests concerned. In contrast, other countries, including the United States, generally prohibited importation of all plants and chose a quarantine measure on the basis of a risk analysis only after the filing of an import permit. Under such a mechanism, a foreign exporter was not able to know in advance whether or not the products were exportable, and which quarantine pests had to be guarded against. In this sense, Japan claimed that its regulations were characterized by a greater degree of transparency.

4.196 The **United States** claimed that the assertion by Japan that these were simply "guidelines" and not "regulations" was a novel claim, and one that departed from the issue at hand. In consultations Japan had indicated that while the varietal testing requirement was not published, the

[152] Japan's response to Question 2 of US Consultation Questions. (US Exhibit 3)

[153] Contained in Japan, Exhibit 10.

lifting of an import ban was based on *specific legislation*. Irrespective of the informal process by which US scientists, in consultation with Japan, had devised procedures to test by variety[154] the fact remained that the requirement itself - that which linked the import prohibition with the requirement that it could only be lifted by variety - had to be published.

4.197 The United States argued that the issue of transparency was indicative of a much larger problem. The requirement at issue arose from specific legislation and regulations and yet there was no published source that explained what procedures were necessary to have a product removed from the import prohibition list. The United States, the European Community and numerous other exporting countries had no access to phytosanitary protocols in which Japan had already negotiated and approved treatment for a particular product.[155] In short, without publication of this information, an exporter had no way to discern what was necessary to move a product from the prohibited list to a list approved by Japan for entry. The purpose of transparency was to ensure that Members were carrying out their obligations under the SPS Agreement. An absence of transparency contributed to the overall impression that this measure was far from being consistent with those obligations.

4.198 In respect of transparency, **Japan** noted that anyone who wished to be informed about approved phytosanitary protocols for approved items could refer to MAFF notifications, published in the Government Gazette. If these were difficult to locate, the MAFF could be contacted directly.

I. ARTICLE 8 (ANNEX C)

4.199 The **United States** claimed that as a matter of control and inspection procedures, the Japanese measure was inconsistent with Article 8. The United States noted that sub-paragraphs (a) through (i) of paragraph 1 of Annex C did not replace any of the requirements of Articles 2, 5, and 7, but complemented them by imposing additional, more specific disciplines on Annex C measures. An Annex C measure therefore could be in breach of Articles 2, 5, 7, and 8. However, if an Annex C measure was inconsistent with Articles 2 and 5, as was the case with the Japanese measure at issue, then it was not a legitimate sanitary or phytosanitary measure. To a certain extent, then, the requirements of Annex C.1(a)-(i) would be secondary with respect to such an illegitimate measure since, under the SPS Agreement, the measure could not be maintained in the first place.

4.200 Article 8 and Annex C set out several standards that Members had to observe in the operation of control and inspection. The varietal testing requirement was such a procedure because Japan required control and inspection of the quarantine treatment of a variety of a product before it could be approved for export into its country. The exporting country had to provide certification that the quarantine treatment applied to the variety in question achieved the appropriate phytosanitary level of protection of Japan.

4.201 Annex C, paragraph 1(c) required that Members limit information requirements to "what is necessary for appropriate control, inspection and approval procedures". Yet, because the varietal testing requirement was not based on scientific principles, was maintained without sufficient scientific evidence, was not based on an assessment of the risks, and was more trade-restrictive than required to achieve the appropriate level of protection, Japan's measure was inappropriate.

4.202 **Japan** noted, in respect of paragraph 1(c), that the information required was what was necessary to demonstrate the efficacy of a treatment. Japan recalled that it did not necessarily demand complete testing of each variety (paragraph 4.31). The requirement under paragraph 1(c) was

[154] The United States noted that these had been printed for the first time in a hand-out in Japan's Exhibit 10.

[155] Third Party Oral Statement by the European Community, paragraph 8.

consequently fully met. Nevertheless, Japan remained willing to consider more appropriate ways to fulfil the informational requirements of exporting governments.

4.203 The **United States** further argued that Japan had, contrary to Article 8 and Annex C, paragraph 1(h), not limited the required procedures for a "modified product" to what was "necessary to determine whether adequate confidence exists that the product still meets the regulations concerned". The United States claimed that a requirement that allowed for uniform treatment for a product without testing by variety would be an appropriate limitation. To require the United States to provide information on the efficacy of treatment for every variety when there was already an existing and efficacious treatment for the product was not *limiting* Japan's information requirements to what was necessary.

4.204 While there were no differences among varieties of a product that affected efficacy of quarantine treatment, there were any number of varieties that were developed for the purpose of improving marketability. The difference could be as benign as improving the color or inducing ripeness more quickly. A variety of nectarine could be modified so it ripened one week faster than another variety. A variety of cherry could be modified so that it had a more vibrant color. A variety of apple could be modified so that it tasted sweeter than another variety. While these were modifications, they did not represent a difference in variety such that it affected efficacy of treatment. These modification were therefore not a change in the specifications of the product for purposes of efficacy treatment for codling moth. The United States had demonstrated that variety did not affect efficacy of MB quarantine treatment. Accordingly, no "further procedure" was "necessary" within the meaning of paragraph 1(h) of Annex C for new varieties. Thus, Japan's measure at issue, which did require further procedures for new varieties, was inconsistent with paragraph 1(h) because it went far beyond what was "necessary".

4.205 In respect of consistency with paragraph 1(h), **Japan** pointed out that the issue of whether different varieties fell within the concept of 'modified products' had to be addressed. Japan claimed that such changes typically referred to alterations of additives or ingredients in processed foods and did not cover varietal differences. Even if the provision were to apply to varietal differences, under the Japanese system, required information was limited to what was "necessary to determine if it is able to obtain sufficient confidence of conformity" of additional new varieties to those approved subject to the quarantine treatment. Japan did not require varietal testing on "modifications of the product" as long as it was demonstrated, based on scientific evidence, that they "represent the sort of variability that in no way affects how effective the quarantine treatment will be at killing the plant pests of concern", as set out by the United States in paragraph 4.23. Even if varieties were "modified products", Japan considered that different varieties had to be tested to "determine whether adequate confidence exists" and that the "modified products" still met the regulations concerned. Moreover, Japan noted that the requirements of confirmation at the time of approval of additional varieties were far less rigorous than the requirements which applied to the initial lifting of the import prohibition. In this sense, the Japanese policy was fully consistent with paragraph 1(h). Japan noted that if there were "no differences among varieties of a product that affect efficacy of quarantine treatment" no demonstration would be required, by tests or otherwise. Japan was therefore in full conformity with paragraph 1(h) of the Annex C.

4.206 Regarding the definition of "modified products", the **United States** noted that, contrary to Japan's assertion, Annex C nowhere circumscribed or narrowed the scope of the phrase "modified products" to mean "alterations of additives or ingredients in processed foods". The text of paragraph 1(h) provided no basis for exclusion of the products at issue.

V. SUMMARY OF THIRD PARTY SUBMISSIONS

A. BRAZIL

5.1 Brazil noted that its interest in the dispute derived from its own experience in dealing with Japanese import prohibition and quarantine requirements for fruits under the Plant Protection Law and the Enforcement Regulation. Japan constituted an important potential market for Brazilian products. Since 1986, Brazilian authorities had been in consultations with Japan with a view to initiating exports of Brazilian mangoes to Japan, which were currently prohibited under the cited legislation.

5.2 In order to eradicate an insect that was of concern to Japanese authorities (the Mediterranean fruit fly, or *ceratitis capitata*), Brazil had undertaken the necessary research and had developed a treatment of immersion in hot water for the Tommy Atkins variety of mangoes. The test results had, in Brazil's view, met Japan's requirement eliminating 30,000 individuals of the pest. Yet Brazil had still not received authorization to initiate exports. Japanese authorities had requested that Brazil use a treatment of hot *vapour*, which was ten times more expensive than the treatment based on immersion in hot water. Brazil had not understood the reasoning behind this request, since the treatment that had been tested and adopted had been proven to be successful and was currently being utilized by another exporter of mangoes to Japan (Mexico) for treatment against the same insect. Brazil believed that the case of the mango could prove to be useful to the Panel, since the import prohibition was based on the same legislation that was used by Japan to establish quarantine treatments and import prohibitions for the fruit varieties that were of direct interest to the United States. Brazil was still pursuing a bilateral solution to the problem, in accordance with the principles set out in Article 3.7 of the DSU.

5.3 On the core issue of varietal testing requirements, Brazil shared the views expressed by the United States that testing by product (commodity-by-commodity) was an alternative measure that was reasonably available and was significantly less trade restrictive. In more general terms, Brazil noted the long history of bilateral negotiations that were necessary to permit the importation of different varieties of fruits into Japan. In the case of a developing country like Brazil, which was still negotiating the lifting of an import prohibition on a *single* variety of a fruit, this was a precedent that certainly did not reflect the balance of rights and obligations under the SPS Agreement, and specifically the operation of the Articles cited by the United States in its complaint.

5.4 In the case before the Panel, there were clearly differences of view concerning such key issues as "risk assessment", "sufficient scientific evidence", "scientific justification" and "appropriate level of protection". There was also an important discussion, from Brazil's point of view, concerning the recourse to alternative measures and the need to avoid discriminating or trade restrictive SPS measures.

5.5 In respect of Articles 2 and 5 of the SPS Agreement, Brazil attached special importance to the issue of necessity and to guaranteeing that measures were based on scientific principles and not maintained without sufficient scientific evidence. These guidelines, alongside the obligation not to discriminate, were important guarantees to avoid SPS measures that resulted in a "disguised restriction on international trade". Article 5 of the SPS Agreement spelled out, in detail, the elements that had to be taken into consideration in analyzing the necessity for a measure and in deciding on the nature of the measure.

5.6 The treatment advocated by Brazil to combat the Mediterranean fruit fly was used by another WTO Member for the same product for export to the Japanese market. Nevertheless, Brazil had been called upon to use another treatment, which was more expensive. While Brazil remained ready to cooperate with Japanese authorities, it noted that it had not yet received adequate explanations - of scientific or other nature - as to the reason for not being accorded the right to use a quarantine treatment that had been proven to be effective in tests conducted by Brazil and which were accepted by Japan for exports of another Member affected by the same pest. It was Brazil's belief that Japanese

authorities had to take into consideration the concepts of a reasonable (and cost-effective) available alternative and of non-discrimination.[156] Brazil also questioned whether the minimization of negative trade effects was being taken into consideration by Japan.

5.7 Since the provisions of Articles 2 and 5 of the SPS Agreement spelled out a series of guidelines that had to be followed both individually by Members and in cooperation between Members concerned, one of Brazil's major concerns was the issue of threshold in the application and interpretation of these provisions. This was more so due to the fact that in the operation of the Plant Protection Law and of the Enforcement Regulation, Japan insisted that the burden of proof, relating to the acceptability of a substitute disinfestation measure (equivalent to an import prohibition), rested on the exporting Member.

5.8 The issue of burden of proof - scientific evidence or scientific justification - and of different interpretations of results recorded in scientific tests constituted an important part both of the US and of the Japanese submissions concerning the need for varietal testing. While Brazil did not wish to comment on the specific discussion of the significance of the statistical differences recorded in the laboratory tests referred to by both parties, it was concerned with the extent to which an exporting country had to go in order to confirm the validity of a specific measure, especially in light of its current experience in the consultations related to tests to prove the efficacy of treatment for the Mediterranean fruit fly in Brazilian mangoes. Since Japan itself recognized that most information was received from the exporting Member, Brazil believed that the concept of equivalence, which was contained in Article 4, should also be taken into consideration in the examination of information provided concerning the pest and the proposed method of treatment.[157]

5.9 The correct implementation of the provisions of Articles 7 and 8 of the SPS Agreement concerning transparency and standards for control and inspection were a further guarantee against unnecessary burdens imposed on exporting Members. Brazil noted the reservations of the United States in relation to the implementation by Japan of these two provisions, especially the problem of lack of sufficient transparency of the SPS measure which Brazil had also experienced. Since Brazil did not yet export mangoes to Japan, it was not in a position to provide its experience with Article 8 requirements, but, since its future exports would be affected by the same procedures, it was concerned with what seemed to amount to unnecessary information requirements.

5.10 Brazil did not question Japan's right to implement sanitary and phytosanitary measures. Brazil was also aware of its rights under Article 5.8 of the SPS Agreement. The objective of Brazil's participation as a third party in the Panel proceedings was to express its concern with the possibility that measures designed to protect plant health were being implemented without the necessary justification and in such a way as to create negative trade effects or even as to constitute disguised barriers to trade.

B. EUROPEAN COMMUNITIES

The factual and scientific aspects of the case

5.11 The European Communities noted that it would comment on the factual and scientific aspects of the case on the basis of its experience in its attempts to export fresh fruits and vegetables to Japan.

[156] Brazil noted that the United States had referred to discrimination in relation to Japanese domestic production of fruits. However, Brazil's present concern was related to discrimination in relation to other WTO Members that exported to Japan.

[157] Brazil noted that although Article 4 was included in the terms of reference of the Panel, it had not been cited by either of the parties to the dispute in their first submissions.

The task was particularly difficult as the first written submissions of the parties contained several conflicting statements on a number of crucial scientific issues. The following aspects of the dispute would be addressed:

(a) the issue of varietal testing of quarantine treatment efficacy against codling moth;

(b) the questions raised by the practice of Japan to require varietal testing for certain types of fruits and pests;

(c) the complexity and lack of transparency of the Japanese system of procedures for granting import authorization for fruits and vegetables; and,

(d) the hindrance to trade which could be a consequence of such repeated varietal testing as applied by Japan.

5.12 The European Communities noted that it had experienced a number of difficulties in its attempts to export fruits and vegetables to Japan and that many of these difficulties arose from a variety of causes linked to the system of phytosanitary measures enacted by the Japanese authorities. The European Communities was directly affected by the measures which the Panel was being asked to consider: for example, authorization was granted in August 1997, after several years of testing and discussion, to allow France to export Golden Delicious apples to Japan. However, if France wished to export any other variety of apple in light of consumer reaction to its Golden Delicious already shipped, the whole approval procedure would have to start anew.

5.13 The European Communities wished to underline that it did not contest the right of Japan, or of any other Member, to protect plants within its territory from the introduction of harmful pests. Indeed, the European Communities operated its own system of measures to protect plant health in full accord with the terms of the SPS Agreement.

5.14 At issue was the conformity with the SPS Agreement of the requirement for varietal testing to prove the efficiency of disinfestation for quarantine pests. In this regard, the European Communities questioned the scientific basis of Japan's application of varietal testing for these purposes. While the application of particular treatments could vary a little for different varieties of the same fruit or vegetable, for example, due to the inherently different physical characteristics of the varieties (as in the example of mangoes pointed out by Japan), the European Communities questioned the need of requiring a completely new series of tests for a different variety of the same fruit or vegetable. Varietal testing could be justified if the characteristics and other properties of the varieties in question were such that differences could be expected which were relevant for the objective to be achieved. However, it appeared to the European Communities that the measure in question was applied to an extent beyond that which was necessary to protect plant life and health.

5.15 The European Communities second concern with regard to varietal testing was the apparent lack of consistency in its application by the Japanese authorities. The attention of the Panel had been drawn by the United States to the requirement of varietal testing in relation to apples, cherries, nectarines and walnuts. However, for other varieties of pests and fruits and vegetables import authorization seemed to have been granted without reference to full varietal testing. In the experience of the European Communities, import prohibition in certain instances was lifted for all varieties at once, while it was evident from the facts of the dispute at issue that this was not the case for other products. The European Communities was unaware of any explanation on the part of Japan of such a differentiated application.

5.16 A third issue that the European Communities raised concerned the low degree of transparency and high degree of complexity of the particular part of the Japanese phytosanitary regulatory system at issue. The European Communities had asked, in recent deregulation requests, for a flow chart of approval procedures for import authorization of plants and plant products. Japan had also been asked to simplify and provide greater transparency of approval procedures for fresh fruit and vegetables. To date, these requests had not been fulfilled. In fact, the import authorization procedure was not clearly

defined from beginning to end and normally proceeded on a step-by-step basis, with Japan defining the successive steps; as soon as one hurdle was overcome another appeared on the list. The whole process usually took several years, even before a trial shipment was allowed. Moreover, it involved extensive series of tests, numerous visits to Tokyo for discussions with Japanese experts, public hearings and extended on-site inspections by Japanese experts in the country wishing to export. It was likely that the chances of exporting agricultural products to Japan would be improved if Japan were willing to make available the phytosanitary protocols which it had negotiated with one country to any other interested Member of the WTO.

5.17 The system of varietal testing as applied by Japan appeared to impede trade. The heavy procedural requirements of Japan imposed a considerable burden on the exporting country, both in terms of manpower, time and money. Under the system of varietal testing, exporters had to take the risk of selecting a particular variety and endure a lengthy and complex procedure to gain approval. Yet, if the initial assessment of Japanese consumer reaction were proven wrong, then the investment of time, money and manpower would be wasted and the procedure had to be started all over again for another variety. This appeared to be further compounded by the fact that Japan did not seem to allow for testing and approval procedures to take place for several varieties at the same time. All this represented a serious deterrent to those exporters wishing to gain a foothold in the Japanese market for particular types of fruits and vegetables which had not been previously exported to that market.

Comments on the legal aspects of the case

Burden of proof

5.18 The European Communities considered that the dispute raised the issue of burden of proof. This was a particularly complex problem in cases where science and law interacted. The allocation of the burden of proof was an important legal question which could directly affect the outcome of a dispute settlement procedure. It was recalled that the Appellate Body had pointed out that the initial burden rested on the complaining party, which had to establish a *prima facie* case of inconsistency with a particular provision of the SPS Agreement. When the *prima facie* case was made, the burden of proof moved to the defending party, which had to counter or refute the claimed inconsistency.[158]

5.19 "Burden of proof" was an ambiguous term. It was important to distinguish between: (1) burden of producing evidence, (2) burden of persuasion, and (3) minimally sufficient evidence. These concepts applied to very different aspects of fact-finding and responded to very different situations.

5.20 First, with respect to any factual issue, there could be various *burdens of producing evidence* placed on parties. Under the DSU structure, a panel was not an investigative institution with the capacity to generate its own evidence. There had to be rules concerning which party had to produce evidence before the Panel and how much evidence had to be produced in order for the party not to suffer adverse findings by default. Initially, a complaining party had to "*present evidence and argument sufficient to establish a presumption*" (*prima facie* case) that a Member had acted inconsistently with its obligations under the SPS Agreement.[159] That is, the complaining party had to produce sufficient evidence on any factual issue essential to its claim that a violation was occurring.[160] Evidence had to be produced: (i) that was sufficient to support its requested finding, *and* (ii) that would be sufficient to persuade the Panel that what was claimed was true, *if no* counter-evidence were

[158] *EC - Hormones*, paragraphs 98, 108-109.

[159] *The United States – Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, WT/DS33/AB/R, adopted on 23 May 1997.

[160] Appellate Body Reports on *EC - Hormones* and *Indian Woven Wool Shirts and Blouses.*

to be produced. A *prima facie* case had, therefore, to be of sufficient weight to persuade the Panel and of sufficient quality to pass appellate review for reasonableness.

5.21 Second, the Panel would have to assess *all* the evidence for and against any factual proposition and should adopt the proposition as a finding only if the evidence supported the proposition. What was required was a determination by the Panel that the proposition at issue was more likely to be true than false. On any factual issue there had to be a "default rule" for making a finding when the weight of evidence was in "equipoise" - that is, when it appeared to the Panel that the evidence for a proposition seemed equal in weight to the evidence for its negation. The party with the *burden of persuasion* was the party who had to suffer an adverse finding unless it persuaded the Panel to its view by a preponderance of the evidence. It did not seem correct, however, to speak (despite the practice and conventional wisdom) of any definitive or permanent "shift" in the burden of proof in such a case, because the proof obligations of both parties continued ("back and forth") throughout the entire litigation process.

5.22 Third, a panel was not authorized to make a finding if there was not, in the record before it, minimal evidence that any reasonable person would consider necessary to support such a finding.

5.23 In the present case, the United States argued effectively that the confirmatory tests were the relevant indicator of efficacy of quarantine treatment. Japan contested this by arguing that its policy of requiring confirmation on a varietal basis was supported by available evidence that suggested a possible presence of varietal difference in the efficacy of disinfestation treatment (MB fumigation). This was a scientific question and it was not clear whether the Panel would be able to resolve it, even with the assistance of scientific experts.

5.24 Japan also contested the US argument that it required complete testing and review of each variety. Yet, Japan did not deny that large-scale testing was required for initial lifting of the import prohibition as well as for additional approval, if the results of the dose-mortality tests were unsatisfactory. Japan did not deny that on-site confirmatory tests for one representative variety was required for additional varieties, even if dose-mortality tests were confirmed. Japan also admitted that dose-mortality tests were required in all cases for all varieties for initial and additional lifting of the import prohibition. Nevertheless, Japan had not provided, in the view of the European Communities, any reasonable response to the US argument that it (or any other country that applied a quarantine treatment for codling moth on fruit to be exported to Japan) had never had to modify a quarantine treatment for codling moth for varieties of the same commodity. The reply of Japan that they had accepted that the proposed treatment (on Hartley walnuts) would disinfest codling moth to the satisfactory level (not because varietal differences were irrelevant) was not convincing. Japan needed to bring forward *minimally sufficient evidence* to convince the Panel that varietal differences did affect, for each product in question, the fumigation efficacy. It did not seem enough to argue that this was a reasonable hypothesis or argument, as posited by Japan.

5.25 Moreover, the European Communities pointed out that it did not share the interpretation made by Japan of the *EC - Hormones* case. Contrary to what Japan appeared to argue, the European Communities had not "only asserted that safety of hormones was not proven beyond doubt".[161] The Appellate Body Report on *EC - Hormones* clarified that the European Communities did "indeed show the existence of a general risk of cancer" and that its studies were "relevant but do not appear to be sufficiently specific to the case at hand".[162] It was clear also from other parts of the Appellate Body Report on *EC - Hormones* that the issue there concerned the incorrect interpretation made by the

[161] This was, according to the European Communities, the wrong interpretation of EC arguments made by the panel.

[162] *Op. cit.*, paragraph 200.

United States and the panel of the concept of risk under Article 5.1 of the SPS Agreement, as requiring a certain magnitude or threshold level of risk to be demonstrated in the risk assessment. [163]

5.26 The European Communities considered that what Japan needed to prove in this particular case, in light of the evidence brought by the United States, was that its risk assessment sufficiently warranted or reasonably supported the SPS measure at stake. [164] It was necessary for Japan to establish the rational link between the measure and its risk assessment.

The Panel's role in reviewing the scientific judgments made by WTO Members

5.27 Under the DSU rules, the Panel had to decide whether the Japanese measures were based on a risk assessment as appropriate to the circumstances (Article 5.1). The Panel should also judge whether these measures were based on scientific principles and were maintained with sufficient scientific evidence (Article 2.2). In this regard none of the parties to the dispute had attempted to shed any light on the interpretation to be given to the concept of "sufficient scientific evidence" in Article 2.2 of the SPS Agreement.

5.28 In respect of the *standard of review* the European Communities noted that the Appellate Body had clarified in *EC - Hormones* that the Panel should make "an objective assessment of the facts". [165] A panel could not conduct its own risk assessment. With respect to any of the many scientific issues involved in the risk assessment conducted by a WTO Member, a panel could not substitute its own scientific judgment for that of the WTO Member applying an SPS measure. It appeared also that panels should not substitute the scientific judgment of individual scientists or experts, which might be chosen by it in accordance with Article 11 of the SPS Agreement, with that of the WTO Member that carried out the risk assessment. A panel's mandate in considering the evidence invoked by a WTO Member maintaining an SPS measure was *not* to determine whether it agreed that such evidence constituted the "best evidence" available, but merely to determine whether that Member's risk assessment sufficiently warranted or reasonably supported the measure at hand.

Arbitrary, unjustifiable or disguised restriction on international trade

5.29 In accordance with Articles 2.3 and 5.6 of the SPS Agreement, the European Communities believed that the United States bore the burden of showing that the Japanese measures were arbitrary, unjustifiable or constituted a disguised restriction on international trade. In particular, the United States had to show that there was another reasonably available measure which was less restrictive on trade and which could achieve the level of protection chosen by Japan.

5.30 In this respect the European Communities observed that, with regard to the varieties of apples, cherries, nectarines and walnuts of US origin which had already been approved for export to Japan, the same varieties coming from another WTO Member should also be allowed to be imported into Japan on the same conditions. As Article 2.3 of the SPS Agreement provided, Members should not arbitrarily or unjustifiably discriminate between Members *where identical or similar conditions prevail*. Therefore, another WTO Member wishing to export the same varieties of products to Japan should be given the opportunity to show that indeed identical or similar conditions prevailed in respect of the varieties in question.

[163] *Op. cit.*, paragraphs 184-186. The European Communities noted that this discussion was linked to the concept of "zero risk" policy, which was not summarized at all in the Appellate Body Report on *EC - Hormones*.

[164] *Op. cit.*, paragraph 193.

[165] *Ibid.*, paragraph 117.

Conclusion

5.31 The European Communities was of the view that the varietal testing system of Japan was too cumbersome and appeared to be applied in a manner which was more restrictive than necessary to achieve its stated objective. The Japanese system was also characterized by lack of transparency which could further impede trade in such products.

C. HUNGARY

5.32 Hungary noted that Article 2.1 of the SPS Agreement clearly stipulated the right of Members to take phytosanitary measures which were necessary for the protection of plant life or health. Nevertheless this right was conditional upon the fulfilment of all relevant provisions of the Agreement. Pursuant to Article 2.2, Members were obliged to "...ensure that any ...phytosanitary measure is applied only to the extent necessary to protect ... plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence...". An exception to the latter provision was provided for in Article 5.7.

5.33 According to its submission, Japan had conducted a full-scale risk assessment concerning the plant quarantine measures in operation, including with respect to codling moth. However there was no indication as to whether, in accordance with Article 5.1, any risk assessment of the varietal testing of codling moth had been performed. Indeed, Japan's main argument with regard to the scientific rationale of varietal testing seemed to relate to the variation of the CxT values between varieties (in MB fumigation test on codling moth). Japan apparently interpreted this variation as an indicator of the degree of efficacy of the fumigation treatment.

5.34 It was Hungary's view that Japan had neither been able to show unequivocally that variation of CxT values was a direct function of varietal differences nor had Japan established unambiguously that differences in CxT values necessarily affected the efficacy of the fumigation treatment at issue. At the very least this had been partly acknowledged by Japan when it argued the possibility of a "presence of varietal difference in the efficacy of disinfestation treatment".[166] Also, Japan had stated that its policy was based only "on a scientific hypothesis".[167] On the basis of available scientific knowledge, Hungary agreed with US arguments which questioned the scientific justification of varietal testing, in that: (i) minor differences in CxT values between varieties did not indicate differences in varieties of a single commodity; (ii) test-to-test variation of one variety was as great as that found between varieties; and, (iii) studies had indicated that the same variety of a commodity could show variations in dose-mortality tests from crop year to crop year, or even according to the stage of ripening of the particular variety. Hungary believed that the fact that there had not, to date, been any instance where the complaining party had had to modify a quarantine treatment for codling moth for varieties of the same commodity was of particular relevance to the dispute as it appeared to constitute strong evidence of the effectiveness of the established fumigation treatment across the different varieties of fruits. On the basis of the Japanese line of reasoning, it would be just as natural to expect numerous cases where modifications of treatment would have been required.

5.35 Hungary maintained that the evidence put forward by the United States clearly demonstrated that the varietal testing requirement was inconsistent with the obligations set out in Article 2.2 of the SPS Agreement. As an alternative justification of the measure, Japan briefly invoked Article 5.7 of the Agreement, but failed to meet the criteria set out therein as the relevant scientific evidence was not "insufficient" but simply did not exist. The lack of a specific risk assessment appeared to support the impression that there had been no "objective assessment of risk" specifically in regard to varietal

[166] Japan's first submission, paragraph 154.

[167] *Ibid.*

testing. Moreover, the long period since the requirement of varietal testing had been applied should have allowed Japan either to scientifically underpin or eliminate this testing requirement "within a reasonable period of time".

5.36 In summary, on the basis of the two first submissions by the parties as well as Hungary's own knowledge of the matter, it was Hungary's view that the Japanese authorities *a priori* assumed the existence of "varietal differences" with regard to basic and processed agricultural products which then supposedly justified the requirement of separate testing of products not considered to be the "same". Hungary was not aware of any scientific basis for the "same-product" concept which seemed to be contrary to Article 2.2. Furthermore, there was, in Hungary's view, no provision in the Agreement, not even Article 5.7, that would allow WTO Members to introduce or maintain phytosanitary measures on the basis of hypotheses, assumptions or assertions. Neither could any support for this position be found in the report of the Appellate Body in *EC – Hormones*. Such interpretation would prevent the SPS Agreement from fulfilling its basic role, that of ensuring that SPS measures were not applied for reasons unrelated to the protection of sanitary and phytosanitary health. A contrary interpretation would open the door for effectively misusing SPS measures as disguised restrictions on trade.

5.37 Finally, Hungary noted in respect of control, inspection and approval procedures that although there was no specific time period established in the SPS Agreement, Annex C paragraph 1(a) required that "such procedures are undertaken and completed without undue delay". As had been stated by the complaining party and borne out by Hungary's own experience, the testing and approval process for a given variety took anywhere from 2 to 4 years to complete. This could hardly be qualified as being a reasonable delay. The extremely long time involved in such procedures added up to the unusually heavy burden countries wishing to export agricultural products had to shoulder when trying to comply with SPS requirements applied by Japan. Hungary believed that the procedural aspects of an SPS measure also deserved a high degree of attention when judging their conformity with the SPS Agreement, as they themselves could act as a disguised restriction of trade which was prohibited under the Agreement.

VI. PANEL'S CONSULTATION WITH SCIENTIFIC EXPERTS

A. PANEL'S PROCEDURES

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

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

6.2 Noting that this Panel involved scientific or technical issues, the Panel consulted with parties regarding the need for expert advice. Neither party objected to the Panel's intention to seek advice from individual experts. On 27 February 1998, the Panel informed the parties of its decision to seek scientific and technical advice as foreseen in paragraphs 1 and 2, first sentence, of Article 13 of the DSU, and pursuant to paragraph 2, first sentence, of Article 11 of the SPS Agreement. The following is an excerpt from the Panel's decision in that regard[168]:

[168] The full decision (which also includes the timetable for the proceedings) is contained in a fax dated 27 February 1998, sent to both parties from the Panel.

Nature of advice

(a) On the basis of the first submissions from both parties, the Panel will determine the areas in which it intends to seek expert advice.

Selection of experts and questions to experts

(a) The Panel will seek expert advice from individual experts.

(b) The number of experts the Panel will select will be determined in light of the number of issues on which advice will be sought, as well as by how many of the different issues each expert can provide expertise on.

(c) The Panel will solicit suggestions of possible experts from the Secretariat of the International Plant Protection Convention (IPPC), and, subsequently, from the parties. The parties should not contact the individuals suggested.

(d) The Panel does not intend to appoint experts who are nationals of any of the parties involved in the dispute unless the parties agree with such appointment or in the event the Panel considers that otherwise the need for specialized scientific expertise cannot be fulfilled. Parties are, however, free to include in their delegations scientific experts of their own nationality and may, of course, submit scientific evidence produced by their own nationals.

(e) The Secretariat will seek brief CVs from the individuals suggested. To the extent possible, these will be provided to the parties.

(f) The Panel will prepare specific questions for the experts. These will be provided to the parties.

(g) The parties will have the opportunity to comment on and to make known any compelling objections to any particular expert under consideration. At the same time, the parties will have the opportunity to comment on the proposed questions, or suggest additional ones, before the questions are sent to the experts.

(h) The Panel will inform the parties of the experts it has selected, and submit the questions to the experts.

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

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

Meeting with Experts

(a) Should the Panel decide it opportune, or should a party so request, a meeting with experts, immediately prior to the second substantive meeting, may be held. Prior to such a meeting, the Panel would ensure that: (i) the parties' comments on the experts' responses would be provided to the experts; (ii) the experts would individually be provided with their colleagues' (the other experts) responses to the Panel's questions.

6.3 The experts were invited to meet with the Panel and the parties to discuss their written responses to the questions and to provide further information. A summary of the written responses provided by the experts is presented below. The transcript of the meeting with the experts, held on 23 June 1998, is contained in Annex A of this report (Section 10).

6.4 The experts advising the Panel were:

(a) Dr. Neil Heather, Entomologist, University of Queensland, Corinda, Australia;

(b) Dr. Patrick Ducom, Fumigation Expert, Lormont, France; and,

(c) Mr. Robert Taylor, Fumigation Specialist, Natural Resources Institute, Chatham, United Kingdom.

B. QUESTIONS TO THE EXPERTS AND THEIR COMPILED RESPONSES (SUMMARIZED)

Question 1: In relation to the concepts: probit analysis, dose-mortality test, and confirmatory test, could you: (i) state your understanding of these concepts; (ii) indicate the purpose of the tests; (iii) comment on the validity of using dose mortality tests for comparing the efficacy of quarantine treatment between varieties of the same commodity by calculating LD50 for each variety; (iv) comment on the confidence in predicting the level of mortality between varieties and the relative efficacy of quarantine treatment when using, for the approval of an additional variety, (1) only the procedure outlined in (iii); (2) the procedure outlined in (iii) and confirmatory tests; and (3) only confirmatory tests (to confirm the efficacy of the treatment already imposed for a variety of the same commodity); and, (v) indicate, in respect of the testing options outlined in (iv), how the type and quantity of the information derived from the tests on different varieties of the same commodity may vary, and what the causes for such variations may be.

6.5 In respect of the understanding of the concepts and the purpose of the tests, **Dr. Ducom** noted that the dose-mortality test, analyzed by the probit method, was the key to all trials concerning a living organism's response to a toxic. The test was widely used by scientists in efficacy studies on pests. It was informative in respect to the *sensitivity* of a species to a toxic. According to Dr. Ducom, the utilization of LD_{50} in dose-mortality test to compare the efficacy of quarantine treatment posed two problems:

(a) Japan had demanded that variety X be compared to a reference variety. However, it was sometimes impossible to have two varieties at the same time in the same physiological conditions if these had different ripening dates. This could lead to abnormal differences in the behavior of gas;

(b) the tests did not render a reliable statistical analysis given the fact that the number of insects and fruit in question was low and that the causes of variation, of whatever nature, had a great influence on the results. The following were two examples based on the Yokoyama nectarine trials, 1987.[169]

- The "Summer Grand" variety had a LD_{50} of 6.3g/m^3 compared to 15 - 18 for the other varieties tested, but the dose that killed 100 per cent of the insects was 40g/m^3, compared to 30 - 35 for the others.

- Yokoyama and Vail, 1997, re-tested the "Summer Grand" and another variety tested in 1987 and found equivalent results in contradiction with those from 1987. [170]

6.6 Dr. Ducom noted that in practice, the LD_{50} test constituted a fairly unreliable method to compare the *efficacy* of quarantine. Furthermore, Japan imposed a subsequent confirmatory test which was long and costly.

[169] *Supra* note 67. (US Exhibit 14)

[170] *Supra* note 79. (US Exhibit 16)

6.7 The confirmatory tests, by using a sufficient number of insects, gave the statistical confidence which permitted achieving the desired threshold of 99.9968 per cent mortality (probit 9). This test obtained a sufficient degree of confidence, but it was also costly.

6.8 Dr. Ducom noted that while the dose-mortality test (LD_{50}) did not give any confidence in respect of the varietal factor, it did give an indication of the relative sensitivity of the products tested. However, these indications undoubtedly did not allow for the determination of the part played by the variety itself in relation to the other factors which could have an influence on the test results, such as fruit ripeness, annual climatic differences, etc. In this respect, the confirmatory test gave absolutely no indication of varietal differences, it either worked or it did not.

6.9 **Dr. Heather** noted that probit analysis was a biometrical technique for analysis of experimental data in which the quantitative response of an organism, usually as mortality, was subjected to regression analysis with respect to treatment dose, i.e., "dose-response" data. Mathematical transformation of mortality to probability units termed "probits" assisted in conversion of the normal distribution (curve) of the response data to a linear distribution to facilitate analysis. Dose data was frequently, but not invariably, logarithmically transformed for the same purpose of linearity. The outcomes of probit analysis were values such as LD (lethal dose), LC (lethal concentration) or LT (lethal time) for a nominated proportion of the population i.e., 50 per cent or 99.99 per cent, together with nominated confidence or fiducial intervals i.e., 95 per cent.[171]

6.10 The main purposes of probit analysis were:

(a) to define susceptibility of a population of target organisms to a treatment in terms of LD, LC or LT values;

(b) subsequent comparisons of susceptibility of populations of target organisms;

(c) subsequent comparisons of varying response according to substrates, such as commodities;

(d) subsequent comparisons of treatments; and,

(e) prediction of the dose required for a specific level of treatment efficacy.

Comparisons were the most appropriate use of probit analysis.

6.11 *Dose-mortality (dose-response) testing* was an experimental procedure in which the response of an organism was estimated for a series of mortality-inducing doses of a specified treatment. It pertained to a group of tests known generally as bioassays. Dr. Heather noted that individual dose-mortality tests had to target a specific stage of an organism wherever possible as the susceptibility to a treatment could vary between life stages. The more direct the effect of the treatment or toxin on the target organism, in general, the more precise and reliable were the results.

6.12 The main purposes of dose-mortality testing were to produce data for analysis, possibly, but not exclusively by probit analysis, for:

(a) determination of above-mentioned parameters categorising the response of an organism;

(b) comparisons of efficacies of different treatments, organisms or substrates; and,

(c) prediction of a treatment dose to meet a required level of efficacy.

[171] Dr. Heather referred to Steel, R.G.D. and Torrie, J.H., *Principles and Procedures of Statistics with Special Reference to theBiological Sciences*, McGraw-Hill (1960) p.22.

6.13 The target organism test unit was usually a sub-sample of 20 to 50 individuals typically replicated 3 times, at each dose level. For a satisfactory result, 5 or more dose levels were usually required, evenly spaced between 0 and 100 per cent mortality. The dose variable could be concentration or duration.

6.14 *Confirmatory test* was a term that had restricted usage in a quarantine sense. By contrast, *probit analysis* and *dose-mortality testing* were widely used in pesticide science. A confirmatory test as used by US researchers equated to a *large-scale test* as used by Japanese researchers. The concept applied to a single dose response test on sufficient numbers of the target organism to ensure that a required efficacy had been attained at a nominated statistical confidence level. Countries such as Japan and New Zealand had customized this test by requiring a number of sub-samples of minimum size. This had the practical advantage that it could then be used in an iterative way to establish the minimum dose required to achieve a desired efficacy.

6.15 *Validity:* In principle, dose-mortality bioassays were a valid method to characterize the responses of test organism populations for comparison of the efficacies of quarantine treatments between varieties of the same commodity, if adequate precision could be achieved. Use of LD_{50} values for this purpose would be acceptable where the more desirable whole response line comparison was not valid. Since the LD_{50} was effectively the mean response of the bioassay test population and where confidence belts were narrowest, it was arguably the most robust point of comparison. Nevertheless it had to be supported by other point-wise comparisons such as at the $LD_{95,}$ making the slopes of the lines more readily apparent. These LD (LC or LT) values would give more precise definition of response if the population of the bioassay organism was relatively homogeneous in its response to the treatment.

6.16 In respect of *confidence*, Dr. Heather noted that in practice, large-scale confirmatory testing was usually the most practicable and reliable assurance that a treatment was effective.

6.17 *Variance*: Dr. Heather noted that in phytosanitary experimentation variance was intrinsic to both commodity[172] and organism. If variance was *not* evident it would be cause for concern. The dose-responses of an organism to a quarantine treatment could be expected to be influenced by unavoidable variation within each commodity sample whether it was based varietally or otherwise. A test organism on the surface of a commodity would be relatively unaffected by interaction with the commodity and hence less variable in response than one present internally. As the stage for most codling moth tests was the egg, an external stage, it could be expected that its intrinsic susceptibility to the fumigant would be the same or closely similar for each commodity, given that all other conditions were the same.

6.18 For a fumigation, variance originating from a commodity would be expected to be mainly the result of *sorption* although other causes were possible. The resultant decay of the concentration affected the dose received by the target organism and warranted monitoring during the course of the fumigation, which was normal practice.

6.19 Dr. Heather noted in addition that other causes of commodity variation included interaction of the parent scion with rootstock and interstock, production locality, weather, site orientation, water management, nutrition, pests and diseases and their treatments, fruit initiation including pollination, orientation of fruit on trees, ripeness and maturity. This meant that where differences between varieties were small, fruit to fruit variation could greatly exceed variety to variety variation. Such

[172] Dr. Heather referred to Beverly,R.B., Latimer, J.K., and Smittle, D.A. *in:* "Postharvest Handling: a Systems Approach" Shewfelt, R.L. and Prussia S.E. , eds. Academic Press Ch 4, pp.74-98. and Hoffman, P.J., and Smith, L.G., *in:"* Postharvest Handling of Tropical Fruits" , eds Champ, B.R., Highley, E. and Johnson, G.I., ACIAR Proceedings No. 50, pp261-268

variation was an inherent characteristic and was usually overcome by ensuring adequate robustness of the treatment.

6.20 **Mr. Taylor** noted that probit analysis was the application of a statistical programme to data obtained from dose-mortality tests. It permitted a straight line to be drawn between dosage and mortality and from this critical dosages and mortality levels to be determined.

6.21 Dose-mortality tests were tests conducted at laboratory level in order to determine the quantity of a toxicant, such as methyl bromide, required to cause a particular level of mortality of an examined insect (i.e., 50 or 90 per cent of the population).

6.22 Confirmatory tests were conducted on a large-scale to confirm that the dose and exposure period derived from smaller tests would provide the level of quarantine treatment required in the field. The principal purpose of a confirmatory test was that by using large numbers of insects, account was taken of any natural variations that might occur within insect populations. This would include the testing of individuals that were more tolerant to methyl bromide than the general population, and which might not be present where much smaller numbers of insects were tested.

6.23 According to Mr. Taylor, LD_{50} values were extremely useful in comparing the toxicity of different chemicals and in the measurement of resistance. However, these values were less useful in investigations of much higher levels of toxic response such as were necessary in relation to quarantine treatments, where LD values of 99 or 99.9 were sought.

Question 2: In Japan's first submission[173], it is stated that "experimental error, physical condition of the fruit, sorption of the fumigant by packing material, and load of fruit in the chamber are the factors which scientists should be responsible for controlling in dose-mortality tests. Indeed, scientists who conducted these tests describe that test conditions were consciously made equal". To what extent is it feasible, technically and scientifically, to control such factors? Does the Japanese statement mean that differences in dose mortality tests for different varieties cannot be attributed to any of these factors?

6.24 **Dr. Ducom** noted that although there were controllable factors such as the load of fruit in the chamber, the temperature, the packing material, the geographic and annual climatic differences[174], there were other factors that were impossible to control: the physical and physiological conditions of the fruit, ripeness, the precise stage of the insects at the time of treatment, small experimental errors, unexpected leaks in the chamber, etc. Those who carried out experiments were aware that the results of tests varied from one to another without the researchers necessarily understanding why. Nevertheless, if, hypothetically, all the factors mentioned above were identical, then the difference, if one existed, could be attributed to variety.

6.25 **Dr. Heather** pointed out that "experimental error" in this context would be expected to include small errors in measurement, equipment imperfections, ambient conditions and biological response variation in test organism populations. It could be minimized and standardized from test to test but would always be present to some degree.

6.26 Variation in "physical condition of the fruit" from test to test could be minimized but not eliminated. Handling injury, range of ripeness and maturity, and the need to have fruit in a condition susceptible to infestation at levels required for experimentation all contributed to unavoidable variation in the physical condition of the fruit. This could have some effect on sorption levels despite best efforts to standardise it.

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[173] Japan's first submission, paragraph 93.

[174] Dr. Ducom referred to Exhibit 1 attached to his answers to the Panel's questions "PD Exhibit 1".

6.27 "Sorption of the fumigant by packaging material" and the walls of the chamber could be standardized by researchers but some variability would always remain.

6.28 "Load in the test chamber" could be standardized by the control of fruit size, weight and number, but again small levels of variation would be unavoidable.

6.29 Any experimental result would have background variation. It was usual to standardize procedures ("consciously made equal") as far as possible but always, some variation would remain. Its presence could be taken as evidence of the integrity of the experimenters. Statistical analyses were used to minimize the effects but it would not be possible to eliminate them totally. Dose-mortality was a bioassay and as such was relatively imprecise compared to a physical measurement, even when measuring the direct effect on an organism.

6.30 **Mr. Taylor** noted that the Japanese position appeared to be that all tests should be conducted under such standardized conditions that any physical differences arising between tests, including those of the fruit, should be accounted for in the experimental procedure. Whilst it might be expected that conditions such as temperature, atmospheric pressure, loading, and even the type and condition of packing material could be controlled very accurately in test programmes, it was difficult to state with exact and absolute confidence that none of these factors could ever affect the results of tests. For this reason it would appear to be too dogmatic to state that differences in dose-mortality could not be attributed to any of the physical factors.

Question 3: Some of the results derived from dose-mortality tests seem to indicate differences for different varieties of the same commodity tested. The parties indicated that a number of factors may explain these differences[175]. Is it possible scientifically or technically to determine, by statistical or other methods, the relevant impact of each of these specific factors? If so, with what degree of scientific and/or statistical certainty for each factor? In your expert view, can one determine that varietal difference is one of these factors? On the basis of the results of the dose-mortality tests presented by the parties to the Panel (if appropriate, for each of the commodities tested), as an expert, is it possible to make such a determination?

6.31 **Dr. Ducom** claimed that it was impossible by a simple dose-mortality test to determine the relevant impact of the factors playing a role in varietal differences, mainly because varieties ripened at different times. This had been adequately explained by the United States.[176] The dose-mortality test presented by the parties were designed to give information on insect *sensitivity*. The search for possible causes of varietal variations could not be determined with precision by them, but only with a specific research program.

6.32 **Dr. Heather** noted that variability of the test organism, the test equipment, the test conditions and the test sample of fruit would all influence differences in LD_{50} values from one variety to another. However, it was probable that in most of the experiments under discussion, the major source of variability would be differential *sorption* by the commodity. Although statistical differences were evident between some varietally based experiments, this did not provide an assurance that the origin of the difference lay predominantly in varietal characteristics.

6.33 Whether it would be possible to statistically identify the magnitude of the varietally based components required expert biometrical comment.

Question 4: In the US first submission[177], it is stated that "the accepted international practice in the area of pest quarantine treatment by virtually every other country in the world is to require

[175] See, e.g., the US first submission, paragraphs 33, 41, 42, 50 and Japan's first submission, paragraphs 92-94.

[176] Dr. Ducom referred to the US first submission, paragraph 41.

[177] US first submission, paragraph 96.

testing by commodity, not by variety". To your knowledge, is it common practice for governments to require variety-by-variety testing for high-risk quarantine pests?[178] How common is the variety-by-variety testing requirement compared to, for example, testing by commodity?

6.34 **Dr. Ducom** stated that he had no knowledge of any variety-by-variety testing requirement for quarantine except the Japanese requirements.

6.35 **Dr. Heather** noted that although the United States submission contended that international practice was to test by commodity and not by variety, at least two countries, Japan and New Zealand had, in the past, adopted the practice of limiting acceptance to varieties tested although their prohibitions might be listed by commodity.[179] That the United States had maintained the general policy of accepting the variety used for testing as fully representative of the commodity was evidenced by their own proclaimed schedules.[180]

6.36 Although the term "international practice" was used, many countries that imported fruit did not actively enforce phytosanitary barriers. It was thus difficult to generalize on the basis of past policy. Before the SPS Agreement came into force, decisions made by countries importing commodities subject to quarantine considerations would have been more influenced by government policies, procedures and precedents.

6.37 **Mr. Taylor** noted that as far as he was aware, it was not common practice for governments to require variety-by-variety testing, and it was more usual for testing to be undertaken on a commodity basis.

Question 5: Considering the current Japanese varietal testing guidelines, how long would it technically take (1) to conduct these tests and (2) once these tests are conducted, to come to an administrative decision on acceptability of a new variety of an already tested commodity?

6.38 **Dr. Ducom** noted that a varietal test according to the Japanese guidelines was a time-consuming procedure. The exact amount of time it would take would differ greatly depending on whether there was already any active research on the insect at issue. If a test site was permanently set up for mass rearing, the preparation of the insect stages for the specific harvest date was not a major problem. It would, however, demand a sufficient number of insects to take into account unavoidable incidents. There were two series of tests to conduct that would necessitate a one-year interval because there was only one harvest per year:

(a) the dose-mortality test which required two to three months (the treatment itself having to be carried out during the harvest); and,

(b) the confirmatory test which was best conducted the following year (this test would entail three more months of work).

6.39 In a case were no mass rearing had been previously set up, it would have to be established. It would take at least 1 to 2 years to domesticate the codling moth.

[178] The footnotes to paragraph 27 of Japan's first submission identify pests considered by Japan to fall within this category.

[179] Dr. Heather referred to Japan, Exhibit 24: New Zealand MAF *Regulatory Authority Standard 155.02.03* (1994).

[180] Dr. Heather referred to USDA APHIS *Treatment Manual* Section 2.15 and T101. (1992 or subsequent).

6.40 In respect of the administrative decision, in theory, the results of the confirmatory test were immediate and authorization could be given soon thereafter. However, an additional year would be reasonable. The whole process could take at least 3 to 4 years.

6.41 **Dr. Heather** noted that the answer to the question depended on whether a *new* pest and commodity were involved, whether a research infrastructure already existed and whether the same or a similar pest and commodity had been the subject of comparable research elsewhere.

6.42 A reasonable expectation for research and preparation of a submission where there was an established rearing method for the pest would be between 2 to 3 seasons. After that, consideration by Japanese experts could take up to 1 year or longer depending on their backlog of submissions. Questions from the Japanese experts to be answered, possibility involving further research, could take a further season or longer. After acceptance of a proposal, there would be a need for a (Japanese) confirmatory trial which, depending on the availability of the commodity, might not be possible before the next production season. Further time would be required for Japanese authorities to prepare for a Public Hearing and subsequent regulatory amendment. Dr. Heather noted that for Australia, the time for the above procedure would usually span over 3 to 7 years.

6.43 **Mr. Taylor** noted that the test would need to be conducted over more than one season and also with fruit of varying maturity, so that a period of two years would be necessary. He maintained that it ought to be possible to reach an administrative decision regarding acceptance of tests on a new variety of a commodity already tested within a period of twelve months.

Question 6: In the submissions before the Panel, which documents do you consider to contain the fullest statement of the scientific *rationale* - if any such rationale exists - behind Japan's current varietal testing requirements in respect of apples, cherries, nectarines and walnuts? Is such scientific rationale (if any) linked to the commodity which is examined, or does it apply equally across the commodities?

6.44 **Dr. Ducom** noted that Japan's concern was reflected in the statement that, in a few cases, the sensitivity of a given insect stage apparently differed according to the variety that it was on. Turning this into a general principle amounted to a precautionary principle more than any scientific rationale. Japan based its precautionary principle on the fact that too high sorption risked resulting in an insufficient CxT value. According to Dr. Ducom, this argument was not without merit, but he questioned why Japan did not then demand as a criterion for approval the obtainment of a defined CxT value, rather than the setting of initial fumigation conditions.

6.45 **Dr. Heather** noted that the *rationale* advanced by Japan for "varietal testing" was given in section III.E of the first written submission of Japan and defended in II.A of their second written submission. Japan therein identified sorption of the fumigant gas as the major reason for differences in LD_{50} and CxT parameters between varietal samples and attributed these to "physical and chemical properties of the fruits, which are then attributable to varietal characters" (paragraph 4.111). In Dr. Heather's view, neither parameter was ideal for showing that there were consistent realistic differences in efficacy of a treatment between varieties of a commodity, yet no alternatives appeared more practicable. The CxT product was an average of the fumigant concentrations measured over the fumigation time and the true LD_{50} was modified by MB sorption by the commodity. Also, individual LD value comparisons did not take into account the slope of the response line and hence did not measure the overall or direct response of the insect population.

6.46 Essentially, the Japanese argument hinged on whether the differences in test samples that affected these parameters were predominantly varietal characteristics and whether they were of sufficient magnitude to realistically affect treatment efficacy. It was the Japanese view that they did both and this was believed to be the basis of their *rationale*.

6.47 The Japanese preferred model first required dose-mortality testing of the pest stage and commodity variety(s) to ensure that differences did not influence treatment efficacy. By using the stage/variety combination, if any, for which the pest was most difficult to kill for the remainder of testing, the greatest risk was deemed to be covered. On this basis subsequent testing of additional varieties should only need to be comparative unless greater difficulty of kill of the pest was demonstrated. The Japanese model acknowledged this but required a further confirmatory test, the reason for which was not readily apparent.

6.48 It was theoretically correct that results of an experiment were only proven for that exact set of conditions, but this overlooked the purpose of experiments, which was to provide guidance for wider use. The major problem was to determine the extent to which differences were varietal in origin.

6.49 **Mr. Taylor** noted that the documents contained within the second written submission of Japan contained the fullest statement of the scientific evidence behind Japan's contention that testing by variety was necessary to establish the efficacy of quarantine treatments. The submission contained references and data to show that differences in sorption and CxT value had been shown between different varieties of cherries, nectarines and walnuts. No data were presented with reference to apple varieties.

Question 7: In respect of the risk of entry, establishment or spread of codling moth due to differences in varieties that could affect the efficacy of the quarantine treatment, what are the technical/scientific factors relevant in an assessment of risk? To what extent has Japan taken these factors into account?

6.50 **Dr. Ducom** stated that he did not know risk assessment techniques adequately enough to respond to this question.

6.51 **Dr. Heather** noted that risk of entry, establishment or spread of codling moth due to differences in varieties that could affect the efficacy of the quarantine treatment would relate predominantly to:

(a) interaction between physical or physiological characteristics of the commodity and the fumigant resulting in higher sorption (fumigant inactivation) in one variety than another, and

(b) higher susceptibility of the commodity to the pest for a range of reasons resulting in consistently higher levels of infestation risk in one variety than another.

Japan had concentrated on the first, paying close attention to LD_{50} and CxT values.

6.52 The practice of quarantine was one of *risk management*. A key criterion adopted by Japan for quarantine treatments for otherwise prohibited commodities was that the treatment had to provide a measure of protection equivalent to import prohibition. While import prohibition could effectively exclude commercially traded commodities, it still had to deal with traveller-carried contraband, so in a sense, exclusion of a pest was always less than absolute. Quality requirements normally ensured that commercially traded fruit was essentially free of codling moth infestation even where a quarantine disinfestation treatment was not obligatory.

6.53 A important factor was the low pre-treatment incidence of codling moth in commercially marketable host commodities from the United States compared to near 100 per cent artificially infested experimental material, i.e., walnuts less than 0.03 per cent; nectarines, less than 0.0003 per cent; cherries, less than 0.00007 per cent; and apples less than 0.00008 per cent as shown in exhibits (these estimates needed to be considered in conjunction with their variance).

6.54 **Mr. Taylor** noted that in 1995, the FAO adopted new guidelines on pest risk assessment (PRA), the purpose of which was to ensure that pests were defined as quarantine pests on the basis of scientific

principles in order to prevent unfair restrictions on trade. In the case of codling moth, Japan, in its first submission to the Panel (pages 9-15) reported on the PRA conducted in 1996, the assessment being conducted together with that for other pests. The Japanese assessment concluded the following:

(a) Codling moth was not present in the country.

(b) Environmental conditions in Japan were such as to give a grade 'a' for the potential for establishment of codling moth within Japan.

(c) In relation to the potential for the pest to spread within Japan, this was graded as 'b' taking into account the insect's relatively low reproductive capacity.

(d) Economic consequences to Japan of the establishment of codling moth were assessed to be of particular significance because host plants such as apples and cherries were produced in great quantity. As a consequence, the PRA analysis resulted in an 'a' grading.

6.55 In summarizing the assessment, Japan concluded that codling moth presented a very high risk and an overall grade 'A' was given. It was noted that the analysis with respect to codling moth incorporated all the guidelines for PRA (recommended and adopted by FAO).

6.56 It would appear that Japan did take into account all of the technical and scientific factors necessary in making a proper risk assessment for the entry of codling moth.

Question 8: In the US first submission[181] it is stated that "[e]very article published on the efficacy of methyl bromide and/or methyl bromide and cold storage for disinfection of codling moth has demonstrated that there are no differences among varieties that affects efficacy of a quarantine treatment". Could you comment on this? On the basis of the scientific evidence before the Panel, to what degree does the mortality of codling moth differ between varieties of the same commodity, of either apples, cherries, nectarines or walnuts, when treated with methyl bromide (MB) or MB and cold storage?

6.57 **Dr. Ducom** noted that the conclusions of authors who had published articles on the efficacy of methyl bromide had always been that the differences in sensitivity that might exist among different varieties was insignificant. The major argument was that the 20 per cent buffer was sufficient to exceed the limit of a possible difference in varietal sensitivity.[182] Dr. Ducom noted that there was a need for research on the factors which influenced sorption. Reported differences between varieties were significant with traditional probit statistical methods (the LD_{50} values were different). However, it was very difficult from that to derive any practical conclusions. A great part of the present problem lay therein.

6.58 **Dr. Heather** noted that the US view, that there were no published differences among varieties that affected efficacy, was true if the criterion used was large-scale test results. If the criterion used was statistically significant differences between experimental samples of different varieties there were differences as identified by Japan, but there was no certainty that they were attributable to unique varietal characteristics. In subsequent research on additional varietal samples these differences were too small to cause the efficacy of a treatment, based on varieties used in initial trials, to fail in further testing. This was equally true for commodity-specific treatments with methyl bromide or methyl bromide and cold storage, for apples, nectarines, cherries or walnuts. For each of these, the Japanese

[181] US first submission, paragraph 83.

[182] Dr. Ducom noted that the amelioration of statistical methods allowed for a reworking of the first results and invalidated the hypothesis of a statistical difference despite the large difference interpreted as significant with traditional methods. (US Exhibit 15)

minimum efficacy test requirement of no survivors from tests on more than 30,000 insects had been met (3 x >10,000).

6.59 The treatments for apples, cherries, nectarines and walnuts differed, in part because the fumigations had to be done at different handling temperatures and this affected the toxicity of methyl bromide to the insects. Also, for apples that were cold tolerant in storage, fumigation was supplemented with cold storage treatment. The actual tolerance of codling moth eggs to methyl bromide was unlikely to differ between these commodities. If all were fumigated at the same temperature, the treatments could be expected to be much closer.

6.60 Japanese concerns were valid, that a low treatment based on dose-mortality testing followed by large-scale trials on a single varietal batch could have resulted in a treatment that would fail on other varieties. It would largely depend on the amount of the "buffer" increase in relation to the difference between varietal samples. Each instance of a very low threshold of susceptibility in a variety in one season's experiments[183] was shown to be anomalous as testing progressed, but some varieties were lower than others in both LD and CxT parameters.

Question 9: Can a difference in the "sorption" level of MB during MB fumigation between different varieties of the same commodity affect the efficacy of the quarantine treatment? If so, do such differences indicate differences in varietal characteristics or are they partly/mostly/completely due to other variables? Could you list the factors which you consider contribute to differences in sorption levels.

6.61 **Dr. Ducom** stated that sorption on cereal grains had been covered by Banks 1992, showing its importance in the success or failure of fumigation[184], but there was little understanding of the sorption of methyl bromide on fresh fruits.

6.62 Sorption levels had a direct influence on the efficacy of a treatment, but this influence was not usually measured directly. It was measured using the CxT value. If the sorption was too high, then the resulting CxT value would be too low, and there was a risk of insufficient efficacy.

6.63 It was, however, possible to find several cases where the influence of sorption on the CxT value was nonexistent: for example in Yokoyama 1994[185], the set of sorption values (sorption having diverse origins: variety, annual climatic differences, packing material, but with the same concentration of 48 g/m^3) was organized in ascending order[186]; the corresponding CxT values were distributed at random but within narrow limits. Generally, the inverse was found, this was the case related in Question 3 by the Research Division of Yokohama Plant Protection Station, where the sorption - CxT value relationship was linear.[187]

6.64 Dr. Ducom stated that to his knowledge, no complete study specific to fresh fruit had been conducted in the United States on the variety-sorption relationship. This would have been a good way to respond to the question in a precise manner or to model possible interactions. Intuitively, it was conceivable that variety could be an intrinsic factor in sorption variation, as was the case, for example,

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[183] *Supra* note 67 (US Exhibit 14); 1992 New Zealand study on cherries for Sam cherries (US, Exhibit 4 and Japan, Exhibit 21).

[184] Dr. Ducom referred to PD Exhibit 2.

[185] Dr. Ducom referred to US Exhibit 36.

[186] Dr. Ducom referred to PD Exhibit 3.

[187] Dr. Ducom referred to US Exhibit 13.

in a study of sorption in raisins.[188] This study was based on the partition coefficient of methyl bromide between the gaseous phase (the only part of gas that is active on the insect) and the solid phase, i.e. the fruit (the part of sorbed gas that is not utilizable by the insect.) This coefficient was directly linked to sorption and allowed it to be modeled. The study showed that this coefficient could vary considerably between varieties and thus influenced the efficacy of a given general "raisin" dose. The varietal aspect could be the result of interactions like the physiological state of the fruit, its ripeness, etc.

6.65 Dr. Ducom noted that there was a lack of precise studies on this subject. *A priori*, one could cite almost anything, the size of the fruit, the nature of the epidermis, the average sugar content, the ripeness of the fruit, its physiological condition, the time between harvest and fumigation, etc. However, in respect of the issue at hand, there was a case which merited study.

6.66 **Dr. Heather** noted that differences in sorption levels attributable to varietal characteristics, together with differences in sorption levels attributable to other causes between batches of a commodity, would cause gas concentrations to decay differentially and hence affect the efficacy of fumigation against the pest. Sorption was an inherent characteristic of fumigation as a treatment method. Factors contributing to differences in sorption levels justified detailed comment by an expert in fumigation chemistry.

6.67 **Mr. Taylor** noted that difference in the level of sorption of methyl bromide between different varieties of the same commodity could affect the efficacy of quarantine treatment if the level of sorption of a particular variety was of sufficient magnitude to reduce the concentration of methyl bromide gas below the level required to cause insect mortality. However, this would require significant differences between varieties to cause this difference in the level of sorption. Three types of sorption of a fumigant could occur: adsorption, absorption and chemisorption.

(a) Adsorption of a gas such as methyl bromide was a physical surface effect and resulted from the attraction of molecules to the surface of a commodity being treated. The larger the surface area the larger may be the adsorption effect. An example would be the case where a commodity had a very rough and therefore greater surface area compared to another with a much smoother surface. Adsorption would be expected to be less in the latter, but the differences in the magnitude of adsorption would probably be small and likely to be insufficient to affect the efficacy of quarantine treatment.

(b) Absorption of methyl bromide was also a physical process, but here the chemical entered into the commodity and was held in either solids or liquids. Methyl bromide was absorbed particularly by oils and fats in which it dissolved and, in commodities with a high oil or fat content such as nuts, application rates of methyl bromide were very much affected by this factor. It had been shown that the level of absorption could be affected by the commodity moisture content; the higher the moisture level the higher the sorption.

(c) Chemisorption was a third type of sorption and, being chemical in nature, was an irreversible reaction in which residues were left in the fumigated commodity. Methyl bromide reacted in particular with proteins and amino acid groups in a reaction known as methylation, which led to a splitting of the methyl bromide molecule and resulted in inorganic bromide residues. The rate of chemical reactions increased with increasing temperature and for this reason chemisorption took place more readily the higher the temperature.

[188] Dr. Ducom referred to PD Exhibit 4.

6.68 Mr. Taylor noted that both adsorption and absorption were reversible reactions and were affected by the temperature, sorption being greater at lower temperatures. For this reason, methyl bromide application rates had to be greater at lower temperatures.

6.69 Sorption of methyl bromide was of particular importance for durable commodities because different types of commodities, depending on their chemical constituents, required more or less fumigant to achieve the level of treatment required. Durable commodities could be conveniently placed in groups according to the dosage rates required. These commodity groups were very much connected with oil and fat content, although other facts such as fineness of the commodity which could affect the rate of gas penetration were important and could even affect the length of exposure necessary for effective treatment.

Question 10: The US states in its submissions to the Panel that "minor differences in CxT values between varieties do not indicate differences in varieties of a single commodity"[189]. They also state that "CxT values differ for tests on the same variety as well as for tests of different varieties"[190]. In respect of walnuts, the US stated in its first submission that "test to test variation of one variety was as great as that found among all three tested varieties"[191]. The US arguments are further expanded in paragraphs 20-32 of their rebuttal submission. Japan states that the "link between varietal differences and divergent efficacy of the fumigation treatment may manifest itself by way of the difference in the 'CxT' value"[192]. Japan uses three empirical cases in its first submission to support its point that there were *statistically significant differences* in the CxT values between the tested variety samples (see paragraphs 80-87, first submission). Japan further elaborates its arguments in paragraphs 35-42 of its rebuttal submission. In light of the above, (i) could you define CxT values and explain what they are an indication of; (ii) could you explain "Tukey's multiple range test" and its relevance to this issue[193]; (iii) have the results of the referenced reports (in the context of CxT values) been accurately assessed in the parties' submissions?; (iv) could you list those factors which might be the cause of variations of CxT values between varieties; and, (v) to the extent that varietal differences is among the listed factors, what kind of varietal differences are you referring to? could such differences affect the efficacy of MB fumigation?

6.70 **Dr. Ducom** noted that the notion of the concentration times product, or here the CxT value, was fundamental in fumigation. What killed the insect was not only the dose of gas introduced, but the quantity of gas inhaled during the entire gas exposure period. The measurement of gas concentrations throughout fumigation permitted the monitoring of the efficacy from the initial condition over the evolution time. The CxT value depended on the gas concentration in the chamber, which varied depending on the following factors:

(a) initial dose introduced into the chamber;

(b) the load, which could increase or decrease the free concentration of gas according to the sorption of the commodity;

(c) the sorption of the commodity and of everything present in the chamber; and

(d) possible leaks.

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[189] US first submission, paragraph 50.

[190] US rebuttal submission, title 1. on p.8.

[191] US first submission, paragraph 50; reference is made to US Exhibit 17, pp. 149-154.

[192] Japan's first submission, paragraph 78.

[193] Japan's first submission, paragraph 84.

6.71 The CxT value was universal once the target stage and the treatment temperature were defined. All the other factors mattered little, even the nature of the commodity, since they were accounted for by the measurement of gas concentration. Dr. Ducom stated that in his opinion, this notion had been criticized wrongly by the United States[194]; it had been stated that the CxT value varied according to the ripeness of the fruit, the geographic conditions, etc. In fact, the CxT value was simply used backwards, because the trials were conducted according to the doses and not the CxT value. If a study using CxT values was undertaken, it was possible to say that to obtain a given CxT value, the initial necessary dose would vary according to the ripeness of the fruit, the geographic conditions, etc. It had also been stated that the "CxT certainly is not indicative of any varietal characteristics"; but this was, according to Dr. Ducom, not true.[195]

6.72 Dr. Ducom reiterated that the CxT value could be specifically set and the parameters could subsequently be manipulated. Contrary to this, present conditions to impose a recognized effective treatment consisted in fixing initial intangible conditions (temperature, treatment length, gas tightness of the chamber, nature of the packing material and load) that would make any variation impossible.

6.73 Dr. Ducom agreed that the confirmatory test constituted a necessary condition to define the quarantine level for a given species of pest. It was furthermore possible to associate the test to a CxT value, which was then acquired once and for all. This was the case, for example, proposed by Yokoyama for nectarines ($68\pm3 gh/m^3$).[196] This objective CxT value could thus become the sole criterion for success in quarantine treatment.

6.74 In respect of Tukey's multiple range test, Dr. Ducom noted that as he was not a statistician, he could not give any precise opinion on the statistic quality of that test. However, as he understood it, it was not relevant to the resolution of the problem. In the precise case of walnuts, the oil content, for example was a factor of varietal selection. It was clear that under that case, there would be varietal differences in sorption, and thus in the CxT values, because methyl bromide was very soluble in oils.

6.75 In respect of the referenced reports (in the context of CxT values in the parties' submissions), Dr. Ducom noted that it seemed, in general, that the notion of CxT had not been studied enough and that that was apparent in the submissions. Indeed, for the Japanese, this notion seemed primordial.[197] But even so, they did not make use of any American data with the notion of CxT and they continued to demand the dose-mortality tests and confirmatory tests without any reference to CxT values. The Americans had also shown to be illogical in the same way.[198] Contrary to the Japanese, the American officials minimized their interest in CxT values, whereas researchers made concrete propositions for confirmatory tests.[199] Dr. Ducom noted that he completely accepted the references presented by Japan in response to Question 9 as set out in US Exhibit 3.[200]

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[194] Dr. Ducom referred to the US Oral statement of 2 April 1998, paragraph 38, third point.

[195] Dr. Ducom referred to PD Exhibit 4, Table A3, p.248.

[196] Dr. Ducom referred to US Exhibit 12 (*supra* note 76).

[197] Dr. Ducom referred to Japans first submission, paragraph 79-86, 104 and 128.

[198] Dr. Ducom referred to the second US submission, paragraph 28.

[199] Yokoyama proposed a CxT of 68 gh/m^3 for the quarantine treatment of nectarines (Dr. Ducom referred to US Exhibit 12; see also *supra* note 76).

[200] Dr. Ducom referred to Japan's references to: Bell 1996; FAO 1983 and Bond 1984 in response to Question 9 as set out in US Exhibit 3.

6.76 In respect of whether varietal difference could affect treatment efficacy, Dr. Ducom noted that it was rarely possible to foresee the influence of a varietal factor on sorption, and thus on the CxT value. Only experimentation and modeling using numerous examples could respond to this question. However, *a priori*, it was difficult to see what significant influence a color or a different ripeness could have on the behavior of gas. On the other hand, one could easily see that a different oil content from one walnut variety to another would lead to a pronounced difference in the behavior of gas, though not necessarily in the efficacy of treatment.

6.77 According to **Dr. Heather**, the CxT value for a fumigation was an expression of the relationship between fumigant gas concentration and time in the fumigation enclosure or chamber. It was generally expressed as CT= *k* but was more properly expressed as $C^nT=k$ where *n* was a toxicity index.[201] As such, it was an expression of the active gas dosage to which the pest or test organism was exposed during the time of the treatment. Because the concentration decayed during the fumigation time from the causes already discussed, "concentration" was an average value derived from a number of measurements and required temperature, load and humidity to be specified for proper definition. It could be inferred from Bond that it would be more usual to manipulate fumigant concentration and time to arrive at a required CxT value than to use CxT as a record of dose.[202] The CxT relationship could be very complex. It was a field of expertise related to physical chemistry of gases and should only be commented upon in detail by an expert in that discipline.

6.78 Dr. Heather stated that Tukey's multiple range test was best explained by an expert in biometry.[203] It compared results between experiments, in contrast to other commonly used tests of significance which compared treatments within an experiment. As such it was said to be less sensitive in the identification of significant differences.

6.79 Dr. Heather claimed that no inaccuracies were apparent in the assessment of referenced reports with respect to CxT values by either Japan or the United States, which, understandably, used specific findings to support their submissions.

6.80 The main factors in experimental variance would be expected to be:

(a) unavoidable experimental variation including those resulting from measurement, equipment function, small temperature fluctuations and chamber load; and,

(b) sorption differences in commodity samples, including variety-linked differences if any.

6.81 Dr. Heather noted that varietal differences of importance would be expected to be mainly sorption related. Further clarification would lie in the spheres of expertise of fumigation chemistry and plant physiology. Such differences would need to be large to affect the efficacy of fumigation and should be apparent to experienced researchers and risk analysts. The consistent success of the large-scale confirmatory tests under discussion indicated that no overall differences of this magnitude occurred.

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[201] Dr. Heather referred to Winks, R.G., The Biological Efficacy of Fumigants: Time/Dose Response Phenomena, in *Pesticides and Humid Tropical Grain Storage Systems* (eds B. R. Champ and E. Highley) ACIAR Proceedings No. 14 pp211-221 1986.

[202] Dr. Heather referred to Bond, E.J., *Manual of Fumigation for Insect Control*. FAO Plant Production and Protection Paper 54 (1984), pp.20-27. (Japan, Exhibit 12)

[203] Dr. Heather referred to Steel, R.G.D. and Torrie, J.H., *Principles and Procedures of Statistics with Special Reference to the Biological Sciences* Mc Graw-Hill Book Company (1960), p109.

Question 11: Japan states that varietal differences accounted for at least some of the observed differences in CxT values between dose-mortality tests (and that CxT values are indicative of treatment efficacy). Technically and scientifically, if additional varieties were tested only for CxT values, and those values were within the range already observed for other varieties, to what extent would any further efficacy testing of the variety be necessary?

6.82 **Dr. Ducom** stated that if varieties were tested to find the CxT value, then no further testing was necessary. The success of the system required:

(a) that the trials be conducted according to precise guidelines approved by both parties (in particular, the number of fruits should be quite large in each replicate to minimize the effects of sampling); and,

(b) that the treatment standard clarify the CxT value necessary to obtain the desired efficacy. This value was the one found in the confirmatory test, for example for nectarines, 68 gh/m3. 204

6.83 Dr. Ducom stressed that the results of these tests were sufficient in themselves to give confidence in the conformity of the candidate variety without having to include the reference variety and insects for efficacy confirmation. This would not bring any supplementary information. Furthermore, research on the CxT value per variety was an operation which could be rapidly conducted, since only the variety of fruit to be tested was used. Fumigation only lasted two hours and the result was known immediately.

6.84 **Dr. Heather** stated that if the CxT value for a required efficacy against a pest was known then a fumigation treatment that met or exceeded that specification could be expected to achieve the quarantine security level required. This would hold true for all batches of a commodity, including those of differing varieties, provided that temperature, load and any other relevant requirements were met.

6.85 Fumigation of agricultural commodities could be specified according to CxT requirements of the pest or pest group with consideration given to levels of concentration which might be phytotoxic to the host commodity. The requirement by the United States in its own gazetted treatments, that specified concentration levels be met part way through the MB fumigations for some commodities, appeared to be an example of this approach.[205]

6.86 **Mr. Taylor** stated that CxT values were used to indicate the fumigant concentration and exposure period required to achieve a 99 per cent mortality of all development stages of an insect, at a particular temperature and humidity, under practical conditions. If these values were obtained for additional varieties and were found to fall within the range already observed for other varieties, it would be difficult to justify why further testing would be necessary.

Question 12: To the extent, if any, that there are varietal differences in apples, cherries, nectarines or walnuts, which could affect the efficacy of MB treatment, can these differences be so high that they are not covered by the 10-20 % "buffer" normally added to the highest minimum dose (minimum dose for 100% mortality) derived from dose-mortality tests for one variety of a given commodity? Is the "highest minimum dose" (to which this "buffer" is added) calculated for each variety separately or, in case an application is made for several varieties, for all these varieties taken together? Could you elaborate on any differences there might be between the general practice and the procedures followed by Japan.

[204] Dr. Ducom referred to US Exhibit 12 (*supra* note 76).

[205] Dr. Heather referred to USDA APHIS PPQ *Treatment Manual* Section 2.15 and T101. (1992 or subsequent)

6.87 **Dr. Ducom** noted in respect of the calculation of the highest minimum dose that it was always measured on one variety, never, to his knowledge, on a mixture of several varieties. This was linked to the fact that generally a single variety was studied and not a mixture of several varieties, to avoid the introduction of systematic heterogeneity.

6.88 The research procedure for quarantine treatment imposed by Japan corresponded to the general guidelines accepted by all countries (research on the least sensitive stage that could be present in fruit, confirmatory test), except concerning the varietal difference aspect. There were no variety-by-variety trials elsewhere.

6.89 **Dr. Heather** noted that there was no evidence apparent from the experiments which formed the basis for treatments for apples, cherries, nectarines and walnuts that the 10-20 per cent buffer added to the experimental dose would be inadequate to cover differences of the magnitude shown between varietal samples.

6.90 If only one variety had been represented in the initial testing, the possibility that other varieties which might be proposed subsequently could have higher predicted minimum dose requirements would be greater. Even so, the likelihood of this exceeding the 10-20 per cent "buffer" appeared low. Also, it would almost certainly have been a matter of scientific rigour on the part of researchers to ensure that the initial test fruit were as representative of commercial exports as possible.

6.91 At the levels of efficacy concerned, the incidence of survivors due to varietal differences would be very low. For a minimum efficacy of 99.99 per cent there would be less than 1 survivor from 10,000 *on average overall*, so the actual effect of varietal differences on quarantine risk was extremely small and difficult to evaluate.

6.92 Normally, the dose to which the 10-20 per cent buffer was added would have been estimated from the varietal trial in which the LD values had been highest hence, "the highest minimum dose". How this dose was chosen was a matter of subjective judgment, but if the minimum efficacy required was 99.99 per cent the $LD_{99.99}$ could be computed together with fiducial limits and either the LD value or its higher fiducial limit used as the dose to which the 10-20 per cent was added. This tended to over-estimate the dose required. Alternatively, the lowest experimental dose for which there were no survivors (100 per cent mortality) in the varietal trial with the highest levels of survival could be used as the minimum effective dose and the "buffer" of 10-20 per cent added.

6.93 The Japanese large-scale confirmatory test differed in size and procedure from some other countries, including the United States, but these were matters of detail. It was in its varietal and country-oriented procedural approach to conditional lifting of import prohibition that Japan differed most from the United States and other countries.

6.94 **Mr. Taylor** noted that any varietal differences affecting the efficacy of MB treatment were unlikely to be so great that the buffer of 10-20 per cent failed to account for these differences. Effective quarantine treatment was therefore to be expected. It was not clear from the documentation submitted whether the highest minimum dose to which the "buffer" was added was calculated for each variety or separately for several varieties taken together.

Question 13: In the US first submission[206] it is stated that "confirmatory tests are the relevant indicator of efficacy of quarantine treatment. Therefore this normal variability in testing results [derived from dose-mortality tests] cannot constitute a legitimate basis for denying approval for other varieties of the same commodities". Could you comment on this in relation to codling moth treated with MB fumigation? Are confirmatory tests (using the treatment

[206] US first submission, paragraph 56.

found to be effective for an original variety) sufficient to demonstrate efficacy of quarantine treatment for additional varieties (e.g., to achieve a probit 9 mortality level)?

6.95 **Dr. Ducom** noted that a dose-mortality test did not replace a confirmatory test. But if one accepted the postulate that whatever the dose-mortality test result was, it would not question the standard already accepted, then what was the purpose of these dose-mortality tests?

6.96 **Dr. Heather** noted that the broader applicability of a confirmatory test done on samples of one variety of a commodity depended on the extent of variation of mortality attributable to varietal characteristics. For quarantine purposes, it was the effect of the treatment on the pest that was of principal importance. A decision on whether to extend acceptance to all varieties of a commodity from a country could be based on factors that included:

(a) past experience with other pests or other treatments on the commodity;

(b) legislative or procedural requirements of the importing country;

(c) the performance of the same or similar treatments in use by other countries for the same or other varieties;

(d) the extent of differences between varieties; and,

(e) small or large-scale tests on a representative range of varieties.

6.97 A large-scale confirmatory test against a pest on a commodity was highly effective in providing assurance that the treatment as tested would meet an efficacy requirement. It provided good assurance for the extension of an existing successful treatment to additional varieties of a commodity, provided that the initial varietal sample was representative of the commodity. The target efficacy had to be adequately specified. Probit 9 as a target efficacy level needed to have a specified confidence level that enabled the required test sample size to be determined. It was better understood when expressed as the percentage mortality to be achieved (99.9968%) and confidence level required.

Question 14: Considering the scientific evidence before the Panel, would the MB treatment approved by Japan for some varieties of apples, cherries, nectarines or walnuts mentioned in US Exhibit 1, meet probit 9 protection for the varieties of each or any of these commodities mentioned in US Exhibit 1 which have not yet been allowed for import into Japan?

6.98 **Dr. Ducom** answered that "yes", a positive confirmatory test constituted the best proof of efficacy. All the species and varieties having passed this test positively would then satisfy all the quarantine requirements.

6.99 **Dr. Heather** noted that where additional varieties of apples, nectarines, cherries and walnuts had been subjected to a successful confirmatory test to meet probit 9 as defined by Japan, there would not appear to be any technical quarantine reason why they would not be acceptable to Japan, subject to their approval procedures. Some of the varieties of apples in question were being accepted by Japan from New Zealand and would necessarily require a codling moth disinfestation treatment the same as, or equivalent to, that developed by the United States for varieties already approved.[207]

6.100 In the absence of a large-scale confirmatory test, it was not possible to be absolutely certain that additional varietal samples would meet the standard required. Where it could reasonably be expected that they would, this had to be the basis of the risk management decision.

[207] Dr. Heather referred to Japan, Exhibit 8, attached table 24.

Question 15: Is it relevant to compare the varietal treatment of apples, nectarines, cherries and walnuts to the differential treatment of other agricultural commodities? (e.g., thermal treatment of mangoes where characteristics such as size and shape influence the treatment of the fruit)[208]. In respect of other agricultural commodities, can you give examples of actual cases where concern over varietal differences has given rise to diverging phytosanitary requirements between varieties of the same commodity?

6.101 **Dr. Ducom** stated that the reactions of a vegetable product to a gas compared to a physical phenomenon such as temperature had, *a priori*, nothing to do with each other. In the first case, one had to deal with the problems of sorption of a chemical or physico-chemical nature. In the second case, it was a question of thermal conductivity. Dr. Ducom was not aware of cases where concern over varietal differences had given rise to diverging phytosanitary requirements between varieties of the same commodity.

6.102 **Dr. Heather** stated that the main relevance of the comparison of the US approach to hot water treatment of mangoes and the Japanese approach to MB fumigation was the possible modification of the treatment by the commodity before it acted on the pest. For mangoes, it was the time taken for the centre of fruit to reach a temperature lethal to any internally feeding fruit fly larvae. Because it was not practicable to use electronic temperature probes in hot water dips, a total time of treatment needed to be specified according to size and shape of fruit, which was a varietal characteristic but not exclusively so. Mangoes from Thailand for export to Japan were "vapour heat" treated using differing schedules according to variety. Part of the reason for this related to perceived varietal susceptibility to treatment injury.

6.103 **Mr. Taylor** stated that fumigation was a very special method of quarantine treatment and bore little relationship to any other method of treatment. Of the factors affecting the efficacy of fumigation, sorption could be considered to be particularly important, but size and shape of fruit were not factors that could affect treatment efficacy such as by influencing the movement of the fumigant. Size and shape of fruit could not be compared to the differences found between some durable commodities, wheat flour for example being very different to whole wheat grains, the former greatly restricting the movement of methyl bromide because of the particle size. Mr. Taylor was not aware of other commodities where concern over varietal differences had caused the need for diverging phytosanitary requirements.

Question 16: Japan states in its second submission[209] that "it is true that existing treatment levels of host plants of codling moth have been found effective for additional varieties. However, as a matter of science, all this proves is the efficacy of the treatment on the *tested* varieties. It falls short of showing absence of varietal difference within a commodity altogether" [emphasis added][210]. Japan also states that the United States cannot possibly provide any information of products yet to be developed which "may utilize rapidly advancing biotechnology"[211]. Yet, the United States considers that "testing by commodity is the only acceptable quarantine measure in the context of this dispute" and that after the first variety of a particular commodity has been tested according to current Japanese procedures, "no further testing is necessary for additional varieties"[212]. Is there a scientific basis for either of the parties views set out above?

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[208] Japan's first submission, paragraphs 108-113; US rebuttal submission 13-16; and, Japan's rebuttal submission paragraph 25.

[209] Japan's second submission, paragraphs 45-48.

[210] Japan's second submission, paragraph 45.

[211] Japan's second submission, paragraph 48.

[212] US answer to the Panel's Question No. 4 (addressed to the United States), 21 April 1998.

6.104 **Dr. Ducom** stated that the arguments put forth by Japan for requiring varietal trials were not based on scientific data. They were supported by a few experimental data in which varietal difference existed, in terms of LD_{50}, among plenty of other data in which they did not. These observations had led Japan to suspect all existing varieties, as well as those of the future (where, in Japan's view, genetic engineering and biotechnology could create even greater differences). This was not based on any scientific data.

6.105 The arguments put forth by the United States were based on a large number of experiments, of which Japan had thoroughly made use. Varietal difference appeared several times, but each time the confirmatory test had revealed sufficient efficacy. Extrapolation to all available varieties was no more scientific than Japan's contrary assertion. This sort of extrapolation was something along the order of intuition. It was unfortunate that there had not been a research program on the subject in order to try to present some scientific proof.

6.106 **Dr. Heather** stated that the Japanese view on applicability of experimental results was technically correct but, in practice, the purpose of experimentation was to provide guidance for decisions on a broader basis. There was a strong case for flow-on where varietal differences were unlikely to impinge on fumigation efficacy. However, most countries would reserve their right to make exceptions if they foresaw a risk that efficacy might be compromised by varietal or other differences. The problem was more one of risk management as the scientifically definable differences would normally be small and difficult to determine due to variability.

6.107 Specification of a treatment as a CxT value for the pest instead of an initial fumigant amount and time could overcome this problem, but would require a level of monitoring which would need to be practicable. The United States used this approach to varying degrees in its methyl bromide quarantine treatments as mentioned in paragraph 6.85 上の.

Question 17: Could you describe the nature of the varietal differences between the varieties of the commodities listed in US Exhibit 1 (e.g., colour, taste, shape). Could the nature of these differences affect the efficacy of MB treatment?

6.108 **Dr. Heather** noted "Granny Smith" and "Delicious" apples differed in colour, shape, flavour and time of maturity. Dr. Heather was not aware of any major differences in susceptibility to codling moth other than those possibly phenology based. As confirmed by US large-scale trials, the required efficacy had been achieved for both of these varieties and, given the combined lethal potential and broad applicability of methyl bromide and cold treatment, it was highly unlikely that there would be any differences in efficacy between any common commercial apple varieties. One problem that might occur was susceptibility of some varieties to treatment injury.

Question 18: Is it scientifically correct to say that "peach" includes "nectarines"?

6.109 **Dr. Ducom** affirmed that "peach" indeed was the general term that referred to the species Prunus persica. The notion of species was well clarified; two individuals belonged to the same species if they were able to exchange genes to produce viable offspring. The peach species had undergone natural mutations. Some mutations concerned the shape; the flat peach variety, platicarpa. Another, of relevance to the question, caused the peach to shed its epidermal fuzz: this was the variety nucipersica, the nectarine.

6.110 **Dr. Heather** noted that Willis gave the systematic botanical (species) classification of peach as *Prunus persica* and categorized nectarine as a variety of peach.[213] The US submission gave sub-

[213] Dr. Heather referred to Willis, *A Dictionary of the Flowering Plants and Ferns*, Cambridge University Press, (1960).

species status to nectarine as *P. p. nucipersica.*[214] Taxonomic status at this level tended to be subjective. Classification as a sub-species implied stable characteristics which could be recognized for descriptive purposes. If the species defined the commodity, nectarine would be a variety of peach.

6.111 **Mr. Taylor** affirmed that it was scientifically correct to say that "peach" included "nectarines" because a nectarine was a smooth-skinned mutant of peach. It was botanically classified as a variety of peach *Prunus persica, nucipersica*.

C. ADDITIONAL WRITTEN QUESTIONS SENT TO THE EXPERTS ADVISING THE PANEL

1. Additional question on walnuts

6.112 On 25 June 1998, the Panel sent the following additional question to the experts advising the Panel:

> "At the second substantive meeting of the Panel, on 24 June 1998, the United States submitted the attached publication (US Exhibit 40[215]) with a cover letter by its author. The Panel would kindly ask for your views on the following:
>
> On the basis of this publication, could you express your view on:
>
> (a) whether and to what extent the oil or fat content differs between varieties of walnuts *because of varietal characteristics*; and.
>
> (b) whether any such differences are significant enough to affect quarantine efficacy."

6.113 Dr. Heather noted that his interpretation of the paper by L. Carl Greve *et al*., was that it examined the genotype – environment relationships affecting the percentage of polyunsaturated fatty acids in oil of walnuts. Dr. Heather did not find any information on total oil content as a varietal characteristic. Therefore, the paper, in his view, did not provide any further clarification on the extent to which the oil content of walnuts could affect quarantine treatment efficacy and, consequently, quarantine security. The paper did, however, provide additional insight into the complexity of the relationship between inherent varietal characteristics and the environment.

6.114 Dr. Ducom noted that differences between varieties in walnut commodities, if any, could easily be shown by way of the oil content. Methyl Bromide was soluble in oil or fat and the decrease in gas concentration in the fumigation chamber resulting from this sorption was measurable in sorption trials. If one variety had a difference in oil content large enough to modify the sorption pattern and consequently the CxT value, then the efficacy of the quarantine treatment could be affected. On the basis of the publication in question (US Exhibit 40), variety was one of the different factors which could affect the oil content of the fruits. However, the authors had shown that its influence was less important than the environmental conditions (location, light, irrigation, etc.). In Dr. Ducom's view, differences such as those presented in the publication appeared not to be large enough to have any noticeable influence on the sorption and thus the CxT value and efficacy. Only trials designed for the purpose of answering that specific question could give an adequate response.

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[214] Dr. Heather referred to US Exhibit 15, p.2.

[215] Variation in Polyunsaturated Fatty Acids Composition of Persian Walnut, L. Carl Greve, et. al., J. Amer. Soc. Hort. Sci. 117 (3), pp. 518-522, 1992.

6.115 Mr. Taylor noted that he agreed with the conclusions of L Carl Greve that environment, genotype, nut maturity and interaction of these factors appeared to be the most important parameters determining the fatty acid content in walnuts. The greater differences in fatty acid content composition found from year to year within the same variety than between varieties in a single year was also very important evidence demonstrating that varietal differences were unlikely to be the most important factor affecting sorption of methyl bromide and, therefore, the efficacy of methyl bromide fumigations.

2. Confirmation of the Panel's understanding of scientific evidence and opinions

6.116 On 28 July 1998, the Panel sent 10 pages of its draft findings (in this report: paragraphs 8.73 to 8.101) to the experts advising the Panel to confirm that the scientific evidence referred to therein had been correctly reflected and, in particular, to ascertain that the references to the experts' opinions had – from a technical and scientific point of view – been accurately reflected. The answers by the experts (summarized in the following three paragraphs), together with the Panel's draft findings as sent to the experts, were provided to the Parties at the time the Panel submitted its interim report to the Parties.

6.117 Dr. Heather stated that the Panel's interpretation of his submissions had been correct with one exception. This exception was with respect to the use of the term probit 9. In the view of Dr. Heather, if the term probit 9 – or any other probit value, or their equivalent mortality percentages – were used in a definitive sense, it was important to give them in conjunction with a confidence (or precision) level. Thus, in order to avoid the need to specify the precision of the probit 9 level of protection, Dr Heather suggested that that level of protection was better stated as "no survivors from tests on a minimum of 30,000 individuals", instead of stating that Japan's level of protection was "probit 9", or "99.9969 per cent mortality".

6.118 Dr. Ducom noted, in general, that the Panel had understood what had been explained and that the text was logical. In particular, Dr. Ducom drew the Panel's attention to the fact that the two treatments for apples (cold treatment and MB fumigation) were independent from one another. While the cold treatment killed the egg stage of codling moth, the MB fumigation killed the fifth larval stage (5^{th} instar).[216] In his view, the sorption problems were the same for apples as for other fruits but did not affect the efficacy of cold treatment.

6.119 Mr. Taylor stated that the draft findings accurately reflected his scientific and technical opinion.

[216] See paragraph 2.2 for the codling moth larval stages.

VII. INTERIM REVIEW[217]

7.1 On 1 September 1998, the United States and Japan requested the Panel to review, in accordance with Article 15.2 of the DSU, precise aspects of the interim report that had been issued to them on 6 August 1998. Japan also requested the Panel to hold a further meeting with the parties on the issues identified in its comments on the interim report. We met, accordingly, with the parties on 21 September 1998.

A. COMMENTS BY THE UNITED STATES

7.2 Following comments from the United States we redrafted paragraphs 8.77, 8.93 and 8.96 in order to clarify that, according to the experts advising the Panel, varietal differences – and the resulting difference in sorption levels between varieties – need to be *significant* to affect the efficacy of the already approved MB treatment.

7.3 With respect to paragraphs 8.82 and 8.99, the United States reiterated its view that – although no disagreement exists as to the level of *mortality* Japan requires – Japan never defined its appropriate level of *protection*. We redrafted these paragraphs to take account of this point of view. We also noted Japan's view that its level of protection is that achieved by the import prohibition and that the level of mortality it requires for lifting the import prohibition is one of the technical requirements to ensure efficacy of an alternative measure.

7.4 As a result of a US comment, we added paragraph 8.102 in order to make clear that our findings under Article 5.6 would stand even if the measure in dispute were not in violation of Article 2.2. Doing so, we agree with Japan that our finding under Article 5.6 is not an alternative finding *stricto sensu*, in the sense that it only stands if we would have decided that Article 2.2 is *not* violated. What we wanted to clarify is that our Article 5.6 finding stands irrespective of our finding under Article 2.2.

7.5 As a result of other comments from the United States, we also slightly redrafted certain other paragraphs of the findings section of our report.

B. COMMENTS BY JAPAN

7.6 Japan, in turn, provided editorial suggestions to the descriptive part. Where the additions requested had been referred to earlier during the proceedings, we incorporated them in the final report.

7.7 As a result of comments by Japan, a question arose as to the product scope of our finding in paragraph 8.42. Japan submitted that nowhere in the report did it find a *prima facie* case of an Article 2.2 violation established by the United States for the products other than apples, cherries, nectarines and walnuts. Japan argued that the United States did not submit any evidence in respect of these other products and that the Panel made an error in substituting the absent evidence, which parties must submit, with the experts' answer to a Panel question. On that ground, Japan requested us to exclude products other than apples, cherries, nectarines and walnuts from the scope of our Article 2.2 finding in paragraph 8.42. The United States responded that for the other four products in dispute (apricots, pears, plums and quince), the presumption of an Article 2.2 violation was

[217] According to Article 15.3 of the DSU, "the findings of the final report shall include a discussion of the arguments made at the interim review stage". The following section entitled "Interim Review" is therefore part of the findings of our report.

established as a result of the fact that Japan did not submit any scientific evidence for these products. According to the United States, the SPS Agreement makes it clear that the burden has never been on it to present scientific evidence that varietal testing is *not* required. Instead, the United States argued, Japan has an obligation under Article 2.2 to base its varietal testing requirement for all products covered by this case on sufficient scientific evidence.

7.8 In paragraphs 8.44 and 8.45 we specify that the scope of our finding that Japan maintains the varietal testing requirement without sufficient scientific evidence extends to four of the eight products at issue (apples, cherries, nectarines and walnuts). When addressing the product coverage of our report, we have distinguished two issues. First, the product coverage of our *terms of reference*. In paragraph 8.6 we find that the Panel was given the task to examine the measure in dispute as it applies to eight products. This is not what Japan contested in its comments on the interim report. Second, the product coverage of our *finding that Japan maintains the varietal testing requirement without sufficient scientific evidence*. This is the issue raised by Japan in its comments on the interim report and dealt with in paragraphs 8.44 and 8.45.

7.9 In our view, Japan is correct when it states that it is for the United States to establish a presumption that there is not sufficient scientific evidence in support of the measure in dispute. It is also true, in our opinion, that the United States has to do so for each of the eight products which fall within our terms of reference. However, we do not agree that, in assessing whether such presumption was established, we cannot take into account both the evidence submitted by the United States and the opinions we received from the experts in accordance with Article 13 of the DSU.[218]

7.10 In our view, the *prima facie* case to be established in a WTO dispute settlement proceeding relates to the substantive issue of what a party invoking a fact or claim needs to prove for that fact or claim to be accepted by a panel; that is, evidence (1) which is sufficient to raise a presumption that the alleged fact or claim is correct and (2) that has not been sufficiently rebutted by the opposing party. In deciding whether a fact or claim can thus be accepted, we consider that we are called upon to examine and weigh all the evidence validly submitted to us, including the opinions we received from the experts advising the Panel in accordance with Article 13 of the DSU.

7.11 With respect to paragraphs 8.38 and 8.39, Japan submitted that the only evidence in support of the Panel's reasoning is a quote from Dr. Heather with respect to only one study before the Panel. We recall, however, that a whole series of other evidence is referred to in paragraph 8.40 and footnotes 273 to 276.

7.12 In response to Japan's comment that there is no support for the statement in paragraph 8.42 that "not a single instance has occurred … where the treatment approved for one variety of a product has had to be modified to ensure an effective treatment for another variety of the same product", we clarified and expanded this paragraph. In so doing, we also addressed Japan's claim that the United States did not submit a *prima facie* case.

7.13 Following a comment by Japan on paragraph 8.46, relating to the quarantine efficacy of the treatment required for apples, we also redrafted that paragraph. We further modified paragraph 8.84 to avoid the possible US misunderstanding that our finding in paragraph 8.84 does not apply to apples.

7.14 With respect to paragraph 8.84, Japan requested the Panel to find that the United States did not establish a *prima facie* case that testing by product would meet Japan's level of protection. In reply we specify in that paragraph that the finding we make is arrived at after a careful examination and weighing of all the evidence before us.

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[218] Article 13 of the DSU provides, in its first paragraph: "Each panel shall have the right to seek information and technical advice from any individual or body which it deems appropriate"; and, in its second paragraph: "Panels may seek information from any relevant source and may consult experts to obtain their opinion on certain aspects of the matter".

7.15 Japan's comments on other parts of our findings also prompted us to slightly redraft certain other paragraphs of our findings.

VIII. FINDINGS

A. CLAIMS OF THE PARTIES

8.1 The United States challenges the way Japan lifts its import ban on products that may carry the pest known as codling moth. Japan requires testing and demonstration of quarantine efficacy for each variety of a product that may carry codling moth. Only once this is done will the import ban be lifted and this only for the particular variety or varieties tested. Hereafter we refer to the contested measure as Japan's "varietal testing requirement". The United States claims that this measure is inconsistent with Articles 2, 5, 7 and 8 of the SPS Agreement. Japan requests the Panel to find that its measure is fully consistent with the SPS Agreement.

B. JAPAN'S PLANT PROTECTION REGIME

8.2 On 4 May 1950, Japan enacted the Plant Protection Law. Article 7 (paragraph 1, item 1) of that Law provides that plants designated by Ministerial Ordinance, which have been shipped from or passed through districts designated by that Ordinance, are prohibited for import into Japan. By Ministerial Ordinance of 30 June 1950 (Plant Protection Law Enforcement Regulations) eight products originating from, *inter alia*, the United States (excluding the Hawaiian Islands) were listed as prohibited plants. These products are: apricot, cherry, plum, pear, quince, peach, apple and walnuts, imported as fresh fruit.[219] They are prohibited for importation on the ground that they are potential hosts of codling moth. The Ministerial Ordinance of 30 June 1950 also lists other products as prohibited for import because they are hosts of other pests. However, there is a possibility to obtain exemptions from the import ban. Such exemptions are granted on a variety-by-variety basis. Since 1969 a series of varieties of certain products, originating from specific areas, have been exempted from the import ban. Moreover, since 1978 the import ban has been lifted for certain varieties of the US products at issue.

8.3 In order to obtain an exemption from the import prohibition, Japan imposes the following procedure. The exporting country has to propose an alternative measure which would achieve a level of protection which is equivalent to that met by the import prohibition. The exporting country bears the burden of proving that the proposed alternative would reach the appropriate level of protection. Japan submits that this procedure is a "fundamental policy orientation". It has not been published as a document. In practice, the alternative measure proposed is disinfestation. With respect to hosts of codling moth, disinfestation consists of fumigation with methyl bromide ("MB") or a combination of MB fumigation and cold storage (as required in the treatment approved by Japan for apples). As a model test procedure for confirmation of the efficacy of this quarantine treatment, the Ministry of Agriculture, Forestry and Fisheries of Japan ("MAFF") developed two guidelines: (1) the "Experimental Guideline for Lifting Import Ban – Fumigation" and (2) the "Experimental Guide for Cultivar Comparison Test on Insect Mortality – Fumigation". These guidelines were introduced in 1987 and have, according to Japan, not "generally been published". They are summarized in paragraphs 2.23 - 2.24 of this report.

[219] With respect to walnuts, the ban also applies to walnuts in the shell.

C. THE PANEL'S PRELIMINARY RULING OF 2 APRIL 1998

8.4 At our first substantive meeting we made the following preliminary ruling at the request of Japan:

> "Having carefully reviewed the written submissions made by the parties on the preliminary issues before us and having heard the oral arguments made by Japan in this respect, we rule as follows.
>
> (i) We first examine Japan's request to exclude Article 7 of the SPS Agreement from our examination on the grounds that it was only mentioned for the first time in the US panel request (document WT/DS76/2) and that no consultations were held on it. We note that our terms of reference (set out in document WT/DS76/3) direct us to examine the matter before us "in the light of the relevant provisions of the covered agreements cited by the United States in document WT/DS76/2". This document, the US panel request, specifically cites Article 7 of the SPS Agreement. We thus consider that claims under that provision fall within our terms of reference.
>
> (ii) We next address Japan's request for a finding that the phrase "including but not limited to", mentioned in the US panel request, does not constitute part of our terms of reference. We note that the United States, in its first submission, did not make any claim with respect to a provision not specifically mentioned in the US request for this Panel. Japan did not contest this. Consequently, there is no claim before us (other than the one under Article 7 of the SPS Agreement we just dealt with) on which to make a ruling of whether or not it falls within our terms of reference.
>
> (iii) Thirdly, as to the Japanese measures in dispute, we note that the United States, in its first submission at paragraph 74, limited these to "the prohibition by Japan on the importation of any variety of an agricultural product on which Japan claims that the pest codling moth may occur until such time as the variety has been separately tested with respect to the efficacy of treatment with methyl bromide or treatment with methyl bromide and cold storage". We regard this statement as setting the factual parameters of this case. It limits the scope of this dispute to (1) agricultural products on which Japan claims that the pest codling moth may occur (in its oral statement Japan stated that there are eight such products: apricot, plum, pear, quince, apple, walnut, peach including nectarine, and cherry; in its first submission, the United States only addressed four products: apples, cherries, nectarines and walnuts) and (2) varietal testing with respect to the efficacy of treatment with methyl bromide or treatment with methyl bromide and cold storage".

D. THE SCOPE OF THE MEASURE IN DISPUTE

8.5 The measure at issue in this dispute is only one element of Japan's plant protection regime. The scope of this measure is limited in several respects.[220]

8.6 Firstly, only the varietal testing requirement imposed by Japan for lifting the import prohibition on *US products on which Japan claims that codling moth may occur* is in dispute. The

[220] See our preliminary ruling at point (iii), quoted in paragraph 8.4.

request for this Panel, which sets out the scope of our mandate[221], does not further limit the product coverage of the Japanese measure challenged to certain specific products only. At our first substantive meeting, Japan stated that it considers the following US products to be hosts of codling moth: apricots, cherries, plums, pears, quinces, peaches (including nectarines[222]), apples and walnuts. We consider, therefore, that we are called upon to examine the measure before us as it applies to all products covered by the contested measure. However, as we already noted in our preliminary ruling[223], the parties only submitted evidence with respect to apples, cherries, nectarines and walnuts. We shall, therefore, examine the measure at issue on the basis of that evidence and refer to the experts advising the Panel when it comes to evaluating the relevance of that evidence for the other products covered by the measure in dispute.

8.7 Secondly, we only need to examine Japan's varietal testing requirement to the extent it applies to the demonstration of efficacy of *MB treatment or of MB treatment combined with cold storage* as a treatment against codling moth. We are not called upon to address the varietal testing requirement as it applies to any other treatment or any other pest.

E. MATTERS NOT IN DISPUTE

8.8 It is important to note what this dispute is *not* about. The United States does not contest that codling moth is a serious pest of quarantine significance. Nor is it in dispute that codling moth is exotic to Japan (i.e., is not found in Japan); that it does occur in the United States; and that the importation of US fruit infected with codling moth could result in the introduction of codling moth in Japan which, in turn, would have serious consequences for Japan's agricultural and forestry production. The legitimacy and need for Japan to protect its plants against codling moth is not at issue.[224]

8.9 Moreover, the United States does not challenge the original import prohibition imposed on US host plants of codling moth. The United States acknowledges that Japan conducted a risk assessment to determine that codling moth is a pest of quarantine significance for which an original import prohibition *might* be justified.[225] The United States refers rather to the possibility of obtaining exemptions from this import prohibition and contests the conditions imposed for lifting this prohibition, in particular the fact that it is lifted variety-by-variety.

8.10 Even with respect to the conditions for lifting the ban, the United States agrees that, as a general proposition, it is reasonable for Japan to require that the exporting country propose and substantiate the efficacy of an alternative approach or a treatment that achieves Japan's level of phytosanitary protection. Following that line of reasoning, the United States does not contest the testing requirements imposed by Japan for approval of imports of the initial variety of a particular

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[221] Our terms of reference are, in accordance with Article 7.1 of the DSU, defined in document WT/DS76/3 and specify that the matter we need to examine is the one referred to in document WT/DS76/2, i.e., the request for the establishment of this Panel.

[222] According to the experts advising the Panel, it is scientifically correct to say that peach includes nectarine (see their answers to Panel question 18, paragraphs 6.109 - 6.111).

[223] See our preliminary ruling at point (iii), quoted in paragraph 8.4.

[224] See, for example, the expert opinions of Dr. Heather and Mr. Taylor, Transcript, paragraphs 10.204 - 10.210.

[225] However, in so acknowledging, the United States did not take a position as to whether this risk assessment complies with the requirements in the SPS Agreement, arguing that this risk assessment does not relate to the matter in dispute. Nor did the United States state that this risk assessment *does* justify the import ban in accordance with the SPS Agreement. See also the expert opinions referred to in footnote 224 and Dr. Heather and Mr. Taylor's answers to question 7 of the Panel, summarized at paragraphs 6.51 to 6.56.

product, i.e., those contained in the "Experimental Guideline for Lifting Import Ban – Fumigation". The United States contends, however, that after such validation no further testing is necessary for additional varieties. It, therefore, challenges not only the content but the very existence of any guidelines imposed for approval of additional varieties, *in casu*, those contained in the "Experimental Guide for Cultivar Comparison Test on Insect Mortality – Fumigation".

8.11 We further note that there is no disagreement as to the efficacy of the treatment applied to the specific varieties of US apples, cherries, nectarines and walnuts which have so far been exempted from the import prohibition. The United States does not dispute the level of mortality, established by Japan, that any quarantine treatment has to achieve (i.e., complete mortality in large-scale tests on a minimum of 30,000 codling moths[226]), nor does the United States, or Japan, contest that this level of mortality is reached for the varieties already approved for import after they have been treated as required.

8.12 Japan does not contest that the measure at issue is a phytosanitary measure covered by the SPS Agreement, invoked by the United States. Referring to Article 1.1 and paragraph 1 of Annex A of the SPS Agreement[227], we agree with the parties that the SPS Agreement applies to the measure at issue.

8.13 Finally, with respect to the question of burden of proof under the SPS Agreement, we note that both parties refer to the Appellate Body Report on *EC – Measures Affecting Meat and Meat Products (Hormones)* (hereafter referred to as "*EC – Hormones"*).[228] Reviewing this report, we agree with the parties that, in this dispute, it is for the United States to establish a *prima facie* case of inconsistency of the Japanese measure at issue with each of the provisions of the SPS Agreement the United States invokes. Once this is done, it is for Japan to counter or refute the claimed inconsistency. In other words, if "[the United States] adduces sufficient evidence to raise a presumption that what is claimed is true, the burden then shifts to [Japan], who will fail unless it adduces sufficient evidence to rebut the presumption".[229] In response to a Japanese comment on the interim report, we stress that the issue of burden of proof in a WTO dispute settlement proceeding set out above is different and should be distinguished from what a Member requires from an exporting country before it will approve the import of that country's products. The latter issue is dealt with in paragraphs 8.10 and 8.30.

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[226] See paragraph 2.23 under "Large-Scale mortality test". See also answer by Dr. Heather summarized in paragraph 6.117.

[227] Article 1.1 of the SPS Agreement provides that the Agreement applies to "all … phytosanitary measures which may, directly or indirectly, affect international trade". Paragraph 1 of Annex A to the SPS Agreement clarifies, *inter alia*, that "[a]ny measure applied: (a) to protect ... plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests" is a phytosanitary measure for purposes of the SPS Agreement.

[228] Adopted 13 February 1998, WT/DS26/AB/R, stating as follows in paragraph 98: "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". See also the Panel Reports on *EC - Hormones*, op. cit., respectively, at paragraphs 8.51 and 8.54.

[229] Appellate Body Report on *United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, adopted 23 May 1997, WT/DS33/AB/R, p.14.

F. SCIENTIFIC BASIS AND RISK ASSESSMENT (ARTICLES 2.2, 5.1, 5.2 AND 5.7)

1. The SPS provisions invoked and their relationship

8.14 We first examine the US claims under Articles 2.2, 5.1 and 5.2. In this respect, Japan also invokes Article 5.7. These Articles provide in relevant parts as follows:

> Article 2.2:
>
> "Members shall ensure that any … phytosanitary measure is applied only to the extent necessary to protect … plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5".
>
> Article 5.1:
>
> "Members shall ensure that their … phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to … plant life or health, taking into account risk assessment techniques developed by the relevant international organizations".
>
> Article 5.2:
>
> "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 or other treatment".
>
> Article 5.7:
>
> "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt … phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from … 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 … phytosanitary measure accordingly within a reasonable period of time".

8.15 We examine these provisions together, in light of the following statement by the Appellate Body in its report on *EC - Hormones*:

> "... 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".[230]

8.16 The United States submits that Article 2.2 does not allow Japan to maintain a phytosanitary measure, in this instance the varietal testing requirement, "without sufficient scientific evidence" and that Article 2.2 requires such measure to be "based on scientific principles". According to the United

[230] Adopted on 13 February 1998, WT/DS26/AB/R, paragraph 180. See also panel report on *Australia – Measures Affecting Importation of Salmon*, currently on appeal, WT/DS18/R, paragraph 8.51: "We recall that Articles 5.1 and 5.2 may be viewed as one of the specific applications of the basic obligations contained in Article 2.2".

States, Articles 5.1 and 5.2 require Japan to base the varietal testing requirement on a risk assessment. We first examine the US claims under Article 2.2, taking due account of the more specific obligations imposed under Articles 5.1 and 5.2.

2. Scientific basis

(a) Claims and arguments by the Parties[231]

(i) The United States

8.17 The United States submits that, at a minimum, to base a measure on scientific principles a WTO Member has to identify a particular risk that the measure is designed to protect against, and to conduct some review of scientific evidence or other relevant scientific information to demonstrate that the measure in fact protects against that risk. According to the United States, the risk to be addressed in this case is the risk of introduction of codling moth *in the absence* of the varietal testing requirement.

8.18 The United States notes that the strongest wording Japan has been able to employ is that it is *possible* there *may* be variation in the efficacy of disinfestation if the same quarantine treatment is applied to different varieties. Referring to the descriptions of variations in dose-mortality tests[232] between varieties, offered by Japan in support of the measure[233], the United States submits that these descriptions ignore the conclusions of the scientific studies carried out on quarantine treatments for codling moth. In this respect, the United States recalls that to date the quarantine treatment approved for one variety of a product has always proven to be effective for all other tested varieties of the same product. The United States submits that it tested seven varieties of apples, nine varieties of cherries, four varieties of walnuts and ten varieties of nectarines and that in every instance the treatment applied for one variety of a product has never varied from that applied to another variety of the same product.

8.19 With respect to the six specific studies submitted by Japan[234], the United States points out that all of the tests reported therein are dose-mortality tests which are small-scale tests. The United States argues that the differences in dose-mortality tests for different varieties in these studies cannot constitute a valid scientific basis for the varietal testing requirement because it is in the nature of dose-mortality tests to vary among varieties and even within the same variety from year to year. The United States points to leakage of the fumigation chamber, fruit load, experimental errors, sorption by packaging material, natural variation of pest population and fruit-to-fruit variation such as different ripening times, seasonal variations and physical condition of the fruit as factors explaining the differential. According to the United States, confirmatory tests (which are conducted on a larger scale) are a better indicator of efficacy of a treatment: since confirmatory tests take account of the variability in (small-scale) dose-mortality tests, they establish a treatment that is appropriate for all varieties of a product. The United States further submits that the highest minimum dose observed in the dose-mortality tests that scientists believe would achieve the level of protection required by Japan, is supplemented by a 10-20 per cent buffer in the second stage of testing (the confirmatory tests). According to the United States, this buffer will offset all sources of variation in the dose-mortality tests, including any possible varietal differences.

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[231] The parties' arguments with respect to Article 5.7, to which Article 2.2 explicitly refers, are outlined later in paragraphs 8.50 and following.

[232] The meaning of a "dose mortality test" is explained in paragraph 2.12.

[233] Set out in paragraphs 8.21 and 8.23.

[234] *Ibid*.

(ii) Japan

8.20 Japan responds that there is a sufficient amount of literature and scientific data which indicates the possible presence of a statistically significant difference in the efficacy of known disinfestation measures across varieties of the same product, and that such a difference could require application of a different treatment.

8.21 First, Japan submits that in the specific case of MB fumigation the link between varietal differences and the divergent efficacy of a fumigation treatment may manifest itself by way of a difference in the CxT value for different varieties, i.e., a difference in the relationship between the fumigant gas concentration in the fumigation chamber and the time-period of fumigation.[235] Japan specifically refers to three studies which allegedly demonstrate a statistically significant difference in CxT values between tested variety samples:[236] (1) 1985 tests on three varieties of American walnuts where, according to Japan, CxT values were significantly different between the Franquett variety and the Payne variety[237]; (2) 1988 tests on three varieties of American nectarines where, according to Japan, CxT values of the May Diamond variety showed a statistically significant difference from the other two cultivars for most of the doses[238]; and (3) 1997 tests on three varieties of Japanese nectarines where there was, according to Japan, a statistically significant difference in CxT values between the Shuhou variety and the Fantasia variety.[239]

8.22 According to Japan, differences in CxT values between varieties could be an indicator of differences in the efficacy of a fumigation treatment. Japan argues as follows: When MB gas is injected into the fumigation chamber to disinfest a particular load of fruit, it is absorbed by the surface or the pulp of the fruit. If the degree of sorption varied depending on the variety of the fruit, the amount of fumigant remaining in the chamber air will vary in an inverse relationship to the sorption. Then the CxT value, which is determined by the gas concentration remaining in the chamber and which is a known indicator to control the degree of efficacy of the treatment, will vary as well depending on the variety of the fruit. According to Japan, the physical and chemical properties of fruits are factors affecting sorption (e.g., differences in oil content or a rougher surface) and can be attributable to varietal characteristics. Therefore, Japan concludes, the reported differences in CxT value are due to varietal differences and are an indicator of differences in the efficacy of a fumigation treatment.

8.23 Second, Japan submits three studies, derived from dose-mortality tests[240], which indicate a difference in LD 50 values (i.e., the level of dose required in the tests to kill 50 per cent of all codling moths[241]) between tested variety samples:[242] (1) 1987 tests on six varieties of American nectarines where, according to Japan, one of the varieties tested, namely Summer Grand, was found significantly

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[235] The concept of a CxT value is further explained in paragraph 2.11.

[236] These studies are described in more detail in the descriptive part of our report, paragraphs 4.109 - 4.135.

[237] Vail, P. V. et al., Walnut On-Site Operational (Demonstration) Test Report to Japanese MAFF, USDA/ARS, Horticultural Crops Research Laboratory, Fresno, California, 2-14 December 1985.

[238] Vail, P. V. et al., Report on Efficacy of Methyl Bromide for Codling Moth on Nectarines: Consideration of Nectarines as a Product Group, Prepared for Approval by the Japanese MAFF, Horticultural Crops Research Laboratory, Fresno, California, December 1988.

[239] Research Division, Yokohama Plant Protection Station, MAFF, 1997, Unpublished.

[240] The meaning of a "dose mortality test" is explained in paragraph 2.12.

[241] The notion of LD values is further explained in paragraph 2.14.

[242] These studies are dealt with in more detail in paragraphs 4.81 - 4.108.

more susceptible to MB fumigation (i.e., had a lower LD_{50} value) than the others[243]; (2) 1987/1988 tests on five varieties of New Zealand cherries where, according to Japan, the LD_{50} value for the Bing variety was significantly lower than that for two of the other varieties tested, namely Rainer and Sam[244]; and (3) 1983/1984 tests on two varieties of New Zealand nectarines where, according to Japan, the Fantasia variety showed a significantly lower LD_{50} value than the Redgold variety.[245]

8.24 Japan agrees with the United States that there may be a range of exogenous factors (e.g., differences in leakage of the fumigation chamber, fruit load, experimental errors, sorption by packaging material, natural variation of pest population and fruit-to-fruit variation such as different ripening times, seasonal variations and physical condition of the fruit) which may also account for the differential in CxT and LD_{50} values reflected in the studies it refers to. However, Japan claims that most of these other variables can be controlled in such a manner as to minimize their effects and that such control is a normal practice for scientists. The Japanese hypothesis is that characteristics of a particular variety may affect fumigation efficacy and that there is not sufficient evidence to disprove this possibility. This is, according to Japan, a reasonable argument. For Japan, its policy of variety-by-variety testing is therefore based on a scientific hypothesis which, in turn, is supported by empirical data, in full conformity with the obligations contained in Article 2.2.

8.25 Japan acknowledges that existing treatment levels of host plants of codling moth have been found effective for additional varieties. However, for Japan, all this proves is the efficacy of the treatment on the *tested* varieties. According to Japan, this falls short of showing absence of varietal difference within a product altogether. Japan notes that only a limited number of varieties have been tested in full-scale trials. On the question of a buffer, Japan claims that in large-scale trials the buffer is not always added to the "highest minimum dose", as the United States argues. Japan submits that in some instances the amount of fumigant absorbed by, *inter alia*, bins or the interior of warehouses may exceed the 10 to 20 per cent buffer. Japan further refers to Dr. Ducom's response to Panel question 12 relating to the buffer[246] and highlights the uncertainty of the effect of the buffer. On these grounds, Japan concludes that the United States has not performed the required demonstration of efficacy of a treatment across all varieties.

(b) Is the varietal testing requirement maintained without "sufficient scientific evidence" in the sense of Article 2.2?

8.26 We first examine that part of Article 2.2 requiring Japan to "ensure that [the varietal testing requirement] … is not maintained without sufficient scientific evidence".

8.27 We recall that Article 2.2 provides for an alternative to the requirement not to maintain phytosanitary measures without sufficient scientific evidence, namely to adopt provisional measures in accordance with Article 5.7.[247] Whether Japan can validly invoke Article 5.7 in this dispute, is addressed below in paragraphs 8.48 and following.

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[243] Yokoyama V.Y. et al., Methyl Bromide Fumigation for Quarantine Control of Codling Moth (Lepidoptera: Tortricidae) on Nectarines, Journal of Economic Entomology 80, 1987, pp. 840-842.

[244] Waddel, B.C. et al., Disinfestation of New Zealand Cherries, Cultivar Comparison Test 1987/1988, Department of Scientific and Industrial Research, Auckland, June 1988.

[245] Batchelor, T.A. et al., Disinfestation of New Zealand Nectarines 1983/1984, Department of Scientific and Industrial Research, July 1984.

[246] See paragraphs 6.87 and following.

[247] Article 2.2 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*" (emphasis added).

(i) The meaning of a measure "maintained without sufficient scientific evidence"

8.28 As referred to above[248], the general obligations in Article 2.2 have to be read together with the more specific obligation imposed on Japan in Article 5.1, namely the obligation to ensure that the varietal testing requirement is "based on" a risk assessment. The Appellate Body, in its report on *EC – Hormones,* elaborated on the meaning of the term "based on" as used in Article 5.1 as follows:

> "We believe that "based on" is appropriately taken to refer to a certain *objective relationship* between two elements, that is to say, to an *objective situation* that persists and is observable between an SPS measure and a risk assessment".[249]

> "We believe that Article 5.1, when contextually read as it should be, in conjunction with and as informed by Article 2.2 of the SPS Agreement, requires that the results of the risk assessment must sufficiently warrant – that is to say, reasonably support – the SPS measure at stake. The requirement that an SPS measure be "based on" a risk assessment is a substantive requirement that there be a rational relationship between the measure and the risk assessment".[250]

8.29 We consider this statement (with respect to Article 5.1) to provide guidance also for our examination as to whether the varietal testing requirement is "maintained without" sufficient scientific evidence (in the sense of Article 2.2). In our view, for a phytosanitary measure to be "maintained without" sufficient scientific evidence, there needs to be a lack of an objective or rational relationship between, on the one hand, the phytosanitary measure at stake (*in casu*, the varietal testing requirement) and, on the other hand, the scientific evidence submitted before the Panel (*in casu*, in particular the six studies referred to by Japan[251]).

8.30 When conducting this examination, we consider it to be important to make a clear distinction between (1) the Japanese requirement that it is for the exporting country (*in casu*, the United States) to demonstrate the efficacy of the quarantine treatment it proposes in order to gain access to the Japanese market for certain products and (2) the Japanese requirement that the exporting country (*in casu*, the United States) needs to make such demonstration *for each variety* of a given product. The United States does not contest the first requirement.[252] It accepts that it needs to demonstrate quarantine efficacy. Only the fact that it needs to do so for each variety, i.e., only the second requirement (the varietal testing requirement), is at issue in this dispute. Under Article 2.2, Japan has the obligation not to maintain this requirement without sufficient scientific evidence.[253]

8.31 Our task in this dispute is to determine whether or not Japan, *to date*, is in breach of this obligation[254]; not whether *in the future* scientific evidence could be produced which would allow Japan to comply with its obligation.[255] If to date there were not sufficient scientific evidence in

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[248] See paragraph 8.15.

[249] Op. cit., paragraph 189, pp. 76-77, italics in original, underlining added.

[250] Op. cit., paragraph 193, underlining added.

[251] See paragraphs 8.21 and 8.23.

[252] See paragraph 8.10.

[253] Unless the Japanese measure is imposed in accordance with Article 5.7, a provision to which Article 2.2 explicitly refers. As noted earlier, this question is dealt with in paragraphs 8.48 and following.

[254] In this respect, we recall the rules on burden of proof we set out earlier in paragraph 8.13.

[255] Article 11 of the DSU directs us to "make an objective assessment of the matter before [the Panel], including an objective assessment of the facts of the case".

support of the varietal testing requirement, Japan would be in breach of its obligations under the SPS Agreement.[256]

(ii) The opinions of the scientific experts advising the Panel

8.32 To determine whether or not the varietal testing requirement is maintained without sufficient scientific evidence (i.e., whether there is a lack of an objective or rational relationship between the measure at issue and the scientific evidence before the Panel), we need to refer to the opinions we received from the experts advising the Panel.[257] We recall that these expert opinions are opinions on the evidence submitted by the parties. We are not empowered, nor are the experts advising the Panel, to conduct our own risk assessment.[258]

8.33 At the end of our meeting with the experts advising the Panel, we requested them to confirm a number of understandings we had drawn from their answers and statements. The experts unanimously confirmed the following understandings:

- First, referring to the evidence before the Panel, there *may* be differences between varieties of the products in dispute which *may*, in turn, be relevant for quarantine purposes, i.e., which *may* affect the efficacy of an MB treatment approved for one variety of a product if applied to another variety of the same product.[259]

- Second, the question whether varietal differences, if any, are significant for quarantine purposes *cannot be determined on the basis of the evidence before the Panel*.[260]

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[256] Assuming the measure cannot be considered to be a provisional measure in accordance with Article 5.7, an issue we examine below in paragraphs 8.48 and following.

[257] For the procedures we followed to appoint these experts and to obtain their views, see paragraphs 6.1 and following.

[258] See also panel report on *Australia – Salmon*, op. cit., paragraphs 8.41, 8.126 and 8.172.

[259] See Transcript, paragraphs 10.268 - 10.273. Dr. Heather stated the following (confirmed by the other two experts):

> "My understanding, my belief is not that there are differences but there may be differences. I don't believe that the occurrence of the differences has been proven and that they may be relevant for quarantine purposes. So there are two sets of uncertainties in my mind in this statement. There's no certainty that even if differences exist that they are relevant for quarantine purposes between varieties of the products in dispute" (Transcript paragraph 10.270, underlining added).

[260] See Transcript, paragraphs 10.274 - 10.279. As noted in the previous footnote, Dr. Heather stated unambiguously:

> "I don't believe that the occurrence of the differences has been proven and that they may be relevant for quarantine purposes".

See also the introductory statement by Dr. Ducom:

> "the questions of the Panel are relevant but often there is no clear response to give because we miss data on the exact subject on variety by variety testing" (Transcript, paragraph 10.39, underlining added).

See also Mr. Taylor:

> "one of the things that has come out from this meeting which I have found extremely interesting is that we do need more information before we can say categorically that variety in fruit is a

- Third, if, and to the extent that, differences between varieties are significant for quarantine purposes, they are mainly or even exclusively related to different levels of sorption of the fruit.[261]

As noted earlier[262], the scientific evidence before the Panel (i.e., the evidence evaluated by the experts advising the Panel) relates to either apples, cherries, nectarines or walnuts. However, in the view of the experts advising the Panel the understandings referred to above equally apply to the other products at issue (apricot, pear, plum and quince).[263]

8.34 Replying to a US question (posed at the meeting with the experts) as to whether the experts are aware of any situation where differences in variety have resulted in a different treatment level for the products at issue in this case, Mr. Taylor stated: "No, I have no information or have seen any published data so the answer I have to give is no"; Dr. Heather replied: "In my experience there have been no differences of this kind. In fact it's been to the contrary. Most of my experience has been with insecticide dips with the material dimethoate and here we find that the same treatment not only goes across varieties but across commodities but I can see that this sorption problem with methyl bromide is something very special and that's why I wish to defer to my colleagues with experience as fumigation experts".[264]

8.35 When we asked the experts advising the Panel whether, in their expert opinion, there is an objective or rational relationship between, on the one hand, the varietal testing requirement imposed by Japan for MB treatment and, on the other hand, any of the evidence submitted by the parties, they stated unanimously that – even though in theory there may be relevant varietal differences – to date there is not sufficient evidence in support of the varietal testing requirement.[265]

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major factor affecting the efficacy of treatment" (Transcript, paragraph 10.266, underlining added).

[261] Transcript, paragraphs 10.280 - 10.285. See also, for example, the introductory statement by Mr. Taylor:

> "So I would just say then that sorption seems to me to be something that we need to know more about. If it can be shown that the levels of sorption are such that they are significant enough to remove the fumigant to an extent that it is going to raise some doubt as to the efficacy of the treatment, then of course we could say that varietal testing was necessary. But unless we can show that it seems to me that the need to test by variety does still need to be established. (Transcript, paragraph 10.48, underlining added).

See also Mr. Taylor, Transcript, paragraph 10.140:

> "I don't think any of us are in dispute that sorption would be a major factor affecting the efficacy of treatment, and if it can be demonstrated that sorption is of sufficient magnitude between different varieties, this would affect the efficacy of treatment, but I think that this has still to be shown and to be demonstrated" (underlining added).

[262] See paragraph 8.6.

[263] Transcript, paragraphs 10.223 - 10.225.

[264] Transcript, paragraphs 10.155 - 10.158. The question was not directed at Dr. Ducom who did not answer it.

[265] Transcript, paragraphs 10.167 - 10.174:

Dr. Ducom: "… the arguments are not statistically good. Scientifically, they may be good, but in practice they may be too narrow. But the answer is really difficult".

Mr. Taylor: "I have to agree with Dr. Ducom. The answer is very difficult otherwise perhaps we would not be here. Again I think in theory there may be some differences which perhaps exist, but in practice it is difficult to show these and it seems very difficult in fact to say that at this time the differences that might make the difference between treatments efficacious and non-efficacious have not

8.36 In his written answer to Panel question 16, Dr. Ducom states the following:

> "The arguments put forth by Japan for requiring varietal trials are not based on scientific data. They are supported by a few experimental data in which varietal difference exists, in terms of LD_{50}, among a lot of other data in which it does not. These observations lead them to suspect all existing varieties and even more so those of the future, in which, in their eyes, genetic engineering and biotechnology might well create even greater differences. This is not based on any scientific data".[266]

8.37 According to the experts advising the Panel, there is scientific evidence before us – in the form of small-scale dose-mortality tests[267] carried out on different varieties of the same product – which indicate different test results (either a different CxT value[268] or a different LD_{50} value[269]) for different varieties.[270] This cannot be disputed. The statistical and biological relevance of the differences in these test results and, especially, the factors causing them are less clear.

8.38 First, the experts advising the Panel question the value to be attached to the test results for purposes of checking quarantine efficacy.[271] They express doubts as to whether LD_{50} values derived from dose-mortality tests can be used to compare the efficacy of quarantine treatment between varieties.[272] They also note that even though the test results – both with respect to CxT and LD_{50}

> yet been reached and therefore I think at this moment in time that the evidence is not sufficiently strong although in theory it does have some possible validity. But at this stage, as Dr. Ducom has said, and in practical terms, it's very difficult to say yes there is something which is sufficiently demonstrated to show that there is a real problem which has to be addressed in terms of maybe variety-by-variety testing, and which could lead to differences in the treatment techniques that are used".
>
> Dr. Heather: "More to agree with both of my colleagues. I'd say yes there is a relationship but it is an incomplete one but this is a real world and to totally complete the relationship of these and decide on how important it is, I think would probably be beyond the resources even of the United States and Japan in the time available, and I'm not sure that it would really add anything of great value to the argument".

[266] See paragraphs 6.104 - 6.105.

[267] The concept of a dose-mortality test is explained in paragraph 2.12.

[268] The concept of a CxT value is explained in paragraphs 2.11 and 8.21.

[269] The concept of an LD50 value is explained in paragraphs 2.14 and 8.23.

[270] See paragraphs 8.21 - 8.23.

[271] In this respect, it should, from the outset, be recalled that all the studies referred to by Japan were designed and carried out in order to *comply* with the varietal testing requirement. None of the studies before us specifically examines the appropriateness of the requirement itself.

[272] See answers to Panel question 1 by Dr. Ducom: "In practice, the LD50 test constitutes a fairly unreliable method to compare the efficacy of quarantine" and Mr. Taylor: "LD50 values are extremely useful in comparing the toxicity of different chemicals and in the measurement of resistance. However, these values are less useful in investigations of much higher levels of toxic response such as are necessary in relation to quarantine treatments, where LD values of 99 or 99.9 are more appropriate and useful". In his answer to Panel question 12, at para. 6.8, however, Dr. Ducom noted that "while the dose-mortality test (LD_{50}) did not give any confidence in respect of the varietal factor, it did give an indication of the relative sensitivity of the products tested". See also Dr. Heather's statement at the meeting with the experts:

> "[The LD50 value] is not a precise numerical measure and of necessity it has had to be used in a rather less precise way than it would otherwise be. It is not a direct measurement on the insect, it is a measurement on the insect where it is influenced by the fruit in the chambers so it is not a precise measurement. In fact, if you look at an LD value it's easy to take one figure but realistically you should be looking at what we call the confidence limits or the fiducial limits and these are ranges within which that value falls and perhaps would lead to a better understanding if we thought of it in that way. As you recall, because the quarantine treatments

values – show statistical differences between varieties, biologically speaking these differences are not pronounced.[273]

8.39 Second, and more importantly, the experts advising the Panel are of the view that even if confidence is given to these differences in the test results there is no evidence before the Panel that these differences – both in CxT and LD_{50} values – are due to varietal differences.

8.40 In the studies referred to by Japan, the same tests were carried out on different varieties and in some instances the results differed. However, according to the experts advising the Panel, these differences could have been caused by a series of factors which are *not* related to varietal differences, such as differences in leakage of the fumigation chamber, fruit load, experimental errors, sorption by packaging material, natural variation of the pest population and fruit-to-fruit variation such as different ripening times, seasonal variations and physical condition of the fruit. Japan contends that experimental factors can be and were controlled to the extent possible. However, Japan does not contest that other factors (not related to varietal differences) could also explain the differences in the test results. The differences *might* also be linked to varietal differences. However, on this Dr. Ducom states the following (confirmed by the other two experts advising the Panel[274]):

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are not measured at the median dose or the LD_{50} dose but at the extreme dose, these limits become very wide and it is not wise to take arithmetic cognizance" (Transcript, paragraph 10.41).

[273] At the meeting with the experts Dr. Ducom stated:

> "… the scientific facts given by Japan are may be too narrow. I mean, for example, when they give some differences between varieties the confidence limit is not a biological fact, it is a statistical fact. I mean, biologically speaking, the difference does not matter … just one per cent makes, statistically speaking, there is a significant difference while biologically speaking there is no difference" (Transcript, paragraph 10.39. See also Dr. Ducom at Transcript, paragraph 10.186).

See also the statement by Dr. Heather at the meeting with the experts:

> "… statistically demonstrated differences … must always be viewed against the background of the biological conditions which give rise to them. What is biologically unlikely, but statistically shown, must be viewed with some reserve. Biological creditability is just as important as statistical demonstration of differences." (Transcript, paragraph 10.43).

[274] Addressing, for example, a study conducted on three varieties of nectarines and 13 apple varieties (Kawakami, F., et. al., Methyl Bromide Sorption in Fruit Varieties, Research Division, Yokohama Plant Protection Station, Japan Exhibit 36), Dr. Heather, speaking on behalf of all three experts, stated:

> "… the authors obviously attributed the differences to varietal characteristics. We are of the opinion that it is not possible to attribute them solely to varietal characteristics on the evidence that's present in this paper. It may well be true but it requires, it would require… to reach that firm conclusion would require more information." (Transcript, paragraph 10.218).

With respect to the same study, Dr. Ducom noted the following:

> "This study was very interesting but the problem is that it was made on apples, which were not at the same stage of storage because some were one month in storage and others had three month's storage – so the variety is not the only factor which can change the value we can read. So in practice that means that varieties may be a factor but maybe not very important and maybe some other factors influence that data. The problem of all these studies is that they are just descriptive studies. We take some apples, or peaches, or nectarines, and we look at the concentration but the reason why it differs, we don't know. There is no fundamental work on that and we can just say this works, or it does not work and so on" (Transcript, paragraph 10.259, underlining added).

See also Dr. Heather's answers to Panel question 1: "… where differences between varieties are small, fruit to fruit variation could greatly exceed variety to variety variation. Such variation is an inherent characteristic and is usually overcome by

> "It is impossible by a simple DMT [dose-mortality test] to find out the relevant impact of the factors playing a role in the varietal differences … mainly because varieties ripen at different times … The DMT presented by the parties are designed to give information on insect sensitivity. The search for possible causes of varietal variations cannot be determined with precision by them, but only with a specific research program".[275]

> "There is a lack of precise studies on this subject. *A priori*, one could cite almost anything, the size of the fruit, the nature of the epidermis, the average sugar content, the ripeness of the fruit, its physiological condition, the time between harvest and fumigation, etc. However, in this, there are hypotheses that merit studying".[276]

8.41 The experts advising the Panel point out that so far no attempt has been made to determine whether varietal differences actually constitute a factor which causes the differences in the test results.[277] And this even though, according to the experts advising the Panel, technically speaking such determination can relatively easily be made, for example, by conducting sorption tests on different varieties of a product.[278] Japan did not further test or try to confirm its so-called hypothesis

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ensuring adequate robustness of the treatment"; to Panel question 3: "Although statistical differences are evident between some varietally based experiments, this does not provide an assurance that the origin of the difference lies predominantly in varietal characteristics"; and to Panel question 8: "If the criterion used is statistically significant differences between experimental samples of different varieties there are differences as identified by Japan, but there is no certainty that they are attributable to unique varietal characteristics. In subsequent research on additional varietal samples these differences were too small to cause the efficacy of a treatment based on varieties used in initial trials, to fail in further testing".

[275] Dr. Ducom's answer to Panel question 3.

[276] Dr. Ducom's answer to Panel question 9. Answering a US question at the meeting with the experts – as to whether varietal differences are widely known to result in significant differences in efficacy of treatment as opposed to a number of sources of fruit variation which include temperature, moisture, daylight, rainfall, cultivation conditions and other natural conditions of the harvest year, which according to Japan are not widely known to result in significant differences in efficacy of treatment – Dr. Ducom stated as follows:

> "It's the same. My opinion is that differences are of the same [nature], maybe, of the same amount [importance]. I mean, I do not understand what Japan says. I mean why temperature, moisture and so on? Since they are not known they are counted for nothing. That I cannot understand. The same thing for variety. If we use the same argument varieties [aren't more significant than other variables] are just nothing because [we have little data for varieties] we don't know the answer for varieties. Or, if we take into account variety we should take into account daylight, moisture, rainfall and so on" (Transcript. paragraph 10.62).

[277] See footnote 260.

[278] Since, according to the experts advising the Panel, varietal differences, if and to the extent they exist, would mainly or exclusively be due to differences in sorption, tests could, for example, be conducted on different varieties of a product to check whether there are any such differences in sorption. See Dr. Ducom's statement at the meeting with experts:

> "I just advise something about sorption. Levels are important for varieties but that means no insects, no LD50 trials to show that sorption is different. I mean we don't need any insects and any dose mortality tests to show that sorption is different and it makes very different, it's very easy, it's easier to run a sorption test than the dose mortality test. That's an important point in practice" (Transcript, paragraph 10.142).

See also the following statement of Mr. Taylor at the meeting with the experts:

> "I think we're all agreed that sorption is one of the major factors involved and, I think that, as Dr. Ducom said earlier, one of the things that should be done is the testing of samples just with methyl bromide [no insects to be involved] to see if we can determine the extent to which these varieties do absorb methyl bromide. Also it would be nice to try and relate any differences we find to chemical or physical characteristics more definitely" (Transcript, paragraph 10.266).

See also statements by Dr. Ducom and Mr. Taylor, Transcript, paragraphs 10.187 - 10.196.

according to which varietal differences affect quarantine efficacy. However, as Japan itself notes: "The task of scientific demonstration begins, not ends, with a discovery of variables".[279]

(iii) Evaluation by the Panel

8.42 We carefully reviewed all the evidence before the Panel in accordance with the rules on burden of proof we set out earlier.[280] After this review and referring, in particular, to the expert opinions quoted above[281], we consider that, to date, it has not been sufficiently demonstrated that there is a rational or objective relationship between the varietal testing requirement and the scientific evidence submitted to the Panel. In our view, the United States established – on the basis of scientific reports and with the support of the opinions of the experts advising the Panel[282] – that so far not a single instance has occurred in Japan or any other country, where the treatment approved for one variety of a product has had to be modified to ensure an effective treatment for another variety of the same product. We acknowledge that this part of the evidence before us, of course, only relates to those products and varieties for which to date an application for approval to import was made. The United States further provided evidence, supported by the opinions received from the experts advising the Panel, which suggests that varietal differences do not matter for quarantine efficacy, at least not to the extent reflected in the current Japanese varietal testing requirement.[283] Moreover, even though Japan may have some data – taken from several individual studies – possibly hinting at relevant varietal differences, no evidence before this Panel makes the actual causal link between the differences in the test results and the presence of varietal differences. On these grounds and after having carefully weighed the evidence and opinions of the experts advising the Panel submitted to us, we thus consider that the United States has raised a presumption that Japan's varietal testing requirement is maintained without sufficient scientific evidence and that this presumption has not been sufficiently rebutted by Japan.

8.43 We thus find that Japan maintains the varietal testing requirement without sufficient scientific evidence in the sense of Article 2.2.

8.44 According to the scientific experts advising the Panel, the statements they provided on varietal differences are – to the best of their knowledge – equally valid for all US products here at issue.[284] At the meeting with the experts, we asked them the following:

> "You know that the scope of this dispute does not cover only the four products, apples, cherries, nectarines and walnuts, but also apricots, plums, pears and quince, even if we have not received any material from either party concerning those four other products. So now the Panel wants to ask you the following question: To the best of your knowledge is what you have stated about varietal differences concerning apples, cherries, nectarines and walnuts, would that also be valid for apricots, plums, pears and quince?".[285]

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[279] Second submission of Japan, p. 15.

[280] See paragraph 8.13.

[281] See paragraphs 8.32 - 8.41.

[282] See paragraph 8.34.

[283] See, for example, paragraphs 8.35, 8.39 and 8.40.

[284] See paragraph 8.33 *in fine* and footnote 263.

[285] Transcript, paragraphs 10.223 - 10.225.

We put this question before the experts since the scope of our mandate covers all eight products[286] and taking into account the Appellate Body's view that a panel needs to make findings with respect to all products falling within its terms of reference.[287]

8.45 Dr. Heather answered "yes" to this question and the other two experts concurred. However, the experts did not further elaborate on their answer. Nor did any of the parties provide any additional comments or information which could enlighten us as to the existence or relevance of varietal differences for the four products for which no specific studies are before us. After careful examination we do not consider, therefore, that there is sufficient evidence before us to extend our finding in paragraph 8.43 also to apricots, pears, plums and quince. We only find that Japan maintains the varietal testing requirement without sufficient scientific evidence with respect to apples, cherries, nectarines and walnuts.

8.46 With respect to two of the four products to which our finding in paragraph 8.43 does apply (apples and walnuts), the experts advising the Panel made certain additional remarks. First, with respect to apples and the cold treatment they undergo before entering Japan (in addition to fumigation), the experts advising the Panel were even more categorical in their opinion that no evidence before the Panel provides a causal link between varietal differences and a divergent efficacy of the required treatment. Since, according to the experts advising the Panel, the efficacy of cold treatment is not linked to the sorption characteristics of the fruit – the allegedly most important factor which could explain possible varietal differences, if any exist[288] – most (if not all) varietal differences which might exist would be offset by the cold treatment.[289] One expert advising the Panel noted, however, that cold treatment kills the codling moth eggs whereas MB fumigation kills the larvae.[290] The quarantine efficacy across varieties of apples due to the cold treatment would thus only seem to apply to the killing of codling moth eggs.

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[286] See paragraph 8.6.

[287] See Appellate Body report on *Japan – Taxes on Alcoholic Beverages*, adopted on 1 November 1996, WT/DS8/AB/R, p. 26.

[288] See paragraph 8.33 and footnote 261.

[289] In reply to the Panel's question whether "anything in the apples study submitted by Japan [Kawakami, F., et. al., Methyl Bromide Sorption in Fruit Varieties, Research Division, Yokohama Plant Protection Station, Japan Exhibit 36]… change any of your earlier opinions as to the relevance of varietal differences for quarantine efficacy", Dr. Heather replied:

> "I don't think there is anything in the apple study which impinges on this. Apples are unique in that they have a combined treatment of cold and of methyl bromide and both of these are quite efficacious in their own way. Perhaps I should say at this stage there was a question also from Japan as to why I believe that apples would not differ very much amongst themselves varietally. The reason for this is that cold treatment as a contributing treatment to the codling moth control does not have a sorption problem so there should not be the same degree of variation between varieties of apples because of this cold treatment factor that you would find in a treatment which relied only on methyl bromide" (Transcript, paragraph 10.257).

See also Dr. Heather's reply to Panel question 17:

> "… given the combined lethal potential and broad applicability of MB and cold, it is highly unlikely that there would be any differences in efficacy between any common commercial apple varieties".

[290] In his comments on the Panel's draft findings now contained in paragraphs 8.73 - 8.101 (received according to the procedure outlined in paragraph 6.116), Dr. Ducom clarified that the combined treatments for apples (MB fumigation and cold treatment) affect two different stages of the codling moth: the cold treatment kills the codling moth eggs, the MB fumigation the larvae (see summary in paragraph 6.114). Dr. Ducom noted the following: "There are indeed two treatments for apples, but they apply to two different and separate stages. The cold kills the eggstage and the gas the fifth larval stage" (translation from French)".

8.47 Second, with respect to walnuts, the experts advising the Panel pointed at a specific factor which may influence the sorption level of walnuts, namely their oil or fat content. This could also explain the different test results referred to by Japan.[291] However, according to the experts advising the Panel, so far no information is available which shows that the total oil content is a varietal characteristic which could – by means of a different sorption level – affect the quarantine efficacy of an MB treatment.[292] Therefore, the fact that no evidence before this Panel makes the causal link between the differences in the test results and the presence of varietal differences, also applies to walnuts.

(c) Is the varietal testing requirement a provisional measure under Article 5.7?

8.48 At this juncture – and before we can find, following our considerations and finding in paragraphs 8.42 and 8.43, whether or not Article 2.2 is violated in this dispute – we recall that Article 2.2 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*" (emphasis added). We note that Japan invokes Article 5.7 in support of its varietal testing requirement. We therefore need to examine next whether the varietal testing requirement is a measure meeting the requirements in Article 5.7. If the varietal testing requirement meets these requirements, we cannot find that it violates Article 2.2.

8.49 Article 5.7, in relevant parts, provides as follows:

> "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt … phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from … phytosanitary measures applied by other Members. In such circumstances,

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[291] See paragraph 8.21.

[292] As outlined in paragraphs 6.112 - 6.115, after the Panel's second substantive meeting, we addressed an additional question to the experts dealing with walnuts (with reference to a study submitted by the United States, Variation in Polyunsaturated Fatty Acids Composition of Persian Walnut, L. Carl Greve, et. al., J. Amer. Soc. Hort. Sci. 117 (3), pp. 518-522, 1992, US Exhibit 40) namely "whether and to what extent the oil or fat content differs between varieties of walnuts *because of varietal characteristics*" and "whether any such differences are significant enough to affect quarantine efficacy" (emphasis in original). Dr. Heather answered, *inter alia*:

> "I did not find any information on total oil content as a varietal characteristic … Therefore, [the US study] does not provide any further clarification of the extent to which oil content of walnuts might affect quarantine treatment efficacy and consequently, quarantine security".

Dr. Ducom stated, *inter alia*:

> "… the differences between varieties in walnut commodities could be, if any, easily showed since we have a very good tool with the oil content … variety is one of the different factors which may affect the oil content of the fruit. But the authors have shown that it's influence is less important than the environmental conditions … Differences like presented in the publications seem to be not large enough to have a noticed influence on the sorption and thus on CT and efficacy. But only trials designed for that purpose could definitively give the good answer".

Mr. Taylor stated, *inter alia*:

> "The greater differences in fatty acid content composition found from year to year within the same variety than between varieties in a single year is also very important evidence demonstrating that varietal differences are unlikely to be the most important factor affecting sorption of methyl bromide and, therefore, the efficacy of methyl bromide fumigations".

See also the statements by Mr. Taylor, Transcript, paragraph 10.140 and by Drs. Heather and Ducom, Transcript, paragraphs 10.290 - 10.292.

> Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the … phytosanitary measure accordingly within a reasonable period of time" (underlining added).

(i) Arguments by the parties

8.50 Under Article 5.7, Japan argues that the *rationale* for its varietal testing requirement is that "available pertinent information" suggests a possible presence of varietal differences in the efficacy of a disinfestation treatment. Once the import prohibition is lifted for a particular variety, Japan expects that new data will be accumulated on the effects of the treatment approved for that variety in order to reach a sufficient level of confidence as to the broader applicability of that treatment to other varieties. Until such level of confidence is achieved, Japan claims to have the right to maintain, on a provisional basis, the import prohibition for all other varieties of the same product. In this respect, Japan further submits that it has not been demonstrated that the present treatment for any of the US products allowed for import will control the risk at the required level with respect to all other varieties.

8.51 Japan recognizes, however, that under Article 5.7 it is required to "seek to obtain the additional information necessary for a more objective assessment of risk and review the … phytosanitary measure accordingly within a reasonable period of time". In this respect, Japan submits that its obligation to collect information is discharged by Japan's practice of requiring the exporting countries to submit data each time approval of additional varieties is sought, as well as by MAFF at the Yokohama Plant Protection Station (Research Division) which is seeking to collect information and continues to study the effectiveness of the existing treatments for new varieties.

8.52 In response, the United States submits that Japan's construction of Article 5.7 is patently incorrect. For the United States, Article 5.7 has a threshold requirement that in order for a measure to be provisional, there must be an insufficient amount of relevant scientific evidence to be able to perform a risk assessment. According to the United States, in this case there is a sufficient amount of evidence. For the United States, all evidence in this case, including the success of uniform treatments on different varieties exported to Japan and the absence of failures by commodity-based testing regimes in other countries, indicates that varietal differences do not affect treatment efficacy.

8.53 The United States further submits that it strains credulity to describe a 50-year old measure as "provisional". The United States argues that, contrary to what is required in Article 5.7, there is no evidence that Japan has undertaken a process to produce a more objective assessment of risk "within a reasonable period of time" so that it can review whether the "provisional measure" should be continued.

(ii) Evaluation by the Panel

8.54 In our view, the first sentence of Article 5.7 allows Members to provisionally adopt phytosanitary measures if two elements, cumulative in nature, are met:

- the measure is imposed in respect of a situation where "relevant scientific information is insufficient"; and

- the measure is adopted "on the basis of available pertinent information".

However, even if a measure meets both of these elements, the second sentence of Article 5.7 imposes additional obligations on the Member provisionally adopting the measure, namely the obligation to

- "seek to obtain the additional information necessary for a more objective assessment of risk"; and

- "review the … phytosanitary measure accordingly within a reasonable period of time".

8.55 Therefore, even if we were to assume that the varietal testing requirement is a phytosanitary measure provisionally adopted in accordance with the first sentence of Article 5.7, i.e., even if we were to assume that in this case "relevant scientific information is insufficient" *and* there is "available pertinent information" before the Panel on which Japan can base the varietal testing requirement, the second sentence of Article 5.7 obliges Japan to "seek to obtain the additional information necessary for a more objective assessment of risk" *and* to "review the … phytosanitary measure accordingly within a reasonable period of time".

8.56 As to the obligation imposed on Japan to "*seek to obtain the additional information necessary for a more objective assessment of risk*", Japan refers to the fact that exporting countries provide additional information when they apply for access. We note, however, that the studies these countries provide are designed and carried out to *comply* with the varietal testing requirement. They do not examine the appropriateness of the requirement itself. This is also the case for the two reports before the Panel which were carried out by MAFF's Research Division.[293] No further information or evidence was submitted to us. As pointed out earlier[294], not a single study before the Panel actually addresses the specific issue as to whether varietal characteristics cause a divergency in quarantine efficacy. The requirement that the information necessary to review an SPS measure must be specific enough, was referred to by the Appellate Body in *EC – Hormones*.[295] In this respect, we further recall that the experts advising the Panel stated that a study or research project to determine whether varietal differences do matter for quarantine efficacy – which would mainly involve sorption tests – could be carried out relatively easily.[296]

8.57 Moreover, with respect to the obligation imposed on Japan to "*review the … phytosanitary measure accordingly within a reasonable period of time*", we note that, according to Japan, testing variety-by-variety for lifting the import ban imposed in the Plant Protection Law, was first applied in 1969 when the ban was lifted for Hawaiian papayas of the Solo variety, i.e., on a variety basis. For the US products at issue, hosts of codling moth, the import ban was first lifted in 1978. The issue of varietal testing, and the question as to whether it can be scientifically justified, has thus been around for almost 30 years and, with respect to the specific products and pest at issue, for 20 years. During this period of time Japan has been in a position to obtain further information on varietal differences and their relevance to quarantine efficacy. Moreover, since the entry into force of the SPS Agreement on 1 January 1995, Japan has been under an explicit obligation to collect additional information to enable it to more objectively review the appropriateness of the varietal testing requirement.

8.58 On these grounds, we consider that there is no evidence before us which indicates that Japan sought to "obtain the information necessary for a more objective assessment of risk" and reviewed the varietal testing requirement accordingly "within a reasonable period of time". We consider, therefore, that the United States has established a presumption that Japan did not comply with the requirements in the second sentence of Article 5.7. We also consider that Japan has not been able to rebut this presumption.

8.59 Following the rules on burden of proof we set out earlier[297], we thus find that even if the varietal testing requirement were considered as a provisional measure adopted in accordance with the

[293] All but two of the studies before the Panel were conducted on behalf of exporting countries. The two exceptions are two studies carried out by MAFF's Research Division (1997 tests on three varieties of Japanese nectarines, Research Division, Yokohama Plant Protection Station, MAFF, 1997, Unpublished, Japan Exhibit 16 and Kawakami, F., et. al., Methyl Bromide Sorption in Fruit Varieties, Research Division, Yokohama Plant Protection Station, Japan Exhibit 36).

[294] See paragraph 8.42: no evidence before this Panel makes the causal link between the differential in the test results and the presence of varietal differences.

[295] Op. cit., paragraph 200.

[296] See footnote 278.

[297] See paragraph 8.13.

first sentence of Article 5.7[298], Japan has not fulfilled the requirements contained in the second sentence of Article 5.7.

8.60 In its comments on the interim report, Japan noted that the information gathered through successive demonstrations by exporting countries constitutes experience and that experience is a legitimate means to gather information under Article 5.7. We agree with this point of view. Of course, Japan can take into account the evidence submitted so far by exporting countries. However, in our view, this method of collecting information has, to date, not provided the information "necessary for a more objective assessment of risk" and an appropriate review of the varietal testing requirement "within a reasonable period of time".

(d) The Panel's conclusion under Article 2.2

8.61 We have found above that the varietal testing requirement – in so far as it applies to imports of apples, cherries, nectarines and walnuts – is neither (1) maintained with sufficient scientific evidence in the sense of Article 2.2[299] nor (2), in the event it were a provisional measure in accordance with the first sentence of Article 5.7, a measure maintained in conformity with the second sentence of Article 5.7.[300] We recall, however, that Article 2.2 requires Japan to ensure that the varietal testing requirement is "not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5". Consequently, we come to the conclusion that Japan, by maintaining the varietal testing requirement with respect to apples, cherries, nectarines and walnuts, acts inconsistently with its obligations under Article 2.2.

8.62 Given this conclusion under Article 2.2, we see no need to further examine what is required for a phytosanitary measure to be "based on scientific principles" in the sense of Article 2.2, nor to determine whether in this dispute the varietal testing requirement is so based.

3. Risk assessment

8.63 Since we have found earlier[301] that the varietal testing requirement violates Article 2.2, we see no need to further examine whether it also needs to be based on a risk assessment in accordance with Articles 5.1 and 5.2 nor to determine whether in this dispute it is so based.

G. MEASURES NOT MORE TRADE-RESTRICTIVE THAN REQUIRED (ARTICLE 5.6)

1. Arguments by the parties

8.64 The United States further claims that the Japanese varietal testing requirement is inconsistent with Article 5.6 in that it is significantly more trade-restrictive than required to achieve Japan's appropriate level of phytosanitary protection. The United States submits that because there are no varietal differences that affect the efficacy of a quarantine treatment, the same established treatment will achieve for all varieties of a product the appropriate level of protection. The United States argues that neither it, nor any other country exporting to Japan, has ever had to modify a quarantine treatment for codling moth for additional varieties of the same product. According to the United States, these

[298] See paragraph 8.54.

[299] See paragraph 8.42.

[300] See paragraph 8.58.

[301] See paragraph 8.61.

results conclusively demonstrate that Japan's varietal testing requirement has no value in providing additional quarantine protection.

8.65 The United States posits testing by product as a reasonable alternative under Article 5.6. The United States accepts that the first variety of a particular product from any source should be subject to the full gamut of testing. However, it is the US view that after such validation, no further testing at all for additional varieties is necessary. Because testing by variety takes a minimum of 2-4 years to complete per variety, is resource intensive and costly to perform, and seriously delays market access of US products, the United States argues that testing by product is also less trade-restrictive.

8.66 The United States submits that to be required to only conduct confirmatory tests for each additional variety (as referred to in a question by the Panel to the United States), would be virtually as time-consuming and burdensome as the current requirement to do dose-mortality tests for each variety and confirmatory testing on representative varieties.

8.67 Although the United States pointed out, in its rebuttal submissions, that it considers testing by product to be the only acceptable quarantine measure in the context of this dispute, in its oral statement at the second substantive meeting it also referred to an alternative measure posited by the experts advising the Panel[302] as a confirmation of the fact that Japan's varietal testing requirement is more trade-restrictive than required.[303] The alternatives submitted by the experts advising the Panel are outlined below.[304]

8.68 Japan responds that its lifting of the import prohibition for specific varieties is a result of the discharge of its obligation under Article 5.6. According to Japan, whenever it finds a measure which achieves its appropriate level of protection and is significantly less restrictive, the import prohibition is replaced with such a measure. In this particular case, however, Japan submits that it found data which suggests the presence of varietal differences in efficacy of MB fumigation, and a hypothesis which explains such a variation. On that basis Japan requires testing by variety. As the United States has not proven product-wide efficacy, Japan concludes that it should not be obliged to accept the US alternative at this stage.

8.69 Japan points out that it already made efforts to alleviate the burden put on exporting countries. First, Japan accepts the concept of a representative variety. This means, for example, that for an application for access of five varieties of a product, a large-scale confirmatory test will only need to be carried out for one of the five varieties, i.e., the variety which is shown to be the least sensitive to the treatment in dose-mortality tests. This is why, Japan submits, there is no requirement of full-scale testing of each variety. Second, for approval of additional varieties, the number of codling moth insects required in large-scale demonstrations has been reduced from 30,000 to 10,000.

2. Elements under Article 5.6

8.70 We note that Article 5.6 provides in relevant part:

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[302] An approach to treatment based on a fixed CxT value to be met by monitoring the MB dose in the fumigation chamber. See additional Panel question 9, posed at the meeting with experts (Transcript, paragraph 10.197), and below paragraph 8.76.

[303] In its answer to an additional Panel question at the second substantive meeting, the United States no longer seemed to consider testing by product as the only alternative, stating that "it remains the *preferred* quarantine measure" (US answers of 24 June 1998, question 1, p.1, emphasis added).

[304] See paragraphs 8.76 and 8.77.

> "… when establishing or maintaining … phytosanitary measures to achieve the appropriate level of … phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of … phytosanitary protection, taking into account technical and economic feasibility" (underlining added).

A footnote to Article 5.6 states the following:

> "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 … phytosanitary protection and is significantly less restrictive to trade".

8.71 Article 5.6 must be read in context. We consider, in particular, that the more specific language of Article 5.6 should be read in light of the more general language in Article 2.2 providing that:

> "Members shall ensure that any ... phytosanitary measure is applied only to the extent necessary to protect ... plant life or health" (underlining added).

8.72 In this dispute, Article 5.6 provides that the varietal testing requirement not be "more trade-restrictive than required to achieve [Japan's] appropriate level of ... phytosanitary protection, taking into account technical and economic feasibility". According to the footnote to Article 5.6, the varietal testing requirement shall be considered to be "more trade-restrictive than required" if there is another phytosanitary measure which:

- is "reasonably available taking into account technical and economic feasibility";
- "achieves [Japan's] appropriate level of ... phytosanitary protection"; and
- is "significantly less restrictive to trade" than the varietal testing requirement.

These three elements are cumulative in nature. Only when the United States has raised a presumption, not sufficiently rebutted by Japan, that all three elements are present, can the varietal testing requirement be found to be inconsistent with Article 5.6.

3. Alternative measures before the Panel

(a) Testing by product

8.73 The first alternative before the Panel is the one posited by the United States. It involves testing product-by-product (instead of variety-by-variety).[305] Once a variety of a product has been approved, no further testing at all would be required for any other varieties of that product.

(b) Alternatives derived from the testing of possible differences in sorption

8.74 The scientific experts advising the Panel suggest other alternatives based on the testing of possible differences in sorption. We deduced these alternatives from their written answers to our questions and, more particularly, from their statements at the expert meeting. Subsequently, at our second substantive meeting with the parties, both parties have expressed their views on these alternatives. Moreover, before issuing our interim report we sent a draft of those parts addressing these

[305] See paragraph 8.65.

alternatives to the experts for their comments.[306] We shall, therefore, also examine whether any of these alternatives meet the three elements under Article 5.6.

8.75 We recall that one of the basic understandings confirmed by the experts advising the Panel is that if, and to the extent, there are differences between varieties, these would be mainly or even exclusively related to different levels of sorption of the fruit.[307] Therefore, to control any possible varietal differences, the experts advising the Panel note that, as an alternative to the varietal testing requirement, one could either monitor or test the sorption characteristics of the different varieties of the products at issue.

[306] See paragraphs 6.116 and following.

[307] See paragraph 8.33 and the references in footnote 261.

(i) Monitoring a predetermined CxT value during commercial treatment

8.76 According to the experts advising the Panel, quarantine efficacy against codling moth could be achieved by determining a fixed CxT value, i.e., a certain concentration of the fumigant in the chamber during a certain period of time, to be obtained during quarantine treatment. This CxT value would be so determined that if a codling moth were fumigated with this concentration during this time, it would die, irrespective of the host product or variety on which it occurs. To obtain this CxT value during commercial treatment, the MB concentration in the chamber would need to be monitored. If the concentration drops below that required by the CxT value, an additional dose would need to be injected in the chamber. As long as the CxT value were met, varietal differences (if there are any, such as sorption) would not affect quarantine efficacy nor would any other factors.[308]

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[308] See Dr. Ducom's answer to Panel question 10:

> "The notion of the concentration-time product, or here the CT value, is fundamental in fumigation. What kills the insect is not only the dose of gas introduced, but the quantity of gas inhaled during the entire gas exposure period. The measurement of gas concentrations throughout fumigation permits one to correlate the efficacy observed not only at the initial concentration introduced, but also during its evolution over time, that is to say, the CT value. This quantity depends on the gas concentration in the chamber whose variation factors are:
>
> - an initial dose introduced into the chamber,
> - the load which could increase or decrease the free concentration of gas according to the sorption of the commodity,
> - the sorption of the commodity and of everything present in the chamber,
> - eventual leaks.
>
> A CT value is universal once the target stage and the treatment temperature are defined. All the other factors matter little, even the nature of the commodity, since they are accounted for by the measurement of gas concentration … The difference [with the current Japanese testing requirements] is that the CT is definitively acquired and that one could then vary the different initial parameters. On the contrary, the present conditions to impose a recognized effective treatment consists in fixing initial intangible draconian conditions (temperature, treatment length, gas tightness of the chamber, nature of the packing material and load) that would make any variation impossible. … Finally, I completely agree to admit that the confirmatory test constitutes a necessary condition to define the quarantine level for a given species of pest. One can also associate the test to a CT value which is then acquired once and for all … This objective CT value could become the sole criterion for success in quarantine treatment" (See also Dr. Ducom's written answers to the Panel's questions, p. 11).

See also Dr. Heather's answer to Panel question 11:

> "If the CxT value for a required efficacy against a pest is known then a fumigation treatment that meets or exceeds that specification can be expected to achieve the quarantine security level required. This should hold true for all batches of a commodity, including those of differing varieties, provided that temperature, load and any other relevant requirements are met".

See also the experts' answers to additional Panel question 9 at the meeting with the experts, Transcript, paragraph 10.198 - 10.202. See also Mr. Taylor's closing statement at the meeting with experts, Transcript, paragraph 10.267:

> "I would like to say in conclusion that I found one of the most interesting parts of the meeting came in question 9 when the Panel asked us if in that statement rather, whether their understanding of what we were talking about was in fact the case and I think it is clear we are saying here that if you have the right amount of gas for the right amount of time it will kill the pest because basically that's what fumigation's all about. It doesn't matter which gas you're using. If you have the lethal concentration for the required time this will kill the pest and that's really what we want to try and achieve, so this long and somewhat complicated discussion about CxT products is in fact very relevant because if we do achieve the desired CxT product in a commercial treatment we should end up with an efficacious treatment which should satisfy the requirements for quarantine".

(ii) Determine whether the sorption level of additional varieties differs from that of the already approved variety

8.77 For the approval of additional varieties of a product for which a treatment for one or more varieties has already been accepted, Japan currently imposes dose-mortality tests for all varieties and an on-site confirmatory test – preceded, if required[309], by a large-scale confirmatory test – for one representative variety.[310] Instead, the experts advising the Panel suggest that Japan could simply determine the sorption level of each of the additional varieties when treated as required for the already approved varieties.[311] For those additional varieties which do not exceed the sorption level of the already approved varieties, there would be no need for further testing or confirmation. The commercial treatment (i.e., a fixed dose-temperature-time relationship, as is the case today) for the initial variety could then also be approved for the additional variety. For those additional varieties which do have a higher sorption level, it could then be determined – if need be by means of additional tests – whether the level of sorption is of sufficient magnitude to reduce the concentration of MB gas below the level of insect mortality required by Japan.[312] If this were to be the case, a different commercial treatment for the additional variety could then be imposed.

4. Does any alternative meet all of the elements in Article 5.6?

(a) Testing by product[313]

8.78 Japan does not contest that testing by product is "reasonably available taking into account technical and economic feasibility" (i.e., it meets the first element under Article 5.6). We agree.

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[309] *In casu*, in the event any of the additional varieties demonstrate, in the dose-mortality tests, significantly lower disinfestation effects than the already approved varieties.

[310] See paragraph 2.24.

[311] See answer by Dr. Ducom to Panel question 11:

> "If varieties are tested to find the CT value, then no further testing is necessary. The success of the system implies: (1) that the trials be conducted according to precise guidelines approved by both parties. In particular, the number of fruits should be quite large in each replicate to minimize the effects of sampling; (2) that the treatment standard clarify the CT value necessary to obtain the desired efficacy. This value is the one found in the confirmatory test, for example for nectarines, 68 gh/m^3 (Yokoyama, 1990.) The results of these tests are sufficient in themselves to give confidence in the conformity of the varietal candidate without having to include the reference variety and insects for efficacy confirmation. This would not bring any supplementary information".

See also answer by Mr. Taylor to Panel question 11:

> "CxT values are used to indicate the fumigant concentration and exposure period required to achieve a 99% mortality of all development stages of an insect at a particular temperature and humidity under practical conditions. If these values were obtained for additional varieties and were found to fall within the range already observed for other varieties it would be difficult to justify why further testing would be necessary".

See further the answers to additional Panel question 9 at the meeting with the experts, Transcript, paragraph 10.198 - 10.202. See also the experts' answers to questions by Japan dealing with this alternative approach, Transcript, paragraphs 10.233 - 10.253.

[312] The experts advising the Panel noted that the differences in sorption would need to be significant in order to affect treatment efficacy. See Mr. Taylor's answer to Panel question 9, at paragraph 6.67 and his statement at the meeting with the experts, Transcript, paragraph 10.82; Dr. Heather's answer to Panel question 10, at paragraph 6.81.

[313] See paragraph 8.65.

Technically and economically speaking it is easier to implement testing by product, both for Japan and the exporting country, than the various tests and procedural steps currently imposed to obtain approval for additional varieties. Indeed, under the testing by product alternative no further testing at all of additional varieties would be required.

8.79 Japan does not contest either that testing by product is "significantly less restrictive to trade" than the varietal testing requirement (i.e., it meets the third element under Article 5.6). We agree. Under the testing by product alternative, market access for additional varieties would be automatic. No additional testing would be required.

8.80 Japan only contests the remaining element under Article 5.6, namely whether testing by product would "achieve [Japan's] appropriate level of ... phytosanitary protection".

8.81 Both parties agree that it is up to Japan to determine its appropriate level of phytosanitary protection with respect to codling moth. We agree since the SPS Agreement (in paragraph 5 of Annex A) defines the "appropriate level of … phytosanitary protection" as "[t]he level of protection *deemed appropriate by the Member* establishing a ... phytosanitary measure to protect … plant life or health within its territory"[314], *in casu*, the level deemed appropriate by Japan.

8.82 Both parties also agree on the level of mortality that Japan is seeking with respect to coddling moth.[315] We consider that, for present purposes, this level of mortality can be regarded as Japan's appropriate level of protection. Japan will lift the import prohibition if it can be replaced by a measure which achieves the same level of protection as that reached by the import prohibition. With respect to measures imposing disinfestation, this level is complete mortality in large-scale tests on a minimum of 30,000 codling moths.[316] For the testing by product alternative, the question thus becomes *whether the treatment approved for the first variety of a product would meet the same level of protection, i.e., complete mortality in large-scale tests on a minimum of 30,000 codling moths, with respect to all other varieties of that product.*

8.83 Referring to the opinions we received from the experts advising the Panel, we consider that – to date and on the basis of the evidence before the Panel – it is not possible to state with an appropriate degree of certainty that one and the same treatment would be effective for all varieties of a product. In the view of the experts advising the Panel, there is no evidence before us which establishes a causal link between divergent quarantine efficacy and the presence of varietal differences (i.e., evidence which could justify Japan's varietal testing requirement).[317] However, at least one of the experts advising the Panel made equally clear that the US alternative of one treatment for all varieties, including those to be developed in the future, does not, to date, have a scientific basis either. In his answer to Panel question 16, Dr. Ducom states:

> "The arguments put forth by Japan for requiring varietal trials are not based on scientific data. They are supported by a few experimental data in which varietal difference exists, in terms of LD_{50}, among a lot of other data in which it does not …
>
> The arguments put forth by the USA are based on a large number of experiments, of which Japan has thoroughly made use.

[314] Emphasis added.

[315] See paragraph 8.11.

[316] See paragraph 2.23 under "Large-Scale mortality test" and paragraph 8.11. See also answer by Dr. Heather summarized in paragraph 6.117.

[317] See paragraph 8.42.

> Varietal difference appears several times, but each time, the confirmatory test has revealed sufficient efficacy. Extrapolation to all available varieties is no more scientific than the Japanese's contrary assertion. This sort of extrapolation is something along the order of intuition. It is unfortunate that there has not been a research program on the subject in order to try to present some scientific proof".[318]

8.84 Therefore, after having carefully examined all the evidence before us in light of the opinions we received from the experts advising the Panel, we are not convinced that there is sufficient evidence before us to find that testing by product would achieve Japan's appropriate level of protection for any of the products at issue.

(b) Alternatives derived from the testing of possible differences in sorption

(i) Monitoring a predetermined CxT value during commercial treatment[319]

8.85 The United States recognizes that the process of monitoring a predetermined CxT value could be less trade-restrictive than the current regime of testing by variety. For the United States, this would depend on a number of assumptions, including (1) the new treatment methodology would not apply for varieties already approved for entry to Japan nor for those varieties for which an application is currently pending; (2) with respect to new commodities, the initial variety on the basis of which the fixed CxT value would be determined, would not be subject to an on-site confirmatory test; and (3) since the treatment of apples also involves cold treatment, which is not affected by sorption, the approved treatment for some varieties of apples should be extended to all varieties of apples without further testing.

8.86 The United States submits that the question of technical and economic feasibility requires more extensive research and examination. The United States notes that increasing the time and/or dose of an MB treatment to achieve a particular CxT value could result in residues unacceptable for reasons of human health and/or conflict with applicable US environmental laws and regulations.[320] The United States also points out that in order to conduct precise measurements of CxT values, gas chromatographs would be required. However, for commercial applications of MB a fumiscope (which is less precise) is much more commonly available. Fumiscopes are also significantly less expensive and simpler to operate than gas chromatographs. The United States further argues that since monitoring of each treatment would be required, treatments would become more labour intensive than current applications of accepted treatments.

8.87 Japan submits that it does not have information on whether the process of monitoring a predetermined CxT value would be technically or economically feasible for exporting countries. Consequently, Japan is not certain if the process would be less trade-restrictive than the present regime.

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[318] Dr. Ducom's written answers, pp. 10-11, underlining added. At the meeting with the experts, Japan referred to this statement, noting that Dr. Ducom seems to concur "that there is no valid scientific ground to conclude that a treatment established for a particular variety by confirmatory tests would be efficacious for any additional variety" (Transcript, paragraph 10.92). Dr. Ducom replied as follows: " Yes that is correct. I mean I cannot see any more scientific basis on the Japanese side than on the USA's side to say [that each] variety must be carefully treated … or for one we can have all varieties. I hope you understand. In my opinion it is not scientific to say that one variety is equal to all others …" (Transcript, paragraph 10.93).

[319] This alternative is outlined in paragraph 8.76.

[320] In answering an additional Panel question, the parties referred to the Montreal Protocol on Substances that Deplete the Ozone Layer which mandates the phasing-out of MB in developed countries by 2005 (Article 2H). However, they also noted that the use of MB for quarantine and preshipment application is exempted from this phasing-out schedule (Article 2H:6). According to the United States, the production and importation of MB is to be phased-out in the United States by 1 January 2001. The United States noted that its administration has expressed a willingness to consult with the US Congress on changes to US law if alternatives do not exist for control of key pests as the 2001 phase-out date approaches.

8.88 When we asked the experts advising the Panel whether in their expert opinion the process would be technically and economically feasible, Dr. Ducom answered "yes".[321] Mr. Taylor stated that it is technically feasible, but reserved his judgment on the economic feasibility, adding that it is probably economically feasible.[322] Dr. Heather deferred to the other two experts.[323]

8.89 Referring to the arguments made by the parties[324], the evidence before us and the opinions of the experts advising the Panel, we are of the view that, to date, there is not enough evidence before the Panel to enable us to find that the process of monitoring a predetermined CxT value would be technically and economically feasible and significantly less restrictive to trade than the current regime (i.e., fulfils the first and third element under Article 5.6).

8.90 We note, however, that according to the opinions of the experts advising the Panel[325], this alternative would not only guarantee, to a high probability, quarantine efficacy irrespective of possible varietal differences, but also irrespective of any other variables such as crop-to-crop and year-to-year differences within the same variety, i.e., differences which are not taken into account under the current regime.[326]

(ii) Determine whether the sorption level of additional varieties differs from that of the already approved variety[327]

8.91 Japan does not contest that determining the sorption level of additional varieties, and comparing it with the sorption level of an approved variety, is "reasonably available taking into account technical and economic feasibility". The United States has given views which are consistent with this.[328]

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[321] See Transcript, paragraph 10.198.

[322] Mr. Taylor stated:

> "Yes I have to agree with Dr. Ducom. In many cases of course of fumigation of other situations, such as the treatment of flour mills, there is regular monitoring, as we call it, of the fumigant level. It may be necessary to increase the fumigant concentration by adding more fumigant for example, because of some factor, maybe leakage, etc., so I mean this is certainly something that can be done, and is done, and if this type of technology was employed whereby the concentration is monitored regularly and it is found to reach the required level, in other words, you will end up with the CxT product value that you have said is necessary, then this will be an effective treatment and I mean so this is technically feasible. I will reserve judgment on the economic feasibility to those that know more about the topic than myself. But probably it is. I would think it to be probably technically and economically feasible." (Transcript, paragraph 10.200).

[323] Dr. Heather stated:

> "I'd have to defer to my colleagues who know more, who have more practical experience of fumigation, but I am aware that grain in my home State is controlled by the use of a CxT approach rather than an outright dose" (Transcript, paragraph 10.202).

[324] See paragraphs 8.85-8.87.

[325] See paragraph 8.76 and footnote 308.

[326] See, for example, the statement by Dr. Ducom that

> "[a] CT value is universal once the target stage and the treatment temperature are defined. All the other factors matter little, even the nature of the commodity, since they are accounted for by the measurement of gas concentration" (Dr. Ducom's answer to Panel question 10).

[327] This alternative is outlined in paragraph 8.77.

8.92 Under this alternative, the initial variety of a product would be subject to the existing testing requirements; a certain treatment (including a fixed exposure time, dose and temperature) would then be determined. For additional varieties there would only be a need to determine to what extent, if any, the sorption characteristics of the additional varieties differ from those already approved. Such determination would only require a one-time test for each additional variety. According to the experts advising the Panel, this test would be a relatively easy one; at least easier to conduct than the currently required dose-mortality test since it involves neither codling moths nor LD trials. In this respect, Dr. Ducom notes the following:

> "I just advise something about sorption. Levels are important for varieties but that means no insects, no LD_{50} trials to show that sorption is different. I mean we don't need any insects and any dose mortality tests to show that sorption is different and it makes very different, it's very easy, it's easier to run a sorption test than the dose mortality test. That's an important point in practice".[329]

Mr. Taylor, in turn, states:

> "… there are quite well known methods by which accurate levels of sorption can be tested … certainly techniques such as these have been conducted over many years so there should be no problem in actually conducting these trials. As Dr. Ducom said, to determine the sorption of fumigant would not involve insects in these test, just the gas and the commodity, and from these tests to see to what extent there is a difference between varieties as between commodities, and to determine just to what extent this is an important factor and whether the level of sorption is very high or very little difference exists between the two".[330]

8.93 If, as a result of sorption tests, the sorption level of the additional variety is *not* higher than the sorption level of the initial variety, the same treatment can be applied for both varieties, without further testing or confirmation. If the sorption level of the additional variety *is* higher than that of the initial variety, it could then be determined – if need be by means of additional tests – whether the level of sorption is of sufficient magnitude to reduce the concentration of MB gas below the level of insect mortality required by Japan.[331] If this were to be the case, a different commercial treatment for the additional variety could then be imposed.

8.94 On these grounds, we consider that the process of determining the sorption level of additional varieties can be presumed to be "reasonably available taking into account technical and economic feasibility" (i.e., to meet the first element under Article 5.6).

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[328] The United States did not specifically address the technical and economic feasibility of this third alternative. However, the Panel considered all other US arguments in this respect. None of these arguments go against the idea that this third alternative would be technically and economically feasible.

[329] Transcript, paragraph 10.142. See also Dr. Ducom's statement, Transcript, paragraph 10.188.

[330] Transcript, paragraph 10.192. See also Dr. Ducom's written answers, p. 8 ("Research on the CT per variety is an operation which could be rapidly conducted, since only the variety of fruit to be tested is used. Fumigation only lasts two hours and the result is known immediately") and p. 11 ("For the USA, this system is quick and low-cost").

[331] The experts advising the Panel noted that the differences in sorption would need to be significant in order to affect treatment efficacy. See Mr. Taylor's answer to Panel question 9, at paragraph 6.67 and his statement at the meeting with the experts, Transcript, paragraph 10.82; Dr. Heather's answer to Panel question 10, at paragraph 6.81;

8.95 Japan does not contest that the process of determining the sorption level of additional varieties is "significantly less restrictive to trade" than the varietal testing requirement. The United States has given views which are consistent with this.[332]

8.96 Under this alternative, testing for most (if not all) additional varieties would be limited to a sorption test. If the sorption level is *not* higher than that of already approved varieties, no further testing or confirmation would be required. In that event, market access would be obtained significantly more easily than under the current regime. If the sorption level *is* higher than that of already approved varieties, further examination and, if need be, additional testing could then be required. In that case, market access would be obtained in circumstances no more difficult than under the current regime.

8.97 On these grounds, we consider that the process of determining the sorption level of additional varieties can be presumed to be "significantly less restrictive to trade" than the varietal testing requirement (i.e., to meet the third element under Article 5.6).

8.98 Japan has *not* accepted that the process of determining the sorption level of additional varieties would achieve its appropriate level of protection. The United States, on the other hand, suggests that this process *would* meet Japan's appropriate level of protection".[333]

8.99 We recall that it is for Japan to determine its level of phytosanitary protection and that, in this case, the level of mortality sought by Japan for codling moth is not in dispute.[334] Japan's level of mortality is complete mortality in large-scale tests on a minimum of 30,000 codling moths.[335] For the alternative of determining the sorption level of additional varieties, the question thus becomes *whether the treatment approved for the initial variety of a product would meet the same level of protection, i.e., complete mortality in large-scale tests on a minimum of 30,000 codling moths, with respect to all other varieties of that product which have the same (or lower) sorption levels as the initial variety*.

8.100 According to the experts advising the Panel, this would be the case.[336] Dr. Ducom notes, for example:

> "If varieties are tested to find the CT value [an indication of the amount of fumigant sorbed], then no further testing is necessary … The results of these tests are sufficient in themselves to give confidence in the conformity of the varietal candidate without having to include the reference variety and insects for efficacy confirmation".[337]

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[332] The United States did not specifically address whether this third alternative is significantly less trade-restrictive. However, the Panel considered all other US arguments in this respect. None of these arguments go against the idea that this third alternative would be significantly less trade-restrictive.

[333] The United States did not specifically address whether this third alternative would meet Japan's appropriate level of protection. However, the United States submits that testing by product would meet Japan's level of protection. Since this third alternative is more stringent than testing by product, it can thus be presumed that the US view on this alternative would be that it *a fortiori* meets Japan's level of protection.

[334] See paragraphs 8.81-8.82.

[335] See paragraph 2.23 under "Large-Scale mortality test" and paragraph 8.11. See also answer by Dr. Heather summarized in paragraph 6.117.

[336] See the expert opinions referred to in footnote 311.

[337] Dr. Ducom's written answer to Panel question 11, underlining added. See also Dr. Ducom's written answers to the Panel's question, p. 11: "For Japan, [the alternative] is acceptable in terms of efficacy". Dr. Ducom then refers to a statement by Japan itself according to which "the CT value, a known indicator to control the degree of efficacy of the treatment, will vary as well depending on the variety of the fruit" (First submission of Japan, paragraph 78).

Mr. Taylor, in turn, states:

> "CxT values are used to indicate the fumigant concentration and exposure period required to achieve a 99% mortality of all development stages of an insect at a particular temperature and humidity under practical conditions. If these values were obtained for additional varieties and were found to fall within the range already observed for other varieties it would be difficult to justify why further testing would be necessary".[338]

8.101 On the basis of the evidence before the Panel and the views we received from the experts advising the Panel, we thus consider that it can be presumed that the process of determining the sorption levels of additional varieties – so as to ensure that these levels do not differ in a way which would affect the efficacy of MB treatment – "achieves [Japan's] appropriate level of … phytosanitary protection" (i.e., meets the second element under Article 5.6). We also consider that Japan has not been able to rebut this presumption.

(c) The Panel's conclusion under Article 5.6

8.102 Irrespective of whether Article 2.2 is violated in this case, we offer the following conclusion with respect to Article 5.6. Indeed, even if we were to have found that Japan's measure is maintained with sufficient scientific evidence in accordance with Article 2.2, we would then be called upon to examine whether the measure is consistent with Article 5.6.

8.103 We have considered above that – on the basis of the evidence before the Panel and the opinions of the experts advising the Panel – it can be presumed that an alternative measure exists (i.e., determining the sorption level of additional varieties as described in paragraphs 8.76 and 8.91 and following) which would meet all of the elements under Article 5.6.[339] In so doing, we are not endorsing this or any other specific alternative measure as the measure to be put in place by Japan.

8.104 We thus conclude that the varietal testing requirement maintained by Japan is more trade-restrictive than required within the meaning of Article 5.6. For the same reasons as those outlined in paragraphs 8.44 and 8.45, on the basis of the evidence before us, we only make this finding with respect to apples, cherries, nectarines and walnuts.

H. TRANSPARENCY OF PHYTOSANITARY MEASURES (ARTICLE 7 AND ANNEX B OF THE SPS AGREEMENT)

1. Arguments by the parties

8.105 The United States also claims that the varietal testing requirement has not been published, making it inconsistent with Article 7 of the SPS Agreement.

8.106 Japan does not contest that the varietal testing requirement is in effect and applied. Japan acknowledges, moreover, that it has not been published. Japan argues, however, that the guidelines developed by the MAFF concerning confirmation of efficacy of a disinfestation treatment have been distributed to foreign plant quarantine authorities for the purpose of transparency. Japan stresses, moreover, that these guidelines are available to any interested foreign government through Japan's

[338] Mr. Taylor's written answer to Panel question 11, underlining added.

[339] See paragraphs 8.94, 8.97 and 8.101.

Enquiry Point in accordance with paragraph 3 (b) of Annex B to the SPS Agreement and that anyone who wants to know more about approved products can refer to the MAFF notifications published in the Official Gazette or contact MAFF itself. Japan further contends that the guidelines do not constitute enforceable phytosanitary "regulations" under paragraph 1 of Annex B. According to Japan, they are only a model and are not mandatory since exporting countries may choose to demonstrate efficacy of treatment by other means. Finally, according to Japan, these guidelines are not generally published because they are a highly technical document addressed to foreign plant quarantine authorities.

8.107 In response, the United States submits that irrespective of the informal process by which US scientists, in consultation with Japan, have devised procedures to test by variety, the fact remains that the varietal testing requirement itself should be published. According to the United States, the net result is that absent such publication, an exporter has no way to discern what is necessary to move a product from the prohibited list to a list approved by Japan for entry.

2. Evaluation by the Panel

8.108 We note that Article 7 provides in relevant part:

> "Members ... shall provide information on their ... phytosanitary measures in accordance with the provisions of Annex B".

Paragraph 1 of Annex B, in turn, states that:

> "Members shall ensure that all ... phytosanitary regulations which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them".

A footnote to this paragraph specifies that the "phytosanitary regulations" referred to are:

> "phytosanitary measures such as laws, decrees or ordinances which are applicable generally".

8.109 Therefore, in our view, for a measure to be subject to the publication requirement in Annex B, three conditions apply: (1) the measure "[has] been adopted"[340]; (2) the measure is a "phytosanitary regulation"[341], namely a phytosanitary measure such as a law, decree or ordinance[342], which is (3) "applicable generally".[343]

8.110 The fact that the varietal testing requirement challenged by the United States "[has] been adopted" and is "applicable generally" is not in dispute. We only need to examine whether this requirement is a "phytosanitary regulation" in the sense of paragraph 1 of Annex B.

8.111 Even though the varietal testing requirement is not mandatory – in that exporting countries can demonstrate quarantine efficiency by other means – in our view, it does constitute a "phytosanitary regulation" subject to the publication requirement in Annex B. The footnote to paragraph 1 of Annex B refers in general terms to "phytosanitary measures such as laws, decrees or

[340] See paragraph 1 of Annex B of the SPS Agreement.

[341] *Ibid*.

[342] See footnote to paragraph 1 of Annex B.

[343] *Ibid*.

ordinances".[344] Nowhere does the wording of this paragraph require such measures to be mandatory or legally enforceable. Moreover, Paragraph 1 of Annex A to the SPS Agreement makes clear that "phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures". It does not, in turn, require that such measures be mandatory or legally enforceable. The interpretation that measures need not be mandatory to be subject to WTO disciplines is confirmed by the context of the relevant SPS provisions, a context which includes provisions of other WTO agreements and the way these provisions define "measure", "requirement" or "restriction"[345], as interpreted in GATT and WTO jurisprudence.[346] This context indicates that a non-mandatory government measure is also subject to WTO provisions in the event compliance with this measure is necessary to obtain an advantage from the government or, in other words, if sufficient incentives or disincentives exist for that measure to be abided by.

8.112 We consider that in this case the varietal testing requirement, as set out in the "Experimental Guide for Cultivar Comparison Test on Insect Mortality – Fumigation" (hereafter referred to as "the guidelines"), does provide sufficient incentives for it to take effect. Indeed, if an exporting country abides by the guidelines, its request for entry of a certain variety of a product will be granted. If an exporting country accepts the varietal testing requirement and follows the guidelines, it will do so in order to obtain an advantage from the government. We thus consider that the varietal testing requirement is a phytosanitary regulation in the sense of paragraph 1 of Annex B.

8.113 We note, moreover, that even though Japan submits that the guidelines are only a test model and that exporting governments may choose to demonstrate efficacy of treatment by other means, Japan asserts that so far no exporting government ever proposed such other means[347] and that Japan, accordingly, never accepted any alternative means.

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[344] In accordance with Article 3.2 of the DSU and established WTO jurisprudence, we shall interpret these terms in paragraph 1 of Annex A in accordance with the interpretative rules of the 1969 Vienna Convention on the Law of Treaties ("Vienna Convention"), in particular Article 31 thereof which provides in relevant part as follows: "1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose".

[345] For example, the Illustrative List of Trade-Related Investment Measures ("TRIMs") contained in the Annex to the Agreement on TRIMs indicates that TRIMs inconsistent with Articles III:4 and XI:1 of the GATT include those which are "mandatory or enforceable under domestic law or under administrative rulings, *or compliance with which is necessary to obtain an advantage*" (emphasis added).

[346] Recently, for example, the panel on *Japan – Measures Affecting Consumer Photographic Film and Paper* (adopted on 22 April 1998, WT/DS44/R), addressing a claim of non-violation nullification and impairment under Article XXIII:1(b) of the GATT, stated the following (at paragraph 10.49):

> "a government policy or action need not necessarily have a substantially binding or compulsory nature for it to entail a likelihood of compliance by private actors in a way so as to nullify or impair legitimately expected benefits within the purview of Article XXIII:1(b). Indeed, it is clear that non-binding actions, which include sufficient incentives or disincentives for private parties to act in a particular manner, can potentially have adverse effects on competitive conditions of market access".

See also the panel report on *Japan – Trade in Semi-Conductors* (adopted on 4 May 1988, BISD 35 S/116), where the panel found (at paragraph 109) that although measures are not mandatory, they could be considered as "restrictions" subject to Article XI:1 of the GATT in the event "sufficient incentives or disincentives existed for non-mandatory measures to take effect". Similarly, the panel on *EEC – Regulation on Imports of Parts and Components* (adopted on 16 May 1990, BISD 37S/132) considered (at paragraph 5.21) that the term "laws, regulations or requirements" contained in Article III:4 of the GATT included requirements "which an enterprise voluntarily accepts in order to obtain an advantage from the government".

[347] The United States, however, asserts that it did propose alternatives, including 100 per cent inspection of certain apples and inspection for certification of cherries (in both instances without fumigation) and the use of a systems approach for nectarines, but that Japan rejected these alternatives.

8.114 We thus find that the varietal testing requirement meets all three conditions for a measure to be subject to the publication requirement in paragraph 1 of Annex B. The requirement thus needs to be "published promptly in such a manner as to enable interested Members to become acquainted with them".

8.115 Japan acknowledges that it has not published the varietal testing requirement. The fact that Japan distributed the guidelines to foreign plant quarantine authorities does not mitigate the lack of publication. In our view, distribution to a limited number of addressees and MAFF's general availability to answer any queries, does not equal prompt publication which enables interested Members to become acquainted with the varietal testing requirement. The publication by MAFF of the protocols relating to approved products does not ensure publication of the varietal testing requirement itself. It only informs Members of products which have met this requirement. Moreover, we do not consider that the highly technical nature of the varietal testing requirement can excuse Japan from publishing it.

3. The Panel's conclusion under Article 7

8.116 On these grounds[348] we conclude that Japan, by not having published the varietal testing requirement, acts inconsistently with its obligations under paragraph 1 of Annex B of the SPS Agreement and, for that reason, with its obligations contained in Article 7 of that Agreement. Since Japan has not published the measure at issue with respect to any of the products falling within our mandate, our finding applies to all of these products.

I. OBLIGATIONS WITH RESPECT TO CONTROL, INSPECTION AND APPROVAL PROCEDURES (ARTICLE 8 AND ANNEX C OF THE SPS AGREEMENT)

8.117 Given that we have found earlier that the varietal testing requirement is inconsistent with the requirements of Articles 2.2[349], 5.6[350] and 7[351] of the SPS Agreement, we see no need to further examine whether it is also inconsistent with Article 8, referring to Annex C, of that Agreement.

J. CONCLUDING REMARK

8.118 In footnote 320, we noted that the parties to this dispute referred to the fact that the substance methyl bromide – used in the quarantine treatments at issue here – needs to be phased-out in accordance with the Montreal Protocol on Substances that Deplete the Ozone Layer ("Montreal Protocol"). However, the parties to this dispute also noted that Article 2H:6 of the Montreal Protocol exempts the use of Methyl Bromide for quarantine and preshipment application from this phasing-out schedule.

8.119 Without embarking on an examination of the Montreal Protocol, we do want to stress that nothing in this report should be read in a way which would affect the rights and obligations of WTO Members party to the Montreal Protocol.

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[348] See paragraphs 8.108 - 8.115.

[349] See paragraph 8.61.

[350] See paragraph 8.104.

[351] See paragraph 8.116.

IX. CONCLUSIONS

9.1 In light of the findings above, we reach the conclusion that Japan

(i) by maintaining the varietal testing requirement in dispute with respect to apples, cherries, nectarines and walnuts, acts inconsistently with its obligation under 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"; and

(ii) by maintaining the varietal testing requirement in dispute with respect to apples, cherries, nectarines and walnuts, acts inconsistently with its obligation in Article 5.6 of the SPS Agreement to "ensure that [its phytosanitary] measures are not more trade-restrictive than required to achieve [Japan's] appropriate level of … phytosanitary protection, taking into account technical and economic feasibility"; and

(iii) by not having published the varietal testing requirement in dispute with respect to any of the products at issue, acts inconsistently with its obligations under paragraph 1 of Annex B of the SPS Agreement and, for that reason, with its obligations contained in Article 7 of that Agreement.

9.2 Since 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 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 its measure in dispute into conformity with its obligations under the SPS Agreement.

X. ANNEX A - TRANSCRIPT OF THE JOINT MEETING WITH EXPERTS

Chairman

10.1 [*introductory statement by the Chairman*] … with that introduction I would first invite all the participants to introduce themselves and then I would suggest that we start with the opening comments of the experts. Dr. Ducom, Dr. Heather and Mr. Taylor in that order. May I first ask that the experts present themselves?

Dr. Ducom

10.2 Mr. Chairman, thank you. First of all I am French and my mother-tongue is French, is not English, that's why my brief statement will be short. Officially I belong to the French Ministry of Agriculture, but in this session I am not mandated by my Ministry. I am just a private expert here. Some highlights - First of all, pardon? [*Chairman interrupts*]

Chairman

10.3 Thank you. If there is need for translation we have here bilingual persons which can assist you if necessary.

Dr. Ducom

10.4 My problem is that I can understand but to express myself is much more difficult.

Chairman

10.5 And of course you are very correct, all the experts are in their personal capacity and do not represent an institution or country. Ok, Dr. Heather?

Dr. Heather

10.6 I am Neil Heather. I come from Brisbane, Australia where prior to ceasing duty with the Queensland State Department of Primary Industries, I was research leader of what we call the Market Access Quarantine Group, responsible for developing fruit-fly treatments for access to export markets from Australia, i.e., quarantine disinfestation treatments. I am currently affiliated with the University of Queensland at Gatton College where I am termed an Honorary Research Consultant so I have no organisational responsibilities of any kind.

Chairman

10.7 Thank you. And Mr. Taylor?

Mr. Taylor

10.8 Thank you Mr Chairman. Good morning Ladies and Gentlemen. I am very happy to be here and pleased to have been invited to this Panel and to visit Geneva again. I am employed at the Natural Resources Institute in the United Kingdom which until 1996 was a government agency but since that time we've been sold off and we are now part of the University of Greenwich. Much of our work continues in the same manner and we are largely funded by the UK government although I am *here* representing myself, as I do, on the methyl bromide technical options committee. So I stand as an individual. I spend most of my time working overseas in developing countries on pest control activities, particularly with fumigation. Thank you.

Chairman

10.9 Thank you Mr. Taylor. I now turn to the United States delegation.

Mr. Brinza

10.10 Thank you Mr. Chairman. My name is Dan Brinza from the United States. I will ask other members of the US delegation to take the mike very briefly to introduce themselves, starting with the head of delegation.

United States (Mr. Hirsh)

10.11 Good morning Mr. Chairman. My name is Bruce Hirsh and I am an Assistant General Counsel with the Office of the United States Trade Representative.

Mr. Bonner

10.12 Good morning. Peter Bonner, US Department of Agriculture.

Mr. Vick

10.13 My name is Ken Vick, United States Department of Agriculture.

Mr. Thaw

10.14 I'm John Thaw with Plant Protection and Quarantine, Department of Agriculture.

Mr. Leesch

10.15 I'm Jim Leesch. I'm with the US Department of Agriculture, Agricultural Research Service.

Mr. Fedchock

10.16 Craig Fedchock with US Department of Agriculture, APHIS.

Ms. Roberts

10.17 I'm Donna Roberts with the US Department of Agriculture here at the Mission in Geneva.

Ms. Erickson

10.18 Audrae Erickson, US Trade Representatives Office, Washington DC.

Chairman

10.19 Thank you. I now return to the Japanese delegation please.

Mr. Yokota

10.20 Thank you Mr. Chairman. My name is Jun Yokota. I'm the Deputy Director-General of the Economic Affairs Bureau, the Ministry of Foreign Affairs. I would like to turn to my colleagues to present themselves.

Mr. Kato

10.21 My name is Takashi Kato. I'm from the Ministry of Agriculture, Forestry and Fisheries and Deputy Director-General in the Agricultural Production Bureau. Thank you.

Mr. Nakakita

10.22 My name is Hiroshi Nakakita from National Food Research Institute, studying about how to control stored product insect.

Mr. Kawakami

10.23 My name is Fusao Kawakami. I work in the Research Division of Yokohama Plant Quarantine Station. For many years I engage in the development of the disinfestation methods for quarantine so I [was involved in] research data submitted from foreign countries.

Mr. Sato

10.24 My name is Kimihiko Sato, Tokyo University of Agriculture and Technology.

Mr. Sakai

10.25 My name is Masaki Sakai, Agriculture Counsellor, Embassy of Japan, Washington DC.

Mr. Saito

10.26 My name is Noboru Saito. I am working for Plant Production Division, Ministry of Agriculture, Forestry and Fisheries. Thank you.

Mr. Sanatani

10.27 My name is Sanatani. I am from Ministry of Agriculture in Tokyo.

Ms. Hirota

10.28 My name is Mitue Hirota. I come from the Ministry of Foreign Affairs.

Mr. Yokoi

10.29 My name is Yukio Yokoi, Plant Protection Division, Ministry of Agriculture, Forestry and Fisheries.

Mr. Shiragaki

10.30 My name is Tatsunori Shiragaki from the Ministry of Agriculture.

Mr. Motai

10.31 My name is Futao Motai from the Ministry of Foreign Affairs, Japan.

Mr. Yamashita

10.32 My name is Masayuki Yamashita. I'm with the Japanese Mission here in Geneva.

Mr. Nirei

10.33 I am Hideo Nirei from the Authority Bureau of Ministry of Foreign Affairs.

Mr. Chujo

10.34 Kazuo Chujo, Ministry of Foreign Affairs.

Mr. Ito

10.35 My name is Koichi Ito, Japanese Mission in Geneva. Thank you.

Chairman

10.36 Thank you for these introductions. I think that we now can start our discussion according to the procedures I proposed, and that means that I will start by giving the floor one by one to our experts for any general introductory remarks they believe are appropriate.

10.37 So first, in alphabetical order, Dr. Ducom, you have the floor.

Dr. Ducom

10.38 Thank you Mr. Chairman. I have just five remarks on the question and my answers, mainly on the questions.

10.39 First of all, the questions of the Panel are relevant but often there is no clear response to give because we miss data on the exact subject on variety by variety testing. Second point, it seems that both sides want to keep their habits; the arguments can be seen as black or white and each party has found, for example in their answers to the questions, arguments against each other in the same paper. The third point is that the scientific facts given by Japan are maybe too narrow. I mean, for example, when they give some differences between varieties the confidence limit is not a biological fact, it is a statistical fact. I mean, biologically speaking, the difference does not matter … just one per cent makes, statistically speaking, there is a significant difference while biologically speaking there is no difference. We have examples of that. The fourth point. For the USA position one variety for all is maybe uncomfortable because biology or physiology is sometimes surprising. That may be the problem. And the last point is that maybe that the concept of CxT product is not used enough in this dispute, or in this matter.

Chairman

10.40 Thank you Dr. Ducom. Then I turn to Dr. Heather.

Dr. Heather

10.41 Thank you. As with Dr. Ducom I have had some difficulty through not seeing all of the working data but had I seen it, there would not have been sufficient time to perhaps look at it in the detail that's required. Just to perhaps go through your original questions, if I may. The concepts: I think in my view, the most important part here is the interpretation put on the LD values, the LD_{50} value for example. This is not a precise numerical measure and of necessity it has had to be used in a rather less precise way than it would otherwise be. It is not a direct measurement on the insect, it is a measurement on the insect where it is influenced by the fruit in the chambers so it is not a precise measurement. In fact, if you look at an LD value it's easy to take one figure but realistically you should be looking at what we call the confidence limits or the fiducial limits and these are ranges within which that value falls and perhaps would lead to a better understanding if we thought of it in that way. As you recall, because the quarantine treatments are not measured at the median dose or the

LD_{50} dose but at the extreme dose, these limits become very wide and it is not wise to take arithmetic cognizance. You must take into account the truest statistical interpretation of these figures. Sorry I have talked too much on that but I think it is a very important thing; that precision is easily misplaced.

10.42 The confirmatory tests, I have every confidence in and I think that's fairly well accepted throughout [by all parties]. There's been some consideration about the higher susceptibility of (a question asked by Japan) on the higher susceptibility of a commodity for a range of reasons which are outside of the direct interaction between the fruit and the treatment. But here we can have such instances as a late variety of fruit compared to an early variety of fruit; there will be many more insects in the place of origin of the late maturing variety than there were in the beginning. This is the type of background that I wish that comment to be interpreted against.

10.43 The sorption I would like to leave to my colleagues who are rather more wise in the theory of the behaviour of gases and fumigants than I, although I have used them to an extent where I've some understanding of them. The statistical analysis, or the CxT product value, by the way, is a much more precise measure than a LD value, much more precise, because it is a physical measurement rather than a biological one. There's been some misunderstanding perhaps about Tukey's multiple range test. It is simply a less sensitive type of analysis which means that it should be more reliable, but could I say that for statistically demonstrated differences, these must always be viewed against the background of the biological conditions which give rise to them. What is biologically unlikely, but statistically shown, must be viewed with some reserve. Biological creditability is just as important as statistical demonstration of differences. I think that they were the main points that would arise. Could I ask Mr. Chairman do you wish us to address the additional questions? Thank you.

Chairman

10.44 Yes, as you know the Panel has distributed yesterday evening some additional questions. My intention is to raise them after we have discussed the questions raised by the United States and the Japan, and of course I will raise only those of them which have not already been covered by the questions of United States or Japan. So the order will be the questions by the United States, the questions by Japan, the questions by Panel. Ok. Then Mr. Taylor?

Mr. Taylor

10.45 Thank you Mr. Chairman. I don't have too much to say at this particular time. I think one of the things that we must accept is that temperature is very, very important in fumigation and also particularly in the case of methyl bromide sorption is of overwhelming interest and knowledge of what is happening is terribly important.

10.46 If I might just digress very, very briefly - there is another fumigant, phosphine, which is used for durable commodities. There is little or no sorption of phosphine and, therefore, the dosage rates really don't vary much at all for different commodities. It may be rather an over simplification but it could be said that, compared do methyl bromide, there is just one dosage rate for phosphine. Coming back of course to the subject matter of methyl bromide, we do have an overwhelming difference in as much as there is a lot of sorption by commodities, and in fact, in durable commodities which I have to refer to because they are my main area of experience, certainly in the original schedules drawn up for commodity fumigation a commodity dosage was specified. So in fact great importance was taken of the particular commodity in deciding what the application rate should be because there was such a large difference between commodities that you had to define the commodity and then decide what the dose should be based on that commodity, let alone on what insect you were controlling. So in brief, the fact that there may be a high fat or oil content in which the methyl bromide would dissolve meant that a lot of the gas was lost, so certainly the sorption factor is very important and so important that this created differences in terms of dosage rates used. Now whether or not these differences exist in fruit is something which I am certainly not confident to comment on, but the differences certainly, if they were there, would be sufficient to cause different dosage rates to be required and therefore testing

programmes to be necessary. But if the differences between varieties are so small that there is little or no sorption, then it seems to me that varietal testing is perhaps not something which needs to be taken into consideration, particularly if tests have shown, for example, that the chemical composition of the fruit varieties do not vary very much. Because again, going back to what I said about the durable commodities, certainly the differences there are very significant and are so significant that dosage rates are specified for different commodities but not of course for different varieties, for example, of wheat.

10.47 One other point, I would just like to reiterate what Dr. Heather said. LD_{50} values are very useful if you are comparing insects, for example, for levels of resistance. But I don't think in this case we're looking to define dosage rates even for - shall we say, non-quarantine treatments, we would want to use LD_{50} - we'd want to use higher levels of control such as, well, certainly the LD_{99} or $LD_{99.9}$. And therefore the LD_{50} I don't think is at all relevant in this situation.

10.48 So I would just say then that sorption seems to me to be something that we need to know more about. If it can be shown that the levels of sorption are such that they are significant enough to remove the fumigant to an extent that it is going to raise some doubt as to the efficacy of the treatment, then of course we could say that varietal testing was necessary. But unless we can show that it seems to me that the need to test by variety does still need to be established. Thank you Mr. Chairman.

Chairman

10.49 Thank you Mr. Taylor. I now turn to the United States delegation and you have the floor.

United States (Mr. Hirsh)

10.50 Thank you very much Mr. Chairman. First of all, on behalf of the US delegation I would like to thank the experts for agreeing to serve and for their very helpful comments today and their responses. We very much appreciate your taking the time to be with us today. With your permission, Mr. Chairman, I would like to take about five minutes just to consult with the delegation to consider in light of the initial comments by the experts whether we want to ask certain questions, if that's permissible?

[break]

United States (Mr. Hirsh)

10.51 Thank you Mr. Chairman. We just have a few brief questions. All of the questions - for all the questions, any of the experts are welcome to respond. We've noted in some instances that one or more of the experts have focused on the particular question we directed initially to them.

10.52 The first question we have is a request for clarification from Mr. Taylor on his introductory comments. With respect to the differences in sorption that you have noted for durable commodities we want to just clarify that those differences have been observed on a commodity by commodity basis.

Mr. Taylor

10.53 Yes, certainly, on a commodity by commodity basis, yes, the differences are there although some commodities are so similar that certainly for practical purposes commodities are often grouped together. As I say, for practical purposes certain cereals may be grouped together and then other different types of commodities - so that there may be five or six different groups, yes.

United States (Mr. Hirsh)

10.54 But the observed differences have not been on a variety basis but on a commodity basis?

Mr. Taylor

10.55 You're exactly right, yes. And in fact, I've never even heard anybody raise the subject of varieties of rice or wheat or maize requiring to be examined in as much as there might be some differences. So, no, it is merely on a commodity by commodity basis.

United States (Mr. Hirsh)

10.56 Thank you. Also, one or two enquires with regard to the differences in sorption that you have noticed between commodities, durable commodities. Have the magnitude of those differences been obvious?

Mr. Taylor

10.57 Oh yes, yes certainly. The work that was done probably many, many years ago, perhaps even I think before I became involved in this topic, I think maybe even in the 1950s, a lot of work was done and certainly the differences were very obvious to the extent that fumigations carried out at a particular dosage would certainly not control insects to the level required if those same dosage rates were used on perhaps the next group of commodities where the level of sorption was considerably higher. So, yes I think this has been well documented and, as I say, there's a lot of evidence in the literature going back to the 1950s and '60s to substantiate this.

United States (Mr. Hirsh)

10.58 Thank you. The next question we'd like to direct initially at Dr. Heather. Because of the presence of other uncontrollable sources of variation in small scale tests, we don't think that it's possible to conclude that the differences in CxT values referred to by Japan are attributable or can be attributed to varietal differences affecting efficacy of treatment. However, regardless of the source of these variations, were the variations in CxT large enough to affect the efficacy of the fumigation treatments for the commodities that have been raised in this proceeding?

Dr. Heather

10.59 I find it difficult to give a precise, clear answer on that. The problem, … I think I just better leave it at that please.

United States (Mr. Hirsh)

10.60 The next question we note is similar to one that the Panel will shortly be asking but we would like to come at the issue from a slightly different perspective. And that is with regard to the Panel's additional Question 3, Japan refers to various sources of fruit variation including temperature, moisture, daylight, rainfall, cultivation conditions and other natural conditions of the harvest year and Japan states that these sources of variation, quote, are not widely known to result in significant

differences in efficacy of treatment, and this question is for Dr. Ducom initially. Are varietal differences, quote, widely known to result in differences in efficacy of treatment?

Dr. Ducom

Could you repeat please?

United States (Mr. Hirsh)

10.61 We note that Japan has referred to a number of sources of fruit variation which include temperature, moisture, daylight, rainfall, cultivation conditions and other natural conditions of the harvest year, and Japan states that it has not considered these sources of variation because, quote, they are not widely known to result in significant differences in efficacy of treatment. And my question is are varietal differences widely known to result in significant differences in efficacy of treatment?

Dr. Ducom

10.62 It's the same. My opinion is that differences are of the same [nature], maybe, of the same amount [importance]. I mean, I do not understand what Japan says. I mean why temperature, moisture and so on? Since they are not known they are counted for nothing. That I cannot understand. The same thing for variety. If we use the same argument varieties [aren't more significant than other variables] are just nothing because [we have little data for varieties] we don't know the answer for varieties. Or, if we take into account variety we should take into account daylight, moisture, rainfall and so on.

United States (Mr. Hirsh)

10.63 Thank you. I would like to first ask whether any of the experts have had a chance to review the study on apples which Japan recently submitted in Exhibit 36. This only came in last Friday so I'm not sure whether you have had a chance, but before asking my question I want to find out whether any of you have had an opportunity to review that study?

Dr. Ducom

10.64 Which one?

Chairman

10.65 Could you repeat the number of the exhibit?

United States (Mr. Hirsh)

10.66 Sure. It's Exhibit 36. It was submitted, I believe, last Friday together with Japan's comments on Mr. Taylor's responses.

Chairman

10.67 So may I ask the experts, have you received the parties' comments to Mr. Taylor's responses? Ok, they have them, yes.

United States (Mr. Hirsh)

10.68 In that study, with respect to apples, the author states on the final page of the study that the factors affecting different CxT products were not specified in the test. For example, it appears that there were no controls for length of time and storage, maturity of the fruit and fruit size. In addition,

we reviewed the CxT product data in Table 3 and in Table 5. In particular, the data for the Mutsu and the Fuji in each table and that data appears to indicate that the two are not statistically different in Table 5, but they are statistically different in Table 3. In light of the uncontrolled factors in this experiment and the inconsistent data, is Japan's conclusion warranted that the differences in CxT values noted in Table 5, quuote, were obviously attributed to varietal differences?

Chairman

10.69 Ok, I want to give some explanation now. The experts received that document when they arrived in Geneva and they also had other documents which they received yesterday so I think they have not been able to study these documents in detail. So could we agree that we give some time to the experts so that they could answer your question later?

United States (Mr. Hirsh)

10.70 Certainly. Thank you very much.

Chairman

10.71 Ok, so we postpone answer to this question to a later stage, ok.

United States (Mr. Hirsh)

10.72 Those are the only questions which we have right now, Mr. Chairman. We do reserve the right later following Japan's questions to follow up further.

Chairman

10.73 Ok, thank you. Does Japan have any follow-up questions to those questions United States raised?

Japan (Mr. Yokota)

10.74 Mr. Chairman, may we confer within ourselves for a few minutes?

Chairman

10.75 Ok.

[break]

Japan

10.76 Mr. Chairman?

Chairman

10.77 Japan you have the floor.

Japan

10.78 Yes, we have one immediate follow-up question.

Chairman

10.79 Ok.

Japan (Mr. Saito)

10.80 I'd like to have one question but in Japanese so I ask to interpret my question.

Japan (Mr. Saito - interpreted)

10.81 I have a question to Mr. Taylor. Within the response to the US question … [can you hear, can you hear? Can you hear Ok? Let me start again…] I have a question to Mr. Taylor. In the first question from the United States, Mr. Taylor responded saying that the sorption difference among the cereals are commodity wise and varietal differences insignificant. But we would like to ask what is Mr. Taylor's view with regard to the fruits which are the issue here in this Panel?

Mr. Taylor

10.82 Thank you for the question. I am not a specialist in the fumigation of perishables, I regret to say. Therefore I find it very difficult to respond in any firm way to give you a definite reply to this. All I could say is that the differences I would think would have to be very significant in order to make it necessary to, for example, adjust dosage rates and/or time periods for the fumigation. If these differences were so significant that the amount of methyl bromide available for the fumigation process was significantly reduced by different varieties, then, in theory, this would be a significant factor, but I think this has still to be demonstrated. Now you could say well why are there no differences between different varieties of cereals? Again, the answer to that I cannot give you. In fact, I think that in practicable fumigation the application rates always have such a margin [excess over and above the minimum dosage] that any small differences would be accounted for by this margin, or excess that is used. I would imagine that where the United States uses a 10-20% buffer, as I think is the term used, this again would account for it [any small differences]. So in practical terms, as I say, I think we would need to find that there is a significant difference between the varieties and that this needs to be demonstrated. I feel that I cannot say any more on this subject from my own personal point of view. Thank you.

Chairman

10.83 I'd like to ask do the other experts like to add something to this? I don't see. Ok. Then I give the floor to Japan to present your, so to say, own questions.

Japan (Mr. Yokota)

10.84 Thank you Mr. Chairman. May I first of all, and on behalf of the Government of Japan, specially thank Dr. Ducom, Dr. Heather and Mr. Taylor for agreeing to serve as experts on this Panel and to give us their very valuable opinions on this matter. We have prepared a series of questions and I would like to ask Dr. Kawakami to present them.

Japan (Mr. Kawakami - interpreted)

10.85 I would like to speak regarding those questions raised by the Panel and I consider there are five points of importance so I would like to raise them one by one. First of all we should like to express our heartfelt appreciation to the Panel for giving us the opportunity to present our views on

the pending issues of today. Also we should like to give our highest respect to the three respectable experts, Dr. Heather, Dr. Ducom and Mr. Taylor for rendering valuable comments from the technical point of view on the methyl bromide situation of perishable products which we think is a highly complicated aspect of treatment technology and in which much more research and investigation are needed for the situation of the issue in question. The Panel sought for expert comments from technical point of view on as many as 18 questions. Of all these questions we consider that the following five issues of argument are particularly important.

10.86 First issue: Whether or not to be the use of dose response … [*interruption*]

Chairman

10.87 Excuse me, excuse me Japan's delegation that I interrupt. But I think that this submission is better suited for tomorrow, because today we are expected to use the expertise of the experts that are present. Your presentation is welcomed, most welcomed to the Panel but I think it is more appropriate to present it tomorrow when we meet between the parties and the Panel, and today we should devote our time and effort to use the expertise of the experts to the greatest extent. So if you could agree with that, I would like to ask you to postpone this presentation for tomorrow. Thank you. But if you have specific questions to the experts you are welcome of course.

Japan (Mr. Sanatani)

10.88 Ok. Thank you Mr. Chairman. We have prepared five questions to put to the experts. Maybe we can deliver the written questions to the members in this room? The first question is to Dr. Heather and Mr. Taylor. I will read. Dr. Heather states in response to Question 12, quote: if only one variety has been presented in the initial testing the possibility that other varieties which might be proposed subsequently could have higher predicted minimum dose requirements would be greater. Even so, the likelihood of this exceeding 10-20% buffer appears low, end of quote. Similarly, Mr. Taylor states, quote: any varietal differences affecting the efficacy of MB treatment are unlikely to be so great that the buffer of 10-20% fails to account for these differences. Effective quarantine treatment is therefore to be expected, end of quote. Japan wishes to know the grounds for these assumptions that possible varietal differences in most cases could be covered by the buffer 10-20% surrounding the buffer. So, shall I stop here or continue to finish it?

Chairman

10.89 I think it's better to take the questions one by one. So, Mr. Taylor and other experts who..?

Dr. Heather

10.90 Perhaps if I could give the first response on this, please. The grounds for my conclusion were that each of the varieties which had been tested in each of the commodities always met the large confirmatory dose test. There was never any suggestion of failure. Therefore, had the dose been pitched too low in the first place, this would have shown up as survivors from the large scale test. The basis of this problem is partly that we are judging differences at points where they are quite discrete but the effectiveness of the treatment becomes apparent at very, very high efficacies when there are very, very few survivors and this has the effect of bringing together the differences so that they are no longer apparent.

Chairman

10.91 Mr. Taylor, do you want to respond also? Ok. May I ask Japan to proceed to the next question?

Japan (Mr. Sanatani)

10.92 Thank you Mr. Chairman. The second question is posed to all the experts. I read, Dr. Heather states in response to Question 13: The broader applicability of a confirmatory test done on samples of one variety over commodity depends on the extent of variation of mortality attributable to varietal characteristics and a large scale test provides assurance for the extension of an existing successful treatment to additional varieties of a commodity, provided that the initial varietal sample is representative of the commodity. In response to Question 16, Dr. Ducom states: Extrapolation to all available varieties is no more scientific than the Japanese's contrary assertion. They seem to concur that there is no valid scientific ground to conclude that a treatment established for a particular variety by confirmatory tests would be efficacious for any additional variety. Is this correct?

Dr. Ducom

10.93 Yes that is correct. I mean I cannot see any more scientific basis on the Japanese side than on the USA's side to say [that each] variety must be carefully treated … or for one we can have all varieties. I hope you understand. In my opinion it is not scientific to say that one variety is equal to all others, … but [choosing one variety as representative of all is the same sort of argument for me] to say maybe one variety, it's the same for me. Ok.

Chairman

10.94 Thank you. Other experts, do you want to add?

Dr. Heather

10.95 Just responding to the first part of the question. The broader applicability of the context of that statement was to start with the basic facts and say yes, technically, if you develop a treatment on one and seek to apply to others. And then I went on to say that there were no real grounds to be concerned, I think you'll find.

Chairman

10.96 Thank you. Could you now proceed to your third question Japan?

Japan (Mr. Sanatani)

10.97 Mr. Chairman. Before we proceed, can we take some time to reflect on the answers ...?

Chairman

10.98 Of course.

Japan (Mr. Sanatani)

10.99 Mr. Chairman, if you permit us to go back to the question number one, we have some comments to put on our answers to number 1.

Chairman

10.100 I think the place of the comments are tomorrow, but if you have follow-up questions, if your follow-up questions, if you want to seek further clarification from the experts, you are welcome.

Japan (Mr. Saito)

10.101 OK. Thank you Mr. Chairman. So let us go back to question number one and this time in Japanese.

Japan

10.102 (*Interpreted*) Concerning the question one in the replies from experts Dr. Heather stated as follows… we asked in our question whether this buffer of 10-20% could cover all these differences in the varieties, among the varieties, are based on scientific grounds and if this buffer has the scientific grounds and in response to our question we, as far as we can understand, after the various confirmatory test, the efficacy did not show a significant difference and that this is the data of empirical of nature. What we are questioning here is that in all cases whether the buffer 10-20% could absorb all this varietal difference and if that buffer would have the scientific grounds in this manner. And if possible I would like to invite the comments from, or replies from all the experts. Thank you.

Chairman

10.103 OK. I give the floor to the experts.

Dr. Heather

10.104 I am a little anxious if I understood the question clearly enough, but as far as I understand, Japan is questioning where the 10 per cent or 20 per cent buffer came from. It is difficult to project with certainty, by regression analysis, the [dose required for] efficiency and effectiveness of a certain fumigant. By analysing the data, examining a certain range of doses of the fumigant (if the fumigant has 100 per cent effectiveness, or effectiveness of killing insects), by adding to the fumigant some amount, which one actually does in practice, in the actual research, we have examined all varieties under a series of trials. Then we obtain the data from there. A normal procedure then is to confirm the data by a larger-scale confirmation test. However, one can attain this objective by somewhat different means; one is by taking a "single replicate", which Japan is demanding currently. Another would be by setting "confirmatory loss" to as low a level as possible, based on research among them. If there are surviving insects, we conduct such trials repeatedly. We call this the "repeated iterative approach". In other words, it is the idea to seek for, to the extent possible, the lowest value to attain confirmation of effect on a certain target. I think, therefore, that this can be regarded as a somewhat different approach. Both, I think, are means to meet the very difficult problems we have to solve. To be practical does not mean it is unscientific.

Chairman

10.105 I would like to give the floor to Dr. Ducom.

Dr. Ducom

10.106 I would like to add a question: why is the buffer 10 or 20 per cent? This may be accidental and so why not 5 per cent? It is difficult to say these are enough for the variety, because we cannot recognize them as a *fait accompli* [what is needed]. It implies to hypothesize, to some extent, how much the sorption level is for each variety.

Chairman

10.107 OK. Thank you. Japan.

Japan

10.108 [Microphone not on. Probably Japan asking Dr. Taylor to respond as well]

Mr. Taylor

10.109 I agree with the opinion of the two experts, in particular, with Dr. Ducom's. In other words, we have no data on sorption. There are no data indicating the difference of sorption between varieties. So, the 10 to 20 per cent buffer was set arbitrarily (at random); it was not based on scientific examination. However, such numerical difference [is the one which could absorb the difference enough]. A 20 per cent [buffer] would be a substantial increase in volume. I cannot add anything more, but I agree with the opinions so far expressed by my colleagues, the two specialists. We have no data as to what constitutes the rate of sorption of each variety. If we do, we could possibly decide whether this 10 or 20 per cent is too high or too low, and a 5 per cent buffer may well be enough. But we can present no scientific evidence other than that.

Chairman

10.110 Thank you Mr. Taylor. Japan?

Japan

10.111 Thank you, Mr. Chairman. Since we have finished questions number one and two, we would like to move on to question number three, which is a question for Dr. Heather and Mr. Taylor.

Japan (Mr. Sanatani)

10.112 ….. Dose-response testing is a tool commonly used for the purpose of comparing reactive resistance to a treatment such as between development stages of insects. Results of the tests are statistically analyzed using probit analysis, normally by way of comparison of LD50 values. This is supported by Exhibits 19 and 20 of the Japanese submission. There is no disagreement among on this point; in particular, Dr. Heather and Mr. Taylor explicitly acknowledges the effectiveness of dose-response testing and probit analysis. Japan solicits the experts' opinion as to possible application of dose-response data and probit analysis to a comparative inquiry into differential effects of fruit on mortality. Thank you.

Dr. Heather

10.113 It would be a very interesting study, but in such study, from my experience, variation will [originate from both the] fruits and their harmful insects, and it will depend, I think, on how such a treatment is indirectly given. Therefore, it would be difficult to obtain practically useful data from such a study.

Chairman

10.114 Mr. Taylor.

Mr. Taylor

10.115 I agree with the opinion of Dr. Heather. It would be very interesting to know how useful the data will be that comes out as a result. Of course, if Japan is really thinking of doing this, it would be useful. If Japan could make public the result, it will shed light on the issues for which the answer is unknown, or there is no data. Thank you.

Chairman

10.116 Japan.

Japan (Dr. Nakakita)

10.117 I am not good at English and would like to intervene in Japanese. Dr. Ducom, I believe you mentioned that LD_{50} cannot be used for these kind of purposes and as a basis of your saying that, the Journal of Economic Entomology submitted by the United States, the 1987, and which refers to six varieties of nectarines, they are indicating the comparative tests and ... codling moth eggs ... 6.3 grammes per cubic metres. This is the LD_{50} and this was the lowest value obtained among those six varieties. However, with regard to the efficacy at the higher concentration level Summer Grand, is the variety that indicated the highest resistance. So Dr. Ducom seems to be saying that the LD_{50} does not really have the validity, I believe that's what you said. But looking at this report this does indicate the difference between the varieties. And I believe that in this regard this is a report that should command lots of attention. So I believe that this report should attract attention in that regard. But in 1997, in the United States, another report published in the United States which refers to the Summer Grand's test results of 1987 and it came up with a newer data that replaces the old data of '87 and in this new report the value of LD_{50} was not that small. And LD_{95} also indicated the value that is not that much different from the LD_{95} of other varieties. So, the data obtained in the testing done in '87 with regards to the Summer Grand's resistance was in a way negated. And also, May Grand, the variety called the May Grand, the LD_{50} and the LD_{95} are listed next to each other and when you look at those in May Grand LD_{50} and also LD_{95} both indicate a higher resistance than that of Summer Grand but the 100% mortality values is lower by 25% than that of the Summer Grand, so I am somewhat dubious with regards to the reliability of this report. What is your observation on this report Dr. Ducom?

Dr. Ducom

10.118 It is very difficult to answer, to know what happened. For myself we have carried out a lot of trials like that and sometimes we have found black and sometimes white. I don't know why, although I should. I would appreciate it if I could know what happened. But, no, I have no answer. I don't know why. That's the only thing. It's when you do trials like this one with LD_{50} or Probit 9 analysis. Like Dr. Ito says, it depends, sometimes it works. When we say it works, it is logical with what we want to get, but if the results are not what we want, then we say it doesn't work. I don't know what the truth is. I have no more comment about that. I am sorry Kawakami-san.

Chairman

10.119 OK. Thank you.

Japan (Dr. Nakakita)

10.120 Thank you. I would like to ask Mr. Taylor, do you regard this as a scientifically reliable data?

Mr. Taylor

10.121 Could you just refresh my memory as to which, are we comparing the 1987 report with the more recent one? Is this what you are asking me to report on, or to give my opinion on? Please could you just, when you say you would like me to give opinion on to...

Mr. Nakakita

10.122 The report. 1997, sorry. That's the year the Americans submitted report. And '87 which was on general insect product research.

Mr. Taylor

10.123 Thank you Dr. Nakakita. I find it difficult to make any firm statement. I mean I have read these two papers but it's very difficult to know why there is this difference and to actually give with any affirmity which of the two is correct and why there is a difference. I mean Dr. Ducom has already stated that sometimes you get one set of results and sometimes you get another set of results when you may be expecting similar results. I'm sorry, I cannot with any confidence give you any other answer than to say that unless there are any differences that have not been accounted for in these two experimental programmes which we might have to re-examine to see whether there was anything about the two experiments which leads to that conclusion. I don't know whether Dr. Ducom would like to make any comment as whether he thinks there might have been some possible experimental difference which has not been taken into account?

Chairman

10.124 OK. I think you cannot extract more from our experts.

Japan (Mr. Nakakita)

10.125 Thank you very much Mr. Taylor and Dr. Ducom.

Chairman

10.126 OK. Can we move now to your fourth question?

Japan (Mr. Sanatani)

10.127 Thank you Mr. Chairman. I read: In the course of dose-response testing and tests on CxT values, fruit and insects are inserted into a small and highly airtight fumigation chamber. The material of this chamber shows a low level of sorption. Moreover, packages and other factors which might affect the result are consciously eliminated. Japan considers, in light of these experimental conditions, that, should there be any significant differences between test subjects, it is reasonably to estimate a link between fruit and the results. Japan wishes to ask experts about their thinking on this issue. And if it's possible we like to deliver pictures of the dose mortality tests and with your permission I would like to invite my colleagues to put some explanation on it.

Japan cont'd (Dr. Kawakami)

10.128 In these photographs these are the pictures of the dose-response tests. This is testing of the sorption. This is a very small scale gas tight chamber. The chamber itself doesn't really have any gas sorption and we place two different varieties and we examine the rate of sorption for those responses. And of course we have to look at the factors such as the packing materials' existence or chamber's air tightness but those factors are eliminated. Within this chamber only the fumigants and fruits and possibly the pests that are staying when the fruits are inside of the chamber. The Panel seems to share

a view that the data is somewhat varied but we feel that the data obtained from this kind of an experiment is highly reliable so I believe this kind of a test does indicate the different responses or susceptibility of different varieties of fruits to a given measures. So if we could have your comments on this we would appreciate it.

Mr. Taylor

10.129 Could I please ask [the Japanese side if] this chamber is dosed with fumigant when it is completely empty. If this is repeated what level of variation would there be doing a test on the chamber before any fruit is put into it? In other words, what variation would they expect between tests prior to using the chamber actually for experimental work? So an empty chamber of this particular type, would they have any indication of what is a variation if, say, four or five tests were carried out on an empty chamber? What might be the variation it might expect using obviously exactly the same dosage technique and measuring technique?

Japan (Dr. Kawakami)

10.130 Of course before we carry out our test the emptiness and absorption characteristics of gas are studied, but in this regard there is no variation. As for in terms of percentage it would be in the magnitude of under one percent of variation and of course that is based on the empty chamber.

Chairman

10.131 Dr. Ducom?

Japan (Dr. Kawakami)

10.132 In addition these tests using these kind of facilities, are quite generally conducted worldwide. In the United States probably Dr. Ducom would use the same technique and in the United States and New Zealand I note instances where these facilities are used and these kind of tests are conducted and they are all of quite a similar nature.

Chairman

10.133 OK. Who wants to take the floor, Dr. Ducom or Mr. Taylor? Dr. Ducom.

Dr. Ducom

10.134 Yes, we do use something like that but my problem, my concern is the number of fruits used. For example, for stored product sorption trials we use, for example, 200 millilitre glass jars [tape change] ... that means about 100 grammes of wheat, which means 2,000 [cereal grain] kernels. If you take six apples, or something like that, variation must be very high. I mean, if we could use something like 1,000 or 2,000 apples each time it could be very more much precise and confidence limits could be very good. We do [it using the same small amount of apples as you because that is what you ask of us] like you because you ask just that, but I would prefer to know that each variety is tested using a lot of fruits to be able to smooth the differences.

Chairman

10.135 Mr. Taylor, do you want to add?

Dr. Heather

10.136 Perhaps I could just have a word. I would compliment the Japanese researchers on the quality of their laboratory equipment. Speaking from my own view point I had no doubt whatever about the

results coming from such an experimental set up. Where I have reserved my judgment is on the application of those findings or to attribute those findings entirely to varietal differences. It has been my experience with a number of fruits that they vary greatly from year to year, from the locality where they are grown even though they are the same variety, and even in a batch of fruit there will be fruit to fruit variation. Now, I am not certain, I am not convinced that sufficient of the variation is unique to the variety to justify the conclusion that the data, the differences in the data, prove that the cause of this difference is varietal, predominantly varietal, it could never be totally. And this is the reservation I have.

Chairman

10.137 Ok, thank you. Can we now proceed to your next question Japan?

Japan (Mr. Sanatani)

10.138 Thank you Mr. Chairman. Now I move on to question number five. Dr. Heather clearly acknowledges that differential sorption levels due to varieties and other causes could affect efficacy of fumigation. While he refers the question of causes of sorption levels to other experts in fumigation chemistry, Dr. Ducom and Mr. Taylor acknowledge that sorption of methyl bromide takes place in oil contents, surface or protein and variation of these factors result in different sorption levels. Differences in variety often mean differential content levels, such as the oil content in in-shell walnuts. Japan believes from these statements of experts that they recognize possible varietal differences which affect sorption levels and hence efficacy of a treatment, and wishes to ask the experts to confirm this. Thank you Mr. Chairman.

Chairman

10.139 Mr. Taylor?

Mr. Taylor

10.140 Thank you Mr. Chairman. I don't think any of us would fail to agree that sorption and, as I mentioned earlier, temperature are the most important factors affecting the efficacy of fumigation assuming that we're not losing gas due to leakage. And certainly the mention of in-shell walnuts is very applicable. Differences in variety of course, where there is sufficient difference of sorption could well, therefore, affect the efficacy of the treatment. Surface area is again a particular property which, if it was sufficiently great, would affect the treatment. But the oil content, and of course anything else such as the protein which would remove a certain quantity of the gas from the free space, are all important factors that we agree on, and have been researched over many years. So I don't think any of us are in dispute that sorption would be a major factor affecting the efficacy of treatment, and if it can be demonstrated that sorption is of sufficient magnitude between different varieties, this would affect the efficacy of treatment, but I think that this has still to be shown and to be demonstrated. We go back to the obvious difference between durable commodities where some commodities virtually absorb no methyl bromide, rice, for example, compared to in-shell walnuts. I mean the dosage rates would be dramatically different and if we use the dosage rates that we recommend for rice, for high oil content commodity such as walnuts or any of these similar commodities, such as peanuts, then the efficacy of the treatment would not be in doubt, it would not be effective. So I just have to summarise what is your question and what it is that we confirm. I certainly would confirm that if the difference in sorption between varieties was of a sufficient magnitude, then there would be need to consider whether or not the treatment would be efficacious using rates which had been recommended for a variety where there was little or no sorption. Thank you.

Chairman

10.141 Dr. Ducom?

Dr. Ducom

10.142 Just a comment. Yes, I agree totally with Bob's statement. I just advise something about sorption. Levels are important for varieties but that means no insects, no LD_{50} trials to show that sorption is different. I mean we don't need any insects and any dose mortality tests to show that sorption is different and it makes very different, it's very easy, it's easier to run a sorption test than the dose mortality test. That's an important point in practice.

Chairman

10.143 OK, thank you. Have you now concluded your questions Japan?

Japan (Mr. Sanatani)

10.144 Yes, Mr. Chairman.

Chairman

10.145 Thank you. I now turn to the United States. If you have any follow-up questions to the experts on the basis of the questions presented by Japan.

United States (Mr. Hirsh)

10.146 Thank you Mr. Chairman. May we have a few minutes to consult?

Chairman

10.147 Of course.

[*break*]

Chairman

10.148 Ok. United States, are you ready to proceed?

The United States (Mr. Hirsh)

10.149 We are Mr. Chairman. Just one follow-up question for Dr. Ducom. In connection with the question regarding whether it is possible for the United States to prove the negative, that is to say that United States understands that it is not possible to prove a negative and that it's not possible to state with scientific certainty that at no time in the future will there possibly be a varietal difference that might, as a hypothetical matter, affect treatment of efficacy. But, Dr. Ducom, are you aware of any circumstances in which a difference in variety has in practice required a difference in a treatment level among the products at issue?

Dr. Ducom

10.150 I am not a [fortune teller] definition man, or something like that. I cannot answer that. That's why there is a variety problem. We don't know, you don't know. Intuitively I can imagine that there is no difference between varieties. When you see one nectarine next to another it seems the same. It seems to be obvious that they are the same, but sometimes, we cannot [prove it], it's not a proof and to be able to have proof we need some tools.

United States (Mr. Hirsh)

10.151 I understand, but let me rephrase the question. Are you aware of any circumstances in which variety has made a different, not for the purposes of establishing with scientific certainty that there will never be a difference but just simply are you aware of any situation which variety has made a difference in a treatment level and we'll take an answer from any of the experts on this.

Dr. Ducom

10.152 Not as far as I am used to study anything like that. Not in perishables. Yes for stored products like nuts, which are in fact stored products.... There are differences in varieties in walnuts because of oil contents. Maybe we can have the same for raisins, but maybe you do not agree with that, but for perishables, no. I can imagine it like Japan says, but have never seen something like that.

United States (Mr. Hirsh)

10.153 If I might ask one more follow-up question? With regard to walnuts, if in fact the oil content among varieties did not differ, would you then state that there would not be a difference among the varieties?

Dr. Ducom

10.154 Probably yes [not], but I have never done any trials on that. But I can imagine that there is no difference in the [varieties as far as methyl bromide is concerned] because the oil content is the main factor of sorption for walnuts.

United States (Mr. Hirsh)

10.155 Thank you, and if any of the, if either Mr. Taylor or Dr. Heather would like to answer the question regarding whether they're aware of any situations where differences in variety have resulted in a different treatment level for the products at issue in this case.

Mr. Taylor

10.156 No, I have no information or have seen any published data so the answer I have to give is no.

Chairman

10.157 I think that, Ok Dr. Heather?

Dr. Heather

10.158 In my experience there have been no differences of this kind. In fact it's been to the contrary. Most of my experience has been with insecticide dips with the material dimethoate and here we find that the same treatment not only goes across varieties but across commodities but I can see that this sorption problem with methyl bromide is something very special and that's why I wish to defer to my colleagues with experience as fumigation experts.

United States (Mr. Hirsh)

10.159 Thank you very much. That's our only follow-up question.

Chairman

10.160 Ok, thank you. Now I ask your patience for the Panel to have an internal consultation. So this is the same privilege as we have given to the parties.

[*break*]

Chairman

10.161 And thank you for your patience for waiting us.

United States (Mr. Hirsh)

10.162 Mr. Chairman, if I may be recognized? Before proceeding to the Panel's questions would it be possible to ask the experts whether they've had a chance to consider our final question?

Chairman

10.163 I forgot that. Any volunteers? Ok, perhaps we could have a coffee break or a lunch break and we go to that question after that but we will see because now we can anyway proceed with the questions by the Panel. During our recent break we considered whether we could delete some of our questions because they have already been covered and yes indeed that is the case but we have tried to compensate that by elaborating some new questions in addition.

10.164 So, I first note that we will not present the questions one, two and three because we consider that we have already received adequate answers to the questions which are there. So I will straightaway proceed with our question number four and I will read it: In its answer to US question eight Japan states there is a precedent in which Japan has approved importation of all varieties in a commodity, namely lemons, grapefruits and ponkan oranges are approved subject to a cold treatment against fruit flies. This is because varietal differences of these commodities are minor for reasons of their history of development by somatic mutation such as bud mutation, and they are not known to lead to a significant difference in the efficacy of a treatment. Are apples, nectarines, walnuts and cherries different in this respect? Is the Japanese position quoted above scientifically reconcilable with its position on MB treatment for apples, nectarines, walnuts and cherries? Dr. Ducom.

Dr. Ducom

10.165 Thank you. The question is difficult. There is an affirmation. I mean genetically speaking what is the difference between a mutation and crossing to get a new variety? I mean, for example, you can have small differences or big differences. The difference between peach and nectarine is a mutation. We have a big difference and though somatic mutation must lead to big differences, I cannot agree with that argument. But not scientifically speaking.

Dr. Heather

10.166 I would find it difficult to answer directly without seeing the genetic origins of each of the varieties involved but I would have thought that lemons would not have fitted the bud mutant definition but I would like to reserve that decision. It's something that I would have to research.

Chairman

10.167 OK, thank you. I now move to our question number five. In your expert opinion is there an objective or rational relationship between the varietal testing requirement imposed by Japan for MB treatment and any of the evidence submitted by the parties?

Dr. Ducom

10.168 I've a quick answer. In the absolute yes, in practice no.

Chairman

10.169 Could you repeat that?

Dr. Ducom

10.170 In absolute, maybe yes, but in practice no. I mean the arguments are not statistically good. Scientifically, they may be good, but in practice they may be too narrow. But the answer is really difficult.

Chairman

10.171 Ok, Mr. Taylor?

Mr. Taylor

10.172 I have to agree with Dr. Ducom. The answer is very difficult otherwise perhaps we would not be here. Again I think in theory there may be some differences which perhaps exist, but in practice it is difficult to show these and it seems very difficult in fact to say that at this time the differences that might make the difference between treatments efficacious and non-efficacious have not yet been reached and therefore I think at this moment in time that the evidence is not sufficiently strong although in theory it does have some possible validity. But at this stage, as Dr. Ducom has said, and in practical terms, it's very difficult to say yes there is something which is sufficiently demonstrated to show that there is a real problem which has to be addressed in terms of maybe variety-by-variety testing, and which could lead to differences in the treatment techniques that are used.

Chairman

10.173 Thank you. Do you want to add something?

Dr. Heather

10.174 More to agree with both of my colleagues. I'd say yes there is a relationship but it is an incomplete one but this is a real world and to totally complete the relationship of these and decide on how important it is, I think would probably be beyond the resources even of the United States and Japan in the time available, and I'm not sure that it would really add anything of great value to the argument.

Chairman

10.175 OK, thank you. I only want to state already now that we in the Panel also appreciate when you answer that you don't know. Then we move to our question number six. Here perhaps some words of explanation why we are asking this question. It is because the SPS agreement uses these expressions like "specifications of a product" and "modified product". Those are quotations from the SPS Agreement and now that's why we are presenting this question. The question is: From a technical or scientific point of view, first, can the development of new varieties of a product be considered as changes in the specifications of the product, and secondly, can a new variety of a product be regarded as a modified product?

Dr. Ducom

10.176 It is always difficult to answer your questions. It's about the relationship between the product and methyl bromide, you are talking about. I mean that a specification of a product means sorption model with methyl bromide. We are not talking about generally speaking, the colour we don't care about. We just want to know if the change in the new varieties has a different [reaction to] version against methyl bromide. I mean we should have tools to know that. You know, a fruit can be the same, appear in the same shape, the same as a colour and so on and may have another reaction to methyl bromide. Why not? We don't know. If we have no tools we cannot say if a new variety is a new variety of it or .... [*interrupted*]

Chairman

10.177 Excuse me. Now I think I should have explained more in detail what we are asking. Here we are not asking of methyl bromide or the efficacy, anything. This is just a biological question I would say. Whether new varieties can be regarded as that. You see, in our [SPS] agreement we have provisions that if a product for instance has already been approved then if the specification has been changed or the product has been modified then a new approval should concentrate only on those changes which have happened. So that is why we are asking this question. It is not related directly to methyl bromide or any efficacy questions but just how you could, would interpret this or could you interpret these words in our Agreement?

Dr. Ducom

10.178 That's the kind of question we are not experts to answer but I should say, yes, there are some changes in specifications, but it's just in my own opinion.

Chairman

10.179 Do you want to ask something?

Dr. Heather

10.180 Only to say that the judgment becomes a subjective one and it really depends on the breadth of the definition of the product in the first place and the size of the changes in relation to that.

Chairman

10.181 Ok, thank you. We now move to our question number seven. In Dr. Ducom's answer to Panel question three it is stated that the dose mortality tests presented by the parties are designed to give information on insect sensitivity. The search for possible causes of varietal variations cannot be determined with precision by them but only with a specific research program. Is it technically possible by such a research program to determine the degree to which variety matters for quarantine efficacy of MB treatment?

Dr. Ducom

10.182 I am sure that either the US or Japan can imagine the design for a research program on that. I mean as far as I know, never, there has never been a study on that because may be no need had appeared before. Now we are at the point where perhaps that kind of research could be carried out. I'm sure we can find something to approach [evaluate] the varietal differences.

Chairman

10.183 So your answer is yes?

Dr. Ducom

10.184 Yes.

Chairman

10.185 OK, thank you. I then move to question number eight but here we have added something, for Dr. Ducom's delight! Namely we would like Dr. Ducom to elaborate not only on the amelioration of statistical methods which invalidated the hypotheses of a statistical difference mentioned in his answer to Panel question eight, and also if you could elaborate on what you said today on the difference between biologically relevant difference and a statistically relevant difference between varieties of a product, as it relates to the studies before the Panel, because we must admit that we didn't fully understand these two notes of you.

Dr. Ducom

10.186 First of all about amelioration of statistical method, it appears with Yokoyama and Robertson presented in US Exhibit 15. It's about the re-analysis of data from the experiment on nectarines from 1987 and with probit analysis … [found that] there are very big differences between Summer Grand and other varieties of nectarine. And with the new software like Polo and new methods created by Jacqueline Robertson, they found that the difference is not significant, even if the probit lines of the LD_{50} or $_{95}$, are very, very different. With a new statistical approach we [suddenly no longer have] can have no more differences. For people who don't know statistical, it means like poor arrangements but in fact in statistics you can choose the best tool because all are relevant. … For the same experiment you have bad tools and good tools, statistical good tools, statistical bad tools, and times also helps - I mean now we have better tools than before. That's for the first point [change of tape] biological and statistical answer and significance. I mean when you have two differences between, for example, LD_{50} for Fantasia and, or, OK, two varieties of nectarine which is 10 milligram by cubic metres and the overlap, the confidence limits, is maybe 11.36 and the other one is 11.45, you say statistically it's different, but biologically speaking it's not different. But the problem is that statistically we can make the difference biologically we cannot make the difference. We can imagine that there is no difference, but we cannot prove without any further trials. That's the problem.

Chairman

10.187 We now have an additional question to whomever wants to answer it. We have discussed quite with some length already the impact of sorption. Now the Panel would like to know a little bit more about this. First, how is the sorption test conducted and how feasible would it be to test sorption values for each variety? And has this been done in any of the studies before the Panel? Dr. Ducom?

Dr. Ducom

10.188 Sorption tests may be carried out very easily, I guess, for the people who are used to make trials on perishables or stored products. I mean, the interest is that it could be made without insects

and just after the crop, the time exactly when fumigation has to take place. That means, for example, for the apples – the paper we have not time to read exactly from Kawakami-san – when you carry out experiments on apples some are cropped maybe in August or September, others in October. We put all them in the [cold chamber] fridge, in the, ok in the fridge, and the reaction may be different. If you do trials at the August for the August harvest, [or wait until] October and November, each one in his ripeness time or in the time where fumigation has to take place, maybe two months later, for each one, but not three months for one [may lead to different results]. And with enough fruit I guess we could have some good answers on sorption and maybe also try to know what the factors which make a high sorption are; maybe it's due to proteins, I don't know, of the nature of the skin, I don't know. That's the research program could that could be allowed to find the factors which can influence the sorption.

Chairman

10.189 Ok, and the last part of our question was has this been done in any of studies before the Panel?

Dr. Ducom

10.190 No I don't think so, not by itself. But maybe in Kawakami-san ['s paper] I don't know.

Chairman

10.191 Ok, Mr. Taylor?

Mr. Taylor

10.192 Thank you Mr. Chairman. One or two comments. You mention how a sorption test was carried out. Well by exposing the commodity in question to a known concentration and the concentration of the methyl bromide is measured very accurately over a period of time to see to what extent the gas concentration falls. Another way of course, an additional way, is to measure to see if there are reaction products and to see whether there are bromide residues within a commodity treated. So there are several ways to actually test to what degree a particular commodity will absorb the gas. There are quite well known methods by which accurate levels of sorption can be tested. I mean, we have to appreciate that some of the sorption is permanent where the actual gas reacts with a commodity, a sort of chemical reaction which leads to the bromide residues. On the other hand, some of the sorption is reversible and the gas will be eventually released again from the product. But certainly techniques such as these have been conducted over many years so there should be no problem in actually conducting these trials. As Dr. Ducom said, to determine the sorption of fumigant would not involve insects in these test, just the gas and the commodity, and from these tests to see to what extent there is a difference between varieties as between commodities, and to determine just to what extent this is an important factor and whether the level of sorption is very high or very little difference exists between the two. Thank you.

Chairman

10.193 Thank you very much so, and also, to Mr. Taylor the last part of our question, has this been done in any of the studies before the Panel?

Mr. Taylor

10.194 I don't recall having seen this having been done, just on a variety by variety basis in which we could actually say this variety absorbs this much and another variety absorbs a different value or the same value. I don't recall having seen this being done specifically on a sorption test basis for different varieties.

Chairman

10.195 Ok, but do I understand correctly then your answer is that there exist methods, established methods to do such tests and that the results are rather reliable?

Mr. Taylor

10.196 Yes, I think that's correct, yes. This work could certainly be conducted I'm sure either in Japan or the US and their research programs could conduct this technique if they were minded to do so.

Chairman

10.197 OK. Thank you very much. Now I turn to our question number nine which is rather lengthy. We have been made aware of a so-called CxT value and now we try to test whether we have understood anything. And so the question reads as follows: It is the Panel's understanding that quarantine efficacy for a certain pest at a certain stage can be obtained by determining the concentration of the fumigation in the chamber and the time the pest is exposed to it by determining a fixed CxT value, that is to say that if a codling moth is fumigated for a certain amount of time at a certain concentration the test will die. If the fumigation process can be monitored so that the concentration of the gas is maintained at the required level during the required period time varietal differences, such as sorption, as well as any other factors would not affect quarantine efficacy and probit 9 mortality would be ensured. Is this understanding correct? Would such process be technically and economically feasible?

Dr. Ducom

10.198 Yes and yes. Ok.

Chairman

10.199 Yes, I would also ask the other experts. Mr. Taylor?

Mr. Taylor

10.200 Thank you, Chairman. Yes I have to agree with Dr. Ducom. In many cases of course of fumigation of other situations, such as the treatment of flour mills, there is regular monitoring, as we call it, of the fumigant level. It may be necessary to increase the fumigant concentration by adding more fumigant for example, because of some factor, maybe leakage, etc., so I mean this is certainly something that can be done, and is done, and if this type of technology was employed whereby the concentration is monitored regularly and it is found to reach the required level, in other words, you will end up with the CxT product value that you have said is necessary, then this will be an effective treatment and I mean so this is technically feasible. I will reserve judgment on the economic feasibility to those that know more about the topic than myself. But probably it is. I would think it to be probably technically and economically feasible.

Chairman

10.201 Thank you. Dr. Heather?

Dr. Heather

10.202 To the first part of the question, yes, I believe so. To the second part, I'd have to defer to my colleagues who know more, who have more practical experience of fumigation, but I am aware that grain in my home State is controlled by the use of a CxT approach rather than an outright dose.

Chairman

10.203 Ok, thank you. That was most helpful so I conclude that more or less the Panel has understood what you have said. Ok, then I have one last question at this stage and this is of another character and it reads as follows: Does the risk assessment conducted by Japan for preventing the introduction of codling moth provide scientific basis to ban the import of the products in dispute? I repeat, does the risk assessment conducted by Japan for preventing the introduction of codling moth provide scientific basis to ban the import of the products in dispute?

Dr. Heather

10.204 I would agree that codling moth is of sufficient importance as a pest and the risk to Japan, which does not have this insect, is major and, yes, on that basis they are entirely [justified]. Their conclusion that it's a pest which requires an initial ban on importations [I would agree] to be quite appropriate.

Chairman

10.205 Ok, Dr. Ducom and Mr. Taylor, do you want to add?

Dr. Ducom

10.206 I am not an expert on pest risk analysis and therefore I cannot answer.

Chairman

10.207 Ok. Mr. Taylor?

Mr. Taylor

10.208 I would agree with Dr. Heather that certainly it does seem as if there is sufficient risk from the pest to ensure that measures are taken to keep it out but I would not like to go so far as to say that it's a ban on the import of the commodities. I wouldn't like it to be recorded that I would say that. I would certainly say that the risk analysis seems to be sufficient to make sure that the pest is kept out but I would repeat that I would not like it to be taken down in perpetuity that I had said that the products therefore ought not to be allowed in. But I would say that obviously the Japanese government obviously wants to make sure that the measures that they take to keep the pest out are as good as can be possibly effected.

Chairman

10.209 Ok. Dr. Heather?

Dr. Heather

10.210 If I could add to my comment. The initial reaction is prohibition. This is a normal quarantine regulatory approach and then there is conditional admission which usually depends on a treatment. I think conditional was the word Japan uses, it's quite appropriate. So this was my intent to say that initially prohibition and then some measures are required.

Chairman

10.211 Ok. Thank you very much. That was most helpful.

10.212 Now I want to inform you that it is the intention of the Panel to still ask some, I would say, short, and I hope, simple questions which are of a confirmatory nature. That means that we have tried to understand the scientific and technical background for this dispute and now we want to get confirmation or not confirmation by the experts, but before I present those, I would say, confirmatory questions, we need some time. So I announce a coffee break of, say, 15 minutes and I hope that the experts could use those 15 minutes in preparing their answer to the question by United States which is still outstanding. Ok, could we agree so? So, 15 minutes.

[*break*]

Chairman

10.213 ... for the delegations, United States and Japan, whether you still have some additional questions you want to present to the experts? This is the last, ok, last opportunity for that. And after that I will give the floor to the experts one by one for any concluding remarks they want to make. After that I will announce lunch break. After the luncheon we will reconvene again and then, as I announced at the beginning of the meeting, the Panel has the intention to present some, I would say, confirmatory questions to the experts, whether we have understood some of the scientific and technical facts in a correct way. Can we follow this procedure? Ok.

10.214 Ok, so first we take the United States' question. Perhaps you could repeat the question because at least I have not, I cannot quite recollect what it was!

United States (Mr. Hirsh)

10.215 Give me one more chance at it. We refer you to the recent study by Japan included in Japan's Exhibit 36. With respect to apples the author states on the final page of the study, quote, the factors affecting the different CxT products were not specified in the test. For example, it appears that there were no controls for length of time in storage maturety of fruit and fruit size. In addition, we reviewed the CxT product data in Table 3 and Table 5, in particular the data for the Mutsu and Fuji in each table which indicates that the two are not statistically different in Table 5 but they are statistically different in Table 3. In light of the uncontrolled factors in this study and the inconsistent data, is Japan's conclusion warranted that the differences in CxT values noted in Table 5 were, quote, obviously attributed to varietal differences?

Chairman

10.216 Ok, now I give the floor to the experts. Dr. Heather?

Dr. Heather

10.217 It was a little difficult to decide who should answer this. Taking the statistical differences first we've noted that the method used is a Tukey's multiple range test which is a statistical test I believe appropriate to comparing results of trials rather than treatments within trials and statistics are better explained by a biometrician but I would not be surprised to see a difference proven or shown, not proven, shown, in one case and absent in another. This is just one of those aberrations that is possible when you analyze data so that's part of it.

10.218 The second part, if I'm right, was where the author obviously attributed the differences to varietal characteristics. We are of the opinion that it is not possible to attribute them solely to varietal characteristics on the evidence that's present in this paper. It may well be true but it requires, it would

require… to reach that firm conclusion would require more information. The age of the fruit which was involved, it would be normal to treat fruit which was freshly harvested but then again it would also be possible to have involved fruit which had been harvested for some time and which was subsequently determined to export it so that it is not an unreasonable, it's not unreasonable to store fruit for a while before fumigating it but it would have been nice to have a small scale test to show the difference between freshly harvested and stored fruit so it's more the scope of the experiment. Do I have one more other question to answer?

United States (Mr. Hirsh)

10.219 I think that was it.

Dr. Heather

10.220 Thank you very much. I would like to congratulate the authors of this paper. Really, it's a very comprehensive piece of work and our only, the only exception we take to it is that some of the conclusions have gone perhaps a little further than we believe the data supported.

United States (Mr. Hirsh)

10.221 Thank you very much.

Chairman

10.222 Thank you. Taking into account the time I had to change the procedure I proposed. So before the lunch-break I will present one additional question by the Panel to the experts. And after that we will break and that will give the parties also the opportunity to consider any additional questions you wanted to present and also gives opportunity to the experts to consider what kind of concluding remarks you want to present.

10.223 Ok. So I will now present one question by the Panel and after that we have heard the reply we will break for lunch. This question here again I think I need some, I need to give some explanation to the experts. You know that the scope of this dispute does not cover only the four products, apples, cherries, nectarines and walnuts, but also apricots, plums, pears and quince, even if we have not received any material from either party concerning those four other products. So now the Panel wants to ask you the following question: To the best of your knowledge is what you have stated about varietal differences concerning apples, cherries, nectarines and walnuts, would that also be valid for apricots, plums, pears and quince?

Dr. Heather

10.224 Yes.

Chairman

10.225 All? All answered yes. Ok, that was clear and short. And now we can break for lunch and we will continue at three o'clock, thank you.

[*lunch break*]

Chairman

10.226 .... outlined before the lunch-break the procedures would now be that I first give the floor to the United States if they have any additional questions still to the experts, then to Japan for the same purpose, then the Panel still has one small question to present to the experts. After that I will give the floor to the experts in alphabetical order for any concluding remarks, and after as a grand finale I will present some so-called confirmatory questions to the experts from the Panel. Ok. So, I now give the floor to the United States.

United States (Mr. Hirsh)

10.227 Thank you Mr. Chairman. We have no additional questions.

Chairman

10.228 Thank you. Japan?

Japan (Mr. Yokota)

10.229 Thank you Mr. Chairman. We have three additional questions related, all of them related to questions from Panel number nine, so I'll pass the floor to Mr. Sanatani to ...

Chairman

10.230 Ok. You're welcome. Could you take them one by one?

Japan (Mr. Sanatani)

10.231 Allow me to speak in Japanese. This is our follow-up questions, or rather confirmation to the additional question number nine from the Panel. There are three points.

10.232 The first point: Regarding the method described in the point nine, or question nine, when the pest is directly exposed to the fumigant, we understand that model dosage may be constant. Assuming there is a difference of sorption amongst the varieties in order to maintain a certain CxT value and therefore to kill the codling moth we would probably need to change the dosage or the duration of the time of the exposure depending on the varieties. And this is our understanding but was this the understanding on the part of the experts when they answered or commented on this point?

Dr. Heather

10.233 Yes, it's my understanding that either dose or time could be varied but in my reading on this topic and my experience, my contacts with colleagues who have worked in detail on it, I understand it's most unwise to work towards the end of the spectrum on either time or dose.

Mr. Taylor

10.234 Yes, I agree certainly with Dr. Heather's comments. I would have thought that there might be such a situation, if I could just mention a rather similar situation. In some countries cut flowers are fumigated with methyl bromide and the dosage is metered in and I think there are situations where the time would be fixed, but it may also be possible to monitor the concentration and a small amount of gas is injected automatically, if necessary, in order to keep the concentration at the level required. And I also mentioned earlier that this is certainly the sort of situation existing in flour mills, so as to maintain the concentration that has been predetermined while keeping a fixed time. This was the way I assumed that fumigation would probably be done but of course the time or the concentration could be the variable factor. It would seem to me that fixing the time would be better, particularly if it's a

perishable commodity where time is relatively important and therefore, if possible, to have the concentration as a variable and, as I've said, situations exist where automatic injection can take place to maintain the concentration which has been calculated to be necessary.

Chairman

10.235 Dr. Ducom?

Mr. Ducom

10.236 I want to just add something. It may be not necessary to add some methyl bromide or to increase the time. If by habit we know exactly for that variety or that commodity and that load, or that packaging and so, we can maybe have the same kind of things we have now, I mean dosage at the departure, but this dosage may be one time 48, for example, and one time - because it's another variety or another boxes - it's 52 and so on without any change after but with checking CxT. Just what I mean, it's not necessarily obliged to add some methyl bromide or time. We can adjust if you know exactly the product and where we are working.

Chairman

10.237 Ok, thank you. The next question from Japan?

Japan (interpreted Mr. Sanatani)

10.238 The second question relates to the method described in question number nine. Is this relating to the laboratory level or is this also including the commercial scale level or it refers to both situations?

Dr. Heather

10.239 My expectation is that it would refer to the commercial operation, the operational situation rather than laboratory although it may well be necessary to look at it first at the laboratory level, but it would be an operational procedure.

Chairman

10.240 I understand that the question is does there exist commercial applications already now or only on the laboratory level?

Dr. Heather

10.241 My knowledge is only with grain where I know the grain bulks are being fumigated by monitoring the CxT product but I don't know of any fruit but that does not mean that that's not being done because methyl bromide is not widely used for fruit in my country.

Chairman

10.242 Ducom?

Dr. Ducom

10.243 In fact, it's necessary to have a confirmatory test with CxT for one variety, exactly like with insects. But for all other varieties at laboratory but maybe not six or seven or 14 apples, maybe much more, but at the laboratory level could be done on all other varieties.

Chairman

10.244 Thank you. Now I turn back to Japan.

Japan (interpreted Mr. Sanatani)

10.245 What we are discussing here, if including the commercial scale level, then various conditions are different such as the air tightness or methyl bromide dispersion speed and homogeneity. All these conditions may differ between the laboratory vis-à-vis the commercial scale level. What's your comment on these points?

Mr. Taylor

10.246 Yes, thank you for your question. I agree that they're may well be a number of variables, certainly at the commercial level. Temperature may be a variable so it is something we should certainly calculate into our design of dosing and I think one of the reasons why it might be necessary to have some sort of monitoring coupled to an injection system is that, on a commercial scale, in order to achieve the predetermined CxT product we would need to be able to take account of these differences and, as I say, I know certainly in flour mills there are systems where automatic monitoring and automatic dosing can take place. It would be possible to programme into the system such a design that would take account of these differences such as you quite rightly mention, for example leakage, which could account for losses which may vary from time to time, depending on the degree of sealing attained in a chamber. One would hope that these losses would not be too great. But certainly I think at the level of quarantine efficacy we might certainly need, if we were working on CxT values, to be able to take account of these differences and an automatic system I hope would take care of these variables. Thank you.

Chairman

10.247 Thank you Mr. Taylor. Any other comments to this? Dr. Ducom?

Dr. Ducom

10.248 Just one comment. Temperature is normally given. You have to work at a given temperature but for gas-tightness of the chamber we can check before. The Japanese know that and USA too. And for homogeneity we know that we can do that with fans adapted to the size of the chamber. We can do that.

Chairman

10.249 Thank you, Dr. Ducom. Japan you have still the floor.

Japan (interpreted Mr. Sanatani)

10.250 This would be our last question. If the CxT value is one of the useful indicator of the efficacy of fumigation I think Japan agrees to this in the argument so far. However, when it comes to the mode of action of methyl bromide it is not completely clarified yet, so besides the atmospheric concentration of the fumigants which is described in the CxT value, there are other factors that would affect the efficacy such as the structure of the surface and the contents. There are many unknown factors. So we wonder if the CxT value alone could really guarantee the efficacy of the pest control. This may attach upon very much of the expert matters so I would like to call on our expert to expand on this.

Japan (interpreted Mr. Kawakami)

10.251 In case of the grain I understand the fumigation time duration is very long, or relatively long, so that would take care of most of the problems and that's our understanding. But in case of fruits we have to do the fumigation in a relatively short period of time and so that could produce some problems and with regards to the pest insects inside of the fruits, besides the sorption we have to look at the penetration factor as well. As mentioned earlier the surface structure and mode of action, how they would interact or how those pests residing within inside of the fruit meat, how that and the methyl bromide interact, so I would like the experts to share with us your knowledge on these matters.

Chairman

10.252 Thank you. Dr. Ducom?

Dr. Ducom

10.253 I cannot understand this mode of action problem. I don't know of any data on the problem created by something you call mode of penetration. When we are working on CxT value, we are working for efficacy. For example if we work the fifth instar larvae of codling moths, we can run that with just one dose at the beginning or with the CxT value, and then we can do a confirmatory test with that. It doesn't matter if the insect is inside and if the CxT inside the apple is different than the CxT outside, the correlation between both is always the same. It's the same, for example, for wood to kill an insect inside the gallery in the wood. It's always about, for example, for methyl bromide like 20°, it's 200 [grams per cubit meter] or something like that, but the CxT above, the ambient CxT must be something like 1,000 to kill at 200 inside the gallery. It's the same for apples. I mean nevertheless it doesn't matter if the insect is in the apple or outside, the CxT in the confirmatory tests will take take into account. And the problem of surface in context I cannot understand. I cannot understand the question. It was a question I would like to have asked before. I cannot understand the arguments and I don't see any scientific data on that.

Chairman

10.254 Any other experts want to expand to this, or not? Ok, if that concludes the questions from the Japanese delegation I now turn to the United States delegation. Do you have any follow-up questions to this?

United States (Mr. Hirsh)

10.255 We've no follow-up questions.

Chairman

10.256 Thank you. Then I will take up one small question which the Panel still wants to present to the experts and it is simply does anything in the apples study submitted by Japan, which was discussed earlier during this day, change any of your earlier opinions as to the relevance of varietal differences for quarantine efficacy? Dr. Heather?

Dr. Heather

10.257 I don't think there is anything in the apple study which impinges on this. Apples are unique in that they have a combined treatment of cold and of methyl bromide and both of these are quite efficacious in their own way. Perhaps I should say at this stage there was a question also from Japan as to why I believe that apples would not differ very much amongst themselves varietally. The reason for this is that cold treatment as a contributing treatment to the codling moth control does not have a sorption problem so there should not be the same degree of variation between varieties of apples

because of this cold treatment factor that you would find in a treatment which relied only on methyl bromide.

Chairman

10.258 Thank you very much. That was very useful for the Panel also. Dr. Ducom?

Dr. Ducom

10.259 Just one comment. This study was very interesting but the problem is that it was made on apples, which were not at the same stage of storage because some were one month in storage and others had three month's storage – so the variety is not the only factor which can change the value we can read. So in practice that means that varieties may be a factor but maybe not very important and maybe some other factors influence that data. The problem of all these studies is that they are just descriptive studies. We take some apples, or peaches, or nectarines, and we look at the concentration but the reason why it differs, we don't know. There is no fundamental work on that and we can just say this works, or it does not work and so on.

Chairman

10.260 Ok, thank you. I now think that we can move to the concluding remarks by the experts and as I promised I will give the floor alphabetical order, that means first to Dr. Ducom.

Dr. Ducom

10.261 Thank you Mr. Chairman. The work was very intensive, mainly for me because it's in English. But I don't know if our work will be taken into account by both parties because the fact that variety can or cannot be an important factor could be clarified just by studies and not only by talking between people of good civility or something. And that's why it was important to talk about it, but my feeling is that some study are to be made by US, I guess, or people who want to [export to] go in Japan on each variety, something easy to do, and maybe Japan has to accept some rules. And the last point, I am very, my concern is for example the last question they [Japan] ask for, if structure and context makes a difference insects mode of action, that is new and for me it makes no sense and is a problem for me.

Chairman

10.262 Thank you Dr. Ducom. Dr. Heather please?

Dr. Heather

10.263 Thank you Mr. Chairman. We are very fortunate, Mr. Taylor and myself, that Dr. Ducom's name starts with a "D" so he has set the scene for us very well. The only comment that I would like to add to that is one that methyl bromide is what I would like to call a very robust treatment. It has the capacity, the reserve capacity, to overcome many small variations which will occur in operation. Some of these may be fruit variations, others will be operational processes. This is why it has been such a successful treatment over the years so in terms of the confidence which countries have in using methyl bromide, it is a very good treatment. I think this needs to be taken into account and we should not be too distracted, I think is the word I should use, about apparent differences in measurement of some of the parameters that were involved because it is the overall efficacy that works and this has been, I think, very well demonstrated in the large scale trials under discussion here and also on the many other commodities that both Japan and the United States have worked on over the years. Thank you.

Chairman

10.264 Thank you Dr. Heather. Mr. Taylor?

Mr. Taylor

10.265 Perhaps not for the record or for the minutes or whatever we're saying of this meeting, I find it interesting that here I am talking about effectiveness of methyl bromide, etc. when in the last three countries I've been to in the last few weeks I've been talking about nothing but alternatives to methyl bromide and trying to find alternatives which will allow us to phase out methyl bromide quickly and easily, but this of course is not proving an easy task, and for the quarantine and pre-shipment use this is going to be a very difficult task.

10.266 But coming back more to the situation at hand I think one of the things that has come out from this meeting which I have found extremely interesting is that we do need more information before we can say categorically that variety in fruit is a major factor affecting the efficacy of treatment. I think we're all agreed that sorption is one of the major factors involved and, I think that, as Dr. Ducom said earlier, one of the things that should be done is the testing of samples just with methyl bromide [no insects to be involved] to see if we can determine the extent to which these varieties do absorb methyl bromide. Also it would be nice to try and relate any differences we find to chemical or physical characteristics more definitely.

10.267 And the other thing that I would like to say in conclusion that I found one of the most interesting parts of the meeting came in question nine when the Panel asked us if, in that statement, whether their understanding of what we were talking about was in fact the case. I think it is clear we are saying here that if you have the right amount of gas for the right amount of time it will kill the pest because basically that's what fumigation's all about. It doesn't matter which gas you're using. If you have the lethal concentration for the required time this will kill the pest and that's really what we want to try and achieve, so this long and somewhat complicated discussion about CxT products is in fact very relevant because if we do achieve the desired CxT product in a commercial treatment we should end up with an efficacious treatment which should satisfy the requirements for quarantine. I would conclude there Mr. Chairman. Thank you.

Chairman

10.268 Thank you very much Mr. Taylor. I now proceed to the final set of questions by the Panel. I would call this a confirmatory testing of the understanding of the Panel. However this is not a large scale confirmatory test but just a small scale confirmatory test, and because these questions are all phrased, yes, and I ask that this to be distributed to the experts so that you can look on them and also to the parties, because these are phrased in a way that we ask for your confirmation of our understanding, of course we would be most happy if you could answer just "yes" but if our understanding is not correct then of course you have to elaborate in which respect our understanding has not been correct. And because these five questions are inter-linked we decided to distribute them in writing for you because otherwise if we had presented them one by one the questions could have been misunderstood. So I hope you take these five questions in combination, as linked together. And I now give you some time to consider this. And you may of course discuss with each other if you can reach a consensus reply.

[*break*]

Chairman

10.269 Ok, and I will read the questions one by one and ask your responses. And as to the parties you will have the opportunity to comment on these questions and the answers tomorrow. Ok, first, considering your responses to the Panel's questions it is the Panel's understanding that there are differences which may be relevant for quarantine purposes between varieties of the products in dispute, is this understanding correct? Dr. Heather?

Dr. Heather

10.270 My understanding, my belief is not that there are differences but there may be differences. I don't believe that the occurrence of the differences has been proven and that they may be relevant for quarantine purposes. So there are two sets of uncertainties in my mind in this statement. There's no certainty that even if differences exist that they are relevant for quarantine purposes between varieties of the products in dispute.

Chairman

10.271 Thank you. Dr. Ducom?

Dr. Ducom

10.272 Maybe, yes.

Chairman

10.273 Ok, Mr. Taylor?

Mr. Taylor

[*Mr. Taylor gestured his confirmation of the other experts' answers*]

Chairman

10.274 Ok, thank you. The second question is: It is also the Panel's understanding that the question whether these differences are significant for quarantine purposes cannot be determined on the basis of the evidence before the Panel. Do you agree?

Mr. Taylor

10.275 Yes.

Chairman

10.276 Dr. Heather?

Dr. Heather

10.277 Essentially yes, with the proviso of those double uncertainties that I referred to in the first one.

Chairman

10.278 Ok, Dr. Ducom?

Dr. Ducom

10.279 Yes.

Chairman

10.280 Yes? Ok. Then the third question: To the extent that differences between varieties are significant for quarantine purposes, is the Panel's understanding correct that they are mainly or even exclusively related to different levels of sorption of the fruit? Dr. Heather?

Dr. Heather

10.281 Could I defer to the fumigation specialist on this one please?

Chairman

10.282 Ok. Of course. No need that everyone answers to every question, only within the limit of your competence of course. Dr. Ducom?

Dr. Ducom

10.283 Yes. Just two points. The first, we don't need any insects and the second one, we can, we must, we have to do that, at the time when the fumigation has to be made.

Chairman

10.284 Ok, thank you. Mr. Taylor?

Mr. Taylor

10.285 I agree.

Chairman

10.286 You agree. Thank you.

10.287 Now, the most lengthy question no. 4. In respect of the products at issue it is the Panel's understanding that the degree of varietal differences which have an effect on quarantine efficacy may vary between products. For instance, we have stated that methyl bromide is absorbed particularly by oils and fats and that the oil content of walnuts which is a varietal factor has a significant effect over sorption of methyl bromide. Hence it is the Panel's understanding that in the specific case of walnuts varietal differences in respect of oil content may affect quarantine treatment to a greater extent than varietal differences for the other products in dispute. Is this understanding correct? Dr. Heather?

Dr. Heather

10.288 Again on the effect of the oils I would like to defer to Mr. Taylor and Dr. Ducom. But could I please raise the point that walnuts are unique amongst all the commodities which we have been considering at this meeting. They have this oil problem which to my knowledge is not shared by any of the fruits and so they are a commodity which needs to be differentiated against, rather than the varietal problem.

Chairman

10.289 Thank you. Mr. Taylor?

Mr. Taylor

10.290 Thank you Mr. Chairman. Obviously the points that Dr. Heather just mentioned are very relevant. And the distinct differences between the fruit and the walnuts, so in my view I would have thought that the Panel's understanding of this situation is correct.

Chairman

10.291 Thank you. Dr. Ducom, do you want to add?

Dr. Ducom

10.292 Just to add that we have at least for walnuts the reason why the sorption exists and if we had something like that for apples and nectarines we should be in a good way.

Chairman

10.293 Ok, thank you Dr. Ducom. And now the last question, it is also the Panel's understanding that an added buffer of 10-20% will with a high probability cover any varietal differences of apples, cherries and nectarines but that this may not be the case for walnuts. Is this understanding correct? Dr. Heather?

Dr. Heather

10.294 Again, even for walnuts, the work was not done on a single variety, it was done on a number of varieties so it's not just the 10-20%, it's also the fact that you had a spread of samples or representation of walnuts as a commodity. Apart from that, yes.

Chairman

10.295 Ok. Dr. Ducom?

Dr. Ducom

10.296 Why not 30, 40, 5% like I said before? I mean,..

Chairman

10.297 ... No, 10-20 because that is what.....

Dr. Ducom

10.298 Ok, but why not 10-20, why not? But the question, the answer is that when question is answered the question of 10-20 will be answered too? I mean we don't know if 10-20% [is high enough], we can imagine it's large enough but there is no scientific proof of that. The only proof could be to have some sorption data on other varieties to say, oh it's must too high and so on. In practice 10-20 may work, but it may not work. It seems to work because all the data of the confirmatory tests made by the USA work but we don't know for the rest.

Mr. Taylor

10.299 I have nothing to add to that.

Chairman

10.300 Thank you, Mr. Taylor. That concludes our session for today. I will once more thank very much the three experts. Your contribution has been most helpful. I think that the Panel now can work on a much more solid basis as to the scientific and technical facts which we have to take into account. Of course now we have to go further and take into account the legal aspects. And that's our job, but anyway, it is impossible to tackle the legal aspects without having a correct understanding of the underlying scientific and technical issues. So once more very much thanks for your excellent contribution, and I also want to thank the parties for their questions which have also facilitated the understanding of the Panel of the relevant issues in this case and I invite the parties to the second substantive meeting tomorrow morning at 10 o'clock and this will be in Room F. So Room F tomorrow morning at 10 o'clock. Ok, thank you very much and the meeting is adjourned.