WORLD TRADE ORGANIZATION

WT/DS18/R
12 June 1998

(98-2258)

Original: English

AUSTRALIA - MEASURES AFFECTING IMPORTATION OF SALMON

REPORT OF THE PANEL

The report of the Panel on Australia - Measures Affecting Importation of Salmon - is being circulated to all Members, pursuant to the DSU. The report is being circulated as an unrestricted document from 12 June 1998 pursuant to the Procedures for the Circulation and Derestriction of WTO Documents (WT/L/160/Rev.1). Members are reminded that in accordance with the DSU only parties to the dispute may appeal a panel report, an appeal shall be limited to issues of law covered in the panel report and legal interpretations developed by the panel, and that there shall be no *ex parte* communications with the panel or Appellate Body concerning matters under consideration by the panel or Appellate Body.

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

TABLE OF CONTENTS

I. INTRODUCTION

1.1 On 5 October 1995, Canada requested consultations with Australia in accordance with Article 4.4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU"), pursuant to Article XXIII:1 of the General Agreement on Tariffs and Trade 1994 ("GATT 1994") and Article 11.1 of the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"), regarding the Government of Australia's prohibition on the importation of untreated fresh, chilled or frozen salmon from Canada under Quarantine Proclamation No. 86A, dated 19 February 1975. In the request for consultations, the Government of Canada expressed the view that the application of the import prohibition in question was inconsistent with the obligations of the Government of Australia under GATT 1994 and the SPS Agreement. The provisions of these Agreements with which the import prohibition was inconsistent included, but were not limited to: (i) Articles XI and XIII of GATT 1994; and (ii) Articles 2 and 5 of the SPS Agreement. The import prohibition nullified or impaired benefits accruing to Canada under the Marrakesh Agreement Establishing the World Trade Organization ("WTO Agreement").[1]

1.2 Australia accepted Canada's request and consultations were held on 23 and 24 November 1995, in Geneva, with a view to reaching a satisfactory resolution of the matter. These consultations failed to settle the dispute. Following the conclusion of the "Australian Salmon Import Risk Analysis", on 20 December 1996 the Government of Australia announced that it would maintain the measure in force.[2] Canada did not request further consultations.

1.3 On 7 March 1997, pursuant to Article XXIII of GATT 1994, Article 11 of the SPS Agreement, and Articles 4 and 6 of the DSU, Canada requested that the Dispute Settlement Body ("DSB") establish a panel with standard terms of reference. Canada requested that the panel consider and find that the Australian measure was inconsistent with (i) the SPS Agreement, and in particular Articles 2, 3 and 5 thereof; (ii) GATT 1994, and in particular Articles XI and XIII thereof; and (iii) that the application of the Australian measures nullified or impaired benefits accruing to Canada pursuant to the WTO Agreement.

1.4 On 10 April 1997, the DSB established a panel pursuant to the request of Canada, in accordance with Article 6 of the DSU.[3] The parties agreed that the panel should have standard terms of reference:

> "To examine, in the light of the relevant provisions of the covered agreements cited by Canada in document WT/DS18/2, the matter referred to the DSB by Canada 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 The European Communities, India, Norway and the United States reserved their right to participate in the Panel proceedings as third parties.

1.6 On 28 May 1997, the Panel was constituted with the following composition:

Chairman: Mr. Michael Cartland

Panelists: Mr. Kari Bergholm
Ms. Claudia Orozco

[1] WT/DS18/1.
[2] WT/DS18/2.
[3] WT/DS18/3/Rev.1.

1.7 The Panel met with the parties on 9 and 10 September 1997. It met with third parties on 10 September 1997. The Panel consulted scientific and technical experts and met with them on 4 February 1998. The Panel held a second meeting with the parties on 5-6 February 1998.

1.8 On 24 November 1997, the Chairman of the Panel informed the DSB that the Panel would not be able to issue its report within six months. The reasons for that delay were stated in document WT/DS18/4.

1.9 The Panel issued its interim report on 26 March 1998. At the request of Australia, an interim review meeting was held on 21 April 1998. The final report was provided to the parties on 5 May 1998.

II. FACTUAL ASPECTS

1. General

Salmon

2.1 The product subject to the dispute is fresh, chilled and frozen salmon product destined for human consumption that has not been subject to heat treatment according to certain prescribed durations and temperatures, prior to importation into Australia (paragraph). Fresh, chilled and frozen salmon comes within Codes 0302 to 0304 of the Harmonized System of tariff classification. Hereafter this product is referred to as "uncooked salmon" or "fresh, chilled or frozen salmon".[4] The family Salmonidae includes a number of species groups, such as salmon, trout, charr, grayling and whitefish. Salmonidae is the scientific name and "salmonid" is a common name for this family.

2.2 In Canada, there are five sources of uncooked salmon for export[5]:

(i) adult, wild, ocean-caught Pacific salmon;
(ii) adult, wild, freshwater-caught Pacific salmon;
(iii) adult, Pacific salmon cultured in seawater on the Pacific coast;
(iv) adult, Atlantic salmon cultured in seawater on the Pacific coast; and
(v) adult, Atlantic salmon cultured in seawater on the Atlantic coast.

The Canadian salmon farming industry is mainly located in the provinces of New Brunswick and British Columbia.

2.3 Canadian exports of salmon have grown from 30,653 tons in 1969 to 66,234 tons in 1996. The proportion of fresh and frozen salmon during this period has increased significantly: exports of fresh and frozen salmon were 14,683 tons in 1969 (48 per cent of total exports) and 50,838 tons in 1996 (77 per cent).

2.4 "Canadian salmon" is all salmon landed by Canadian vessels. All such salmon is harvested in Canadian waters as no Canadian vessels harvest salmon on the high seas or in foreign waters. This may include salmon that have spawned in the United States and that are intercepted by Canadian fishermen as they pass through Canadian waters on their return migration to the United States.

[4] The importation of live salmonids is not at issue.
[5] Only adult salmon are harvested for export.

TABLE 1

Canadian Exports of Uncooked Salmon

Sources of uncooked salmon for export:	Per cent of total exports (Average, 1990-1997)
(i) adult, wild, ocean-caught Pacific salmon	58%
(ii) adult, wild, freshwater-caught Pacific salmon	3%
(iii) adult, Pacific salmon cultured in seawater on the Pacific coast	12%
(iv) adult, Atlantic salmon cultured in seawater on the Pacific coast	15%
(v) adult, Atlantic salmon cultured in seawater on the Atlantic coast	12%

2.5 The following are considered to be *Pacific salmon* species:

(i) pink salmon;
(ii) chum salmon;
(iii) coho salmon;
(iv) sockeye salmon; and
(v) chinook or king salmon.

2.6 Commercial salmon production in Australia is based on the Atlantic salmon. Atlantic salmon was first imported to Australia in 1864 and last imported live for the establishment of domestic populations in the early 1960s. Until the 1960s, the farming of salmonids was predominantly conducted by government bodies for the purpose of stocking recreational fisheries.

2.7 There are five introduced *salmonid species* in Australia[6]:

(i) rainbow trout;
(ii) chinook (quinnat) salmon;
(iii) brown trout;
(iv) Atlantic salmon; and
(v) brook trout.

In addition, native salmoniforms, or galaxids, are found in south eastern Australia (principally in the States of New South Wales, Victoria and Tasmania) and the south west of the State of Western Australia.

2.8 The first commercial production of Atlantic salmon in Australia took place in Tasmania in 1986-87. Salmonid production in Australia operates at the edge of the climatic range for salmonid survival, and for this reason commercial salmonid aquaculture operations in Australia are concentrated in Tasmania and, to a lesser extent, in the alpine and sub alpine regions of north east Victoria and south east New South Wales. Tasmania continues to supply the bulk of Australian

[6] Australian Salmon Import Risk Analysis, Final Report, December 1996, p.19.

commercial production. Sea-cage farming of Atlantic salmon and rainbow trout is a major part of the Tasmanian aquaculture industry.[7] Atlantic salmon is produced in Victoria and South Australia.[8]

2.9 Production grew from about 20 tons in 1986-87 to around 6,192 tons in 1994-95, with further growth anticipated.[9] Output for 1995-96 was valued at $A 63 million. Australia exports about 40 per cent of its production volume, mainly to Japan. Of the remaining domestic market share, about 60 per cent is sold fresh and one third is smoked. Consumption of Atlantic salmon has increased significantly in Australia during the 1990s. Aside from the salmon industry, salmonids are used in recreational fisheries in Australia.

2.10 The major producers of farmed Atlantic salmon in the world are Norway, Chile and Scotland, jointly accounting for 80 per cent of world supply of Atlantic salmon in the early 1990s.[10]

Diseases of salmon

2.11 In the dispute at issue, Australia has identified 24 disease agents of concern associated with the importation of Canadian salmon. The identified disease agents are listed in Table 3. The Australian Salmon Import Risk Analysis of December 1996 (hereafter "the Final Report") considered the importation of *uncooked, adult, wild, ocean-caught Pacific* salmonid product from the United States and Canada (the first category in paragraph). The Final Report also identifies 24 disease agents of concern; these are identical to those identified in the dispute at issue with the exception of *Kudoa thyrsites* and the addition of Infectious salmon anaemia.[11]

2.12 According to the Office international des épizooties, a **disease** means the "... clinical or non-clinical infection with one or more of the aetiological agents of the disease ...". A **disease agent** is "... an organism which causes or contributes to the development of a disease ...".[12] A disease agent may have several strains with varying degrees of harmfulness.

2.13 The disease agents at issue in this dispute are not of concern from a human health perspective.

2. Australia's current provisions relating to the importation of salmonid product

2.14 Australian Quarantine Proclamation 86A ("QP86A"), dated 19 February 1975, made under the Quarantine Act 1908, states the following in relation to importation of dead salmon[13]:

> "NOW THEREFORE I, Sir John Robert Kerr, the Governor-General of Australia, acting with the advice of the Executive Council, hereby -
>
> ...
>
> (d) prohibit the importation into Australia of dead fish of the sub-order Salmonidae, or any parts (other than semen or ova) of fish of that sub-order, in any form unless:

[7] Ibid., p.93
[8] *Australian Atlantic Salmon: Effects of Import Competition*, p.5, Industry Commission, Research Project, 20 December 1996. See also Final Report, p.20.
[9] Final Report p.93.
[10] *Australian Atlantic Salmon: Effects of Import Competition*, p.5, Industry Commission, Research Project, 20 December 1996.
[11] Final Report, p.133.
[12] OIE International Aquatic Animal Health Code; OIE Code (1995), p.6.
[13] Quarantine Proclamation No. 86A, *Australian Government Gazette*, No. S33, 21 February 1975.

(i) prior to importation into Australia the fish or parts of fish have been subject to such treatment as in the opinion of the Director of Quarantine is likely to prevent the introduction of any infectious or contagious disease, or disease or pest affecting persons, animals or plants; and

(ii) the Director of Quarantine or a person authorized by him has, by instrument in writing, consented to the importation and the instrument is produced to a Collector within the meaning of the *Customs Act 1901-1974* or to a quarantine officer."

Proclamation 86A delegates authority to the Director of Quarantine to determine the conditions of entry in accordance with part (d) referred to above. The Director of Quarantine is the Secretary of the Department of Primary Industries and Energy or his or her nominee.

2.15 Before the promulgation of QP86A on 30 June 1975, Australia imposed no restrictions on the importation of products derived from salmonids. At the time of proclamation, QP86A primarily had application to the protection of the animal health status of trout recreational fisheries in Australia from disease introduction and, potentially, for the purposes of protecting the animal health status of any future commercial salmonid industry which might be developed in Australia. Australia has noted that the Proclamation also has application to the animal health status of native salmoniforms. Australia has advised that the term "introduction" is applied and interpreted in Australia in the same sense as "entry, establishment or spread" referred to in the text of the SPS Agreement.

2.16 In accordance with the delegated authority, pursuant to QP86A, the Director of Quarantine has permitted the entry of commercial imports of heat-treated salmon product for human consumption together with non-commercial quantities of other salmon (primarily for scientific purposes) subject to prescribed conditions. The Director of Quarantine, in accordance with the same delegated authority, has decided that imports of uncooked salmon should be restricted. Specifically, the following requirements have been issued in relation to salmon imports:

(i) "Guidelines for the Importation of Smoked Salmon and Trout into Australia" (the "1983 Guidelines"). Effective 1 September 1983, imports of salmon other than canned salmon were only allowed subject to an assessment that the treatment under which the salmon had been processed was sufficient to prevent the entry of disease. With immediate effect, "cold smoked" salmon was not allowed to be imported, unless evidence was produced that it had been processed in such a way as to inactivate the causative organisms of diseases of salmonids.[14]

(ii) "Conditions for the Importation of Salmonid Meat and Roe into Australia", of December 1986. This circular required an import permit for all uncanned salmon and trout meat and salmon roe to enter Australia. Among other requirements, it listed the major diseases of concern and established the minimum temperature requirements for heating.[15]

(iii) "Conditions for the Export of Salmonid Meat and Roe to Australia", dated May 1987. This Circular dealt with non-commercial importation of salmonid meat and roe in response to difficulties arising in certification requirements for individual consignments (under 5kg. in weight) accompanied by passengers entering Australia.[16]

[14] Chief Quarantine Officer (Animals) Circular Memorandum 82/83, dated 25 July 1983.
[15] Chief Quarantine Officer (Animals) Circular Memorandum 399/86.
[16] Chief Quarantine Officer (Animals) Circular Memorandum 121/87, dated 29 May 1987.

"Revised conditions for the importation of salmonid meat and roe into Australia" were issued in June 1987.[17]

(iv) "Conditions for the Importation of Salmonid Meat and Roe into Australia", issued in June 1988. This circular modified the oven temperatures and time relationships for heating of salmon for importation. Under the new requirements, the minimum processing that salmonid meat would be allowed to undergo was at a temperature of 35ÿC for a period of not less than 7 hours. This circular replaced the 1983 guidelines and are hereafter referred to as the "1988 Conditions".[18] Since the issuance of these 1988 Conditions, there have been no new treatment specifications to date. The term "uncanned heat-treated salmon" and "salmon treated with the 1988 Conditions" are the same.

(v) "Importation of Salmonid Meat in Retortable Pouches", dated in April 1990. This circular announced the approval of the importation of salmonid meat in retortable pouches under certain conditions.[19]

(vi) "Requirements for the Importation of Individual Consignments of Smoked Salmonid Meat", dated in January 1996. This notice by AQIS set new import requirements for individual consignments (under 5kg. in weight). These are hereafter referred to as the "1996 Requirements".[20]

2.17 On 13 December 1996, the Executive Director of the Australian Quarantine and Inspection Service (AQIS) made a policy determination to maintain the existing quarantine policies for the importation of salmon product. This determination was based on the Salmon Import Risk Analysis (Final Report) and is hereafter referred to as "the December 1996 decision":

> "The [Chief Veterinary Officer] recommends 'that the status quo for quarantine policies for uncooked salmon products continue'
>
> - i.e. that the requests from Canada and US for access for uncooked, wild, adult, ocean-caught Pacific salmonid product not be approved.
>
> ...
>
> "On the basis of these considerations I have decided that, having regard to Australian Government policy on quarantine and after taking account of Australia's international obligations, importation of uncooked, wild, adult, ocean-caught Pacific salmonid product from the Pacific rim of North America should not be permitted on quarantine grounds."[21]

3. International recommendations - the OIE

2.18 The SPS Agreement makes reference, in a number of provisions, to the "relevant international standards, guidelines and recommendations". Annex A:3(b) of the SPS Agreement states that the international standards, guidelines and recommendations relevant for animal[22] health and zoonoses are those developed under the auspices of the Office international des épizooties (hereafter the "OIE").

[17] Chief Quarantine Officer (Animals) Circular Memorandum 122/87.
[18] Chief Quarantine Officer (Animals) Circular Memorandum 166/88, dated 9 June 1988.
[19] Chief Quarantine Officer (Animals) Circular Memorandum 93/90, April 1990.
[20] AQIS Quarantine Operational Notice 1996/022, 24 January 1996.
[21] AQIS, File Note by Paul Hickey, Executive Director, 13 December 1996.
[22] In Annex A of the SPS Agreement, a footnote on the title "Definitions" indicates that "[f]or the purpose of these definitions, "animal" includes fish and wild fauna ...".

These standards, guidelines and recommendations are contained in OIE's "International Aquatic Animal Health Code".

2.19 The OIE is an international inter-governmental organization created in 1924. In November 1997 it had 147 member countries. Its main objectives are to:

(i) inform governments of the occurrence and course of animal diseases throughout the world and about ways to control these diseases;

(ii) coordinate, at the international level, studies devoted to the surveillance and control of animal diseases; and

(iii) harmonize regulations for trade in animals and animal products among its member countries.

2.20 The OIE operates under the authority and control of its International Committee which is made up of delegations from the member countries. The International Committee adopts resolutions drawn from the work of subordinate commissions (the Administrative Commission, the Regional Commissions and the Specialist Commissions). One of the specialist commissions is the OIE Fish Diseases Commission (FDC). The FDC was established in 1960. In May 1995, the FDC formally adopted the OIE's "International Aquatic Animal Health Code" (hereafter referred as to the "Code"), and the "Diagnostic Manual for Aquatic Animal Diseases" (the "Manual"). The aim of the Code is to facilitate international trade in aquatic animals and aquatic animal products by "providing detailed definitions of minimum health guarantees to be required of trading partners in order to avoid the risk of spreading aquatic animal diseases. These guarantees are based on inspection by Competent Authorities[23], epidemiological surveillance, and standard methods for laboratory examinations and disease diagnosis". The Code and Manual are updated on a yearly basis at the OIE General Sessions, in May.[24] References in this report are to the Code as updated in May 1997.

2.21 The diseases in the Code are divided into Diseases Notifiable to the OIE (hereafter "Notifiable Diseases") and Other Significant Diseases (hereafter "Other Diseases").

2.22 According to the OIE Code, *Notifiable Diseases* cover those diseases "that are generally regarded as having the potential for serious damage to the national aquacultural industries, or wild populations of fish, molluscs and crustaceans. Introduction of these diseases into countries free from them or into countries with national control or eradication programmes could cause significant economic loss. The Veterinary Administrations or other responsible Competent Authorities of such importing countries have an obligation to ensure that new disease agents are not introduced through imports, and to seek adequate protection in international health certificates".[25] Notifiable Diseases are those "considered to be of socio-economic and/or public health importance within countries and that are significant in the international trade of aquatic animals and aquatic animal products".[26] The Code indicates that "... the list of notifiable diseases of aquatic animals includes only major diseases of proven aetiology and limited geographical range ..." (page 109).

2.23 *Other Diseases* include diseases which: (i) are serious, but have a broad geographic distribution; (ii) those causing significant mortality, are transmissible and are of limited geographic range, but for which the aetiological agent has not yet been identified, or for which diagnostic tests are

[23] A Competent Authority is defined in the OIE Code as "the National Veterinary Services, or other Authority of a Member Country, having the responsibility and competence for ensuring or supervising the implementation of the aquatic animal health measures recommended in this Code."

[24] OIE Code, Foreword.

[25] OIE Code, p. 63.

[26] Ibid., p.7.

not yet standardized; (iii) have the potential for causing large losses, but which are too new for geographic range to be defined or for the essential epidemiological elements to be understood.[27]

2.24 Among the 24 diseases listed by Australia as of concern relevant to this dispute two diseases are included in the OIE list of Notifiable Diseases and four diseases in the list of Other Diseases (Table 2).

2.25 Section 1.4 of the OIE Code deals with risk analysis. The introduction states that:

> "The principal aim of import risk analysis is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of aquatic animals. aquatic animal products, ... The analysis should be transparent. This is necessary so that the exporting country may be provided with clear and documented reasons for the imposition of import conditions or refusal to import. Transparency is also essential because data are often uncertain and the distinction between facts and the analyst's value judgements may blur."[28]

TABLE 2 **"Diseases Notifiable to the OIE" Relevant to Australia's Measure**
Infectious haematopoietic necrosis (IHN)
Viral haemorrhagic septicaemia (VHS)
"Other Significant Diseases" Relevant to Australia's Measure
Bacterial kidney disease (BKD) *Renibacterium salmoninarum*)
Infectious pancreatic necrosis (IPN)
Infectious salmon anaemia[29]
Piscirickettsiosis (*Piscirickettsia salmonis*)

2.26 Chapter 1.4 then goes on to outline items including: (i) the components of risk analysis (hazard identification, risk assessment, risk management and risk communication) and the sequences of the import analysis process[30]; (ii) the methodology; and, (iii) documentation of the results of the analysis. Under Article 1.4.1.3 on methodology, the OIE Code notes that a "[r]isk analysis must be able to deal with the complexities of real life situations and no single method is applicable in all cases. For this reason, countries wanting to conduct import risk analyses may find it necessary to design their own process for carrying out the exercise."

4. Australia's import risk analysis

2.27 Following GATT Article XXII consultations in 1994, Australia agreed to document an import risk analysis on the quarantine issues involved with the importation of uncooked salmon meat from North America. Due to the complexity of the task, by arrangement with Canada and the United

[27] Ibid., p.109.
[28] Ibid, p. 29.
[29] Disease number 24 in Table 3.
[30] Ibid., Figure 1, p.28.

States, Australia restricted the analysis to the importation of wild, ocean-caught Pacific salmon in the first instance. The risk analysis process involved the preparation of two draft reports, issued in May 1995 and May 1996, and a Final Report of December 1996. The reports included identification of potential disease agents, analysis of disease risks, scientific review of data for salmonid diseases, socio-economic assessment of the potential impact of salmonid disease introduction and identification of options for risk reduction and risk management. The May 1996 and Final Reports also included summaries of issues raised by domestic and international respondents as part of the risk communication process. (See also the response to Question 1 by the experts advising the Panel for a summary of the reports, paragraphs 6.13-6.42.)

2.28 The "May 1995 Draft Report" noted that there had been no evidence of the spread of diseases via fish products for human consumption, despite "the wide scale movement of salmonid product within and between continents". Furthermore, the report listed a sequence of events of which each event had to occur for the imported salmon products to cause an exotic disease to become established in Australia. It was noted that although zero risk was not attainable, the risk of disease introduction might be reduced to negligible values if one or more events in the sequence were extremely unlikely to occur or if a number of events in the sequence had a relatively low probability. The May 1995 Draft Report noted that as with any other importation there was a risk of introducing exotic pathogens via the importation of uncooked salmon product derived from wild, ocean-caught Pacific salmon from Canada and the United States, but that this risk was so small as to not merit continuation of the present quarantine restrictions. The Draft Report concluded that: "the importation of eviscerated, headless, wild, ocean-caught Pacific salmon from Canada and the USA should be permitted, under specified conditions ...". The conditions required, *inter alia*, that the fish be suitable for human consumption, certified by the appropriate authorities as processed in Federally approved establishments, inspected and graded, sub-adult or mature fish, etc.[31]

2.29 In May 1996, AQIS published a revised draft Salmon Import Risk Analysis, "An assessment by the Australian Government of quarantine controls on uncooked, wild, ocean-caught Pacific salmonid product sourced from the United States of America and Canada". (The product considered was eviscerated fish.) The "Revised Draft IRA" took into account comments received by AQIS on the May 1995 Draft Report. The Revised Draft IRA made no specific recommendation to permit or not to permit importation but identified a number of risk management options for consideration.

2.30 In December 1996, the Department of Primary Industries and Energy published the final version of the "Australian Salmon Import Risk Analysis (the "Final Report"). In its conclusions, the Final Report noted that there was a possibility that up to 20 disease agents exotic to Australia might be present in Pacific salmon products and although the probability of establishment would be low, there would be major economic impacts which could seriously threaten the viability of aquacultural operations and the recreational fishing industries, in addition to adverse environmental impacts on the built environment of Australia. The Report considered that should any of the 20 diseases become established, they would almost certainly be ineradicable. The Report went on to note:

> "It is likely that scientific knowledge will rapidly advance consideration of these issues over the next few years. Australia will review this information as it becomes available. In particular, countries proposing to export fresh salmon to Australia must provide, to the extent possible, improved epidemiological evidence to support assertions of safety of fresh product."

On 13 December 1996, the Director of Quarantine decided to accept the recommendation of the Final Report that "...given the unique circumstances, range of potential disease agents and potential

[31] "Draft Import Risk Analysis - Disease risks associated with the importation of uncooked, wild, ocean-caught Pacific salmon product from the USA and Canada", Australian Quarantine and Inspection Service, May 1995, Appendix 6, pp.273-275.

socio-economic and environmental impacts, entry of uncooked salmonid products from Canada and the United States not be permitted at this time" and that other issues related to salmon, such as current policies for importing heat-treated salmon, should be considered in the light of priorities recommended by the National Task Force on Imported Fish and Fish Products.

III. CLAIMS OF THE PARTIES

1. Canada's claims

3.1 Canada claimed that the Australia's measure was an illegal import prohibition under Article XI:1 of GATT 1994, that found no justification in Article XI:2 or Article XX or in GATT 1994.

3.2 Australia's measure fell within the definition of a sanitary measure in accordance with Article 1 of the SPS Agreement, and Annex A.1(a) thereto. It was thus subject to that Agreement's provisions. Canada claimed that Australia's measure had not been developed and applied in accordance with the SPS Agreement in that:

(i) the measure violated Article 3.1 of the SPS Agreement as it was not based on existing international standards, guidelines or recommendations pursuant to Article 3.1 (in this case, recommendations of the Office international des épizooties), and did not meet the conditions of Article 3.3 of the SPS Agreement;

(ii) the measure was not based on a proper assessment of the risks to salmonid life or health and accordingly failed to meet the requirements of Article 5.1;

(iii) the measure was not based on an assessment of risks that took into account available scientific evidence contrary to Article 5.2 of the SPS Agreement;

(iv) the measure was inconsistent with Australia's obligation to avoid arbitrary and unjustifiable distinctions in the levels of protection it considered to be appropriate in different situations, distinctions that resulted in a disguised restriction on trade, and accordingly violated Article 5.5;

(v) the measure was more trade restrictive than required to achieve Australia's appropriate level of sanitary protection and accordingly violated Article 5.6;

(vi) the measure was in conflict with Article 2.2 of the SPS Agreement because it was maintained without sufficient scientific evidence; and

(vii) the measure arbitrarily or unjustifiably discriminated between Members where similar conditions prevailed, specifically between Australia and Canada, and accordingly violated Article 2.3.

3.3 Canada furthermore claimed that Australia's measure had nullified or impaired benefits accruing to Canada under the WTO Agreement pursuant to Article XXIII:1(a) or (b) of GATT 1994.

2. Australia's claims

3.4 Australia claimed that it was for the complaining party to present a *prima facie* case of inconsistency before the Panel and that it was therefore for Canada, in the first instance, to provide sufficient evidence to raise a presumption that Australia's measure was inconsistent with the rights

and obligations under the cited Agreements. Australia claimed that Canada had not satisfied its evidentiary and legal burden of proof in respect of the claims it had made. In so doing, Australia claimed that evidentiary standards had not been met and that there was a need to distinguish between facts and assertion, including in regard to the legal relevance of matters raised by Canada which, in Australia's view represented an attempt to ascribe motive to actions.

3.5 Australia claimed that the Panel should first examine consistency with the SPS Agreement. Australia claimed that unless Canada could successfully demonstrate that Australia's measure did not conform to the provisions of the SPS Agreement, the measure would be presumed to be in accordance with the provisions of GATT 1994, as Article 2.4 of the SPS Agreement provided that if a measure conformed with the provisions of the SPS Agreement the measure was presumed to be in accordance with obligations of Members under the provisions of GATT 1994 which related to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b). It would therefore be necessary to first consider the measure against the rights and obligations established under the SPS Agreement. Australia maintained that its measure was in conformity to its obligations under the SPS Agreement.

3.6 Australia further claimed that the Panel's terms of reference did not extend to Canada's claims of non-violation, nullification and impairment under Article XXIII:1(b) of GATT 1994, or to what Australia considered as new claims submitted by Canada in the course of the panel proceedings. Australia also claimed that Article 3 did not have application to the measure at issue. In the alternative, Australia claimed that its measure was not in violation of the SPS Agreement or GATT 1994 and that Canada's claim of non violation could not be sustained.

IV. ARGUMENTS OF THE PARTIES

1. Due Process

4.1 In the course of the Panel proceedings, **Australia** raised concerns that it was disadvantaged by certain procedures. Australia noted that neither the Final Report nor the December 1996 Decision had been discussed in WTO consultations. Australia had therefore not been in the position to respond to the substance of Canada's claims and arguments until receipt of Canada's First Submission on 29 July 1997. Hence, the time frame for Australia to engage in detailed preparation for the first stage of the panel process had been limited to three weeks. In contrast, Canada had the opportunity of several months in which to prepare its claims since receipt of the Final Report in December 1996. As Canada had not identified the specific matters at issue, as required by Article 6.2, Australia could not reasonably have been expected to anticipate the detail of Canada's claims. Indeed, Canada had altered its claims about the specific measure on several occasions throughout the panel process and had added new claims or rebased its legal claims, including in the final stages of the panel process. Australia drew attention to the Appellate Body Report on *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*:

> "All parties engaged in dispute settlement ... must be fully forthcoming from the very beginning both as to the claims involved in the dispute and as to the facts relating to those claims. Claims must be stated clearly. Facts must be disclosed freely. This must be so in consultations as well as in the more formal setting of panel proceedings. In fact, the demands of due process that are implicit in the DSU make this especially necessary during consultations. For the claims that are made and the facts that are established during consultations do much to shape the substance and scope of subsequent panel proceedings ... in the absence of the inclusion of a claim in the

terms of reference, a panel must neither be expected nor permitted to modify rules in the DSU."[32]

4.2 Australia further stated that due process concerns did not involve the development of arguments, but related to new claims, including the basis of claims, and to evidence submitted subsequent to the date determined by the Panel in its working procedures. Australia noted that, in accordance with DSU rules, the establishment of a panel was automatic and that effectively, the complainant determined the terms of reference. Under these circumstances, it was imperative that due process be observed, as confirmed above by the Appellate Body.

4.3 Australia further indicated concern in regard to some of the Panel's questions, including Question 12 of 23 January 1998.[33] It was Australia's view that the question invited Canada to raise a legal claim in respect of Article 5.5 which it had elected not to include in its submissions. A respondent could not be expected to rebut a legal claim that had not been raised by the complainant.

4.4 Australia noted that documentary evidence needed to be provided at the earliest stage of a panel process. The appropriate time would have been the time of the lodging of Canada's first submission, during the first substantive meeting between the parties and the Panel. In this regard, a Secretariat paper regarding panel time frames had indicated that all evidence was to be submitted by 7 October 1997.[34] In light of the above, Australia requested that the Panel exclude the "Quantitative analysis of the risk of establishment of *Aeromonas salmonicida* and *Renibacterium salmoniarum* in Australia as a result of importing Canadian ocean-caught salmon" by David Vose (the "Vose Report") from its consideration of evidence submitted by Canada, together with the article attached to Canada's Second Oral Argument of 5 February 1998. The original Vose Report had been provided by Canada at the end of December 1997. A partially illegible copy had been received by Australia on 18 December, and a legible copy was not received in Canberra until 23 December; i.e., the beginning of the statutory summer holiday period in Australia. No explanation had been offered by Canada why the evidence had not been provided during the consultations or at the beginning of the panel process. Without prejudice to the admissibility of the Vose Report, Australia drew attention to the fact that this had been revised between 5 and 6 February. On 13 February, Australia had furnished initial written comments on the revised report, but the admissibility of this comment had been contested by Canada. Australia noted also that no effort had been made to subject this evidence from Canada to the same legal scrutiny as the Final Report.

4.5 **Canada** noted that Australia had received the Vose Report on 18 December 1997. In their view, this had given Australia ample opportunity to consider it and provide comments, which Australia did at the Second Substantive Meeting, on 5 February 1998, and in its 13 February 1998 submission to the Panel.

4.6 In terms of the scope of the dispute, **Australia** acknowledged that Canada's requests for consultation and a panel extended to fresh, chilled and frozen salmon and was not limited to Pacific salmon. Nonetheless, Australia could not reasonably have been expected to undertake a formal risk assessment on all uncooked salmon of Canadian origin within the time frame in which Canada sought a panel, or for that matter, within the time frames of a panel process. The Final Report was limited to the Pacific product by agreement with Canada, and at no stage had Canada subsequently requested that the product coverage be extended to all Canadian salmon. Canada had not communicated to Australia that it wished to reverse this arrangement until the panel process was under way. Australia, therefore, requested that the Panel limit its findings to fresh, chilled and frozen, adult, wild, ocean-caught Pacific salmon.

---

[32] Adopted 16 January 1998, WT/DS50/AB/R, para. 94.

[33] Question 12: "Can Canada confirm that it is of the view that the contested measure 'results in ... a disguised restriction on international trade' in the sense of Article 5.5? If so, why?"

[34] The Panel's Revised Timetable, distributed to Parties on 10 September 1997.

4.7 **Canada** refuted this argument and noted that according to Article 5.1 of the SPS Agreement, it was for Members taking measures to base those measures on an assessment of risk. The obligation was not limited to those instances where another Member requested that a measure be based on a risk assessment. Canada never excused Australia from its obligations under Article 5.1. Australia's obligation under Article 5.1 was not to *do* a risk assessment, but to *base* its measure on one.

4.8 **Australia** contended that Canada had introduced fundamental changes in the nature of its specific legal claims at the final meeting of the parties with the Panel (5-6 February 1998). Canada's oral statement of 5 February was a 44-page document which had the character of a formal written submission in regard to legal claims and rebased legal claims as well as detailed content. It was not a document that was capable of being addressed fully (in respect of legal claims, the legal basis of claims and evidence) overnight or within the space of one week. This was a violation of due process and had put Australia in a disadvantageous position. In this regard, Australia argued that in relation to new or re-based claims, Canada's claim of inconsistency with Article 5.1 had been extended, on 5 February, to include claims in respect of product coverage (heat-treated salmon and salmon other than salmon covered by the scope of the Final Report). Australia argued that heat-treated product had not been addressed in the Final Report for the very reason that Canada had not sought a risk assessment on heat-treated product, for which it already had access, accounting for some $A 10 million of Australia's import of that product. Australia had been reliant on the agreement reached with Canada on the limited scope of the risk assessment, but because of this, currently faced a claim of inconsistency with WTO treaty obligations, a claim which had not been advanced until 5 February.

4.9 **Canada** stated that Australia had been fully aware since 10 March 1997 that Canada was claiming that Australia had violated Articles 2, 3 and 5 of the SPS Agreement and had done so by way of QP86A and the amendments or modifications to it, which included heat treatment requirements.[35] The requirement of heat treatment and the prohibition on salmon product that had not been heat-treated (i.e. fresh, chilled or frozen salmon) were two sides of the same coin. There was no "new identification of the measure". Canada further noted that the *argument* that Australia's measure was in violation of Article 5.1 was in Canada's First Submission (paragraphs 165 to 181), and, as the Panel had raised the issue of whether Australia had based its measure, including the requirement of heat treatment, on a risk assessment[36], Canada had a right and an obligation to address these issues in its argument.

4.10 **Australia** further alleged that Canada had introduced a new specific claim that Australia had violated Articles 5.1, 5.2 and 2.2 of the SPS Agreement, on the basis that there was no rational relationship between the measure and the scientific evidence. The basis for this claim had been largely heat-treated product, a claim not previously raised in relation to those provisions. Canada had not clearly identified the basis for its claim in the text of the SPS Agreement. It appeared that Canada was requesting the Panel to make a general judgement whether Australia's measure was rationally supported by the available scientific evidence to achieve Australia's appropriate level of protection,

---

[35] The fourth paragraph of Canada's First Submission (28 July 1997) stated that:

"The Australian measure at issue is Quarantine Proclamation 86A ("QP86A") and published requirements pursuant to QP86A that together require salmonid product to be heat-treated for certain prescribed durations and temperatures, prior to importation into Australia, ... The result of Australia's measure is to prohibit the importation of salmonid products destined for human consumption that have not been subject to such heat treatment, (hereinafter "uncooked salmon" or "fresh, chilled or frozen salmon").

[36] The Panel's Additional Questions to the Parties of 8 December 1997.

Question 11: Australia indicates that it will in the future undertake a risk assessment on "uncanned heat-treated salmon". What requirements currently apply to imports of this product? Is there any difference between "uncanned heat-treated salmon" and salmon treated in accordance with the 1988 Conditions? On what scientific or other basis does Australia currently allow imports of salmon products treated in accordance with the 1988 Conditions?

Question 13: To what extent and where precisely in its Final Report has Australia analyzed and compared the risks related to the different sanitary options it considered? To what extent and where precisely in its Final Report did Australia take into account the element of trade restrictiveness in such comparison?

rather than to examine Australia's compliance with specific SPS obligations. Such a request, according to Australia, was in conflict with the DSU (Articles 3.2 and 19.2) in that the findings and recommendations of a panel could not add to or diminish the rights and obligations provided in the covered agreements, as confirmed in the Appellate Body Report *EC - Measures Concerning Meat and Meat Products* (hereafter "*EC - Hormones*"):

> "To adopt a standard of review not clearly rooted in the text of the SPS Agreement itself may well amount to changing that finely drawn balance [in the Agreement] ..." "... between the jurisdictional competences conceded by Members to the WTO and the jurisdictional competences retained by the Members themselves ...." [37]

4.11 **Canada** noted that it had argued throughout the proceedings that Australia's measure was maintained without sufficient scientific evidence. The "rational relationship" between a scientific basis for a measure in Article 2.2 and the "based on" requirement in Article 5.1 reflected the approach taken by the Appellate Body in *EC - Hormones*.[38] Furthermore, the Panel had itself raised the issue of scientific basis for heat treatment in the written questions that it had put to the Parties at the First Substantive Meeting.[39]

4.12 In respect of Article 5.5, **Australia** claimed that Canada had not previously made a legal claim that the measure resulted in a disguised restriction on international trade, including as a discrete legal obligation under Article 5.5. Hence, Canada had introduced a new claim of inconsistency in regard to purported differences between heat-treated and other salmon. This was an entirely different claim from allegations of differences between live and bait fish and salmon. Canada had, in seeking to demonstrate that the alleged arbitrary or unjustifiable distinctions in Australia's level of protection resulted in a disguised restriction on trade, attempted to infer motive to Australia's decisions. There was a fundamental difference between an attempt to demonstrate a disguised restriction on trade through inferring motive, and presenting evidence based on an analysis of the architecture and structure of Australia's measure which Canada had failed to do. Canada was in essence requesting the Panel to undertake a *de novo* review and had ignored due deference and the standard of review referred to in paragraphs 115 to 117 and 244 to 245 of the Appellate Body Report on *EC - Hormones*.

4.13 **Canada** noted that it had argued from the outset that Australia had violated Article 5.5 and that there were three elements to a violation of Article 5.5 and that the third element "disguised restriction on international trade" had been satisfied (Canada's First Submission paragraphs 182 to 216 and 197). Furthermore, Canada's argument in its Second Oral Statement reflected the approach of the Appellate Body in *EC - Hormones*.

4.14 **Australia** further maintained that in regard to Article 3.3, Canada had not previously requested the Panel to make a finding of violation in respect of Article 3.3. The legal claim had been one of inconsistency with Article 3.1. Australia noted that it did not have benefit of WTO consultations in which to address the specific claims of Canada in relation to the Article 3. Article 3 was not identified in Canada's request for consultations, but in keeping with the objective of WTO dispute resolution, Australia agreed to discuss Canada's claims in respect of Article 3. However, no

---

[37] Adopted 13 February 1998, WT/DS26/AB/R and WT/DS48/AB/R, para. 115.

[38] Ibid., para. 193.

[39] Question 23 of 10 September 1997: The 1996 Final Report addresses the risks related to import of uncooked wild caught adult Pacific salmon from Canada and the United States into Australia. Is there any scientific evidence available related to the effectiveness of the technique of cooking (as prescribed by the Australian measure) as a tool to reduce risk (or on the effectiveness of any other alternative suggested in the 1996 Final Report). What is the relationship between the risks alleged in the 1996 Final Report and cooking as a tool to reduce these risks? What is the difference in effectiveness of cooking versus evisceration with respect to the diseases at issue?

Question 13 to the experts of 31 October 1997: With respect to the diseases at issue, what is the difference in effectiveness, with regard to reducing the risk of disease transmission, of evisceration as compared to heat treatment of the product? as opposed to full cooking of the flesh of the product?

details were forthcoming at the consultations. Australia's due process concerns had been compounded by the last- minute introduction of a new legal claim by Canada.

4.15 **Canada** maintained that prior to the Report of the Appellate Body in *EC - Hormones*, the question of whether Article 3.3 was an exception to Article 3.1 was in issue. However, the Appellate Body had found that Article 3.3 was an obligation in and of itself. Canada's arguments in its Second Oral Statement reflected the Appellate Body's reasoning in *EC - Hormones*. In addition, Canada argued that "does not meet the conditions of Article 3.3" and "is inconsistent with Article 3.3" was a distinction without a meaningful difference.

4.16 In regard to Article 5.6, **Australia** argued that Canada had introduced a new legal claim in respect of heat-treated product. Canada's claims that Australia's requirements on heat-treated product were not sufficiently restrictive to achieve Australia's level of protection did not constitute evidence that a significantly less trade restrictive measure was available that would achieve Australia's appropriate level of protection in relation to uncooked salmon. Canada's new legal claims in regard to heat-treated product implied that consistency with Article 5.6 could be assured by placing a quarantine prohibition on heat-treated product.

4.17 **Canada** stated that it had argued from the outset that Australia had violated Article 5.6 and that this violation was due in part to Australia's inability to distinguish among the risks entailed by various sanitary measure of differing trade restrictiveness (Canada's First Submission, paragraphs 224 to 227). These measures included heat treatment, the most trade restrictive of the measures identified in the Final Report and the one that Australia had chosen to maintain. The Terms of Reference made it clear that heat treatment had always been at issue in this case. The Panel had furthermore raised the issue of heat treatment and the other options identified in the Final Report in its Additional Question 13 to the Parties of 8 December 1997.[40]

4.18 Regarding Australia's due process claims in general, Canada contended that Australia had confused the distinction, made clear by the Appellate Body, between claims and arguments. According to the Appellate Body in *EC - Regime for the Importation, Sale and Distribution of Bananas*:

> "... there is a significant difference between the claims identified in the request for the establishment of a panel, which establish the panel's terms of reference under Article 7 of the DSU, and the *arguments* supporting those claims, which are set out and progressively clarified in the first written submissions, the rebuttal submissions and the first and second panel meetings with the parties." [41] (emphasis in the original)

4.19 Hence, while *claims* had to be "specified sufficiently in the request for the establishment of a panel in order to allow the defending party ... to know the legal basis of the complaint" [42], the *arguments* in support of those claims were to be set out and refined in the course of the proceedings. The Appellate Body had concluded:

> "There is no requirement in the DSU or in GATT practice for arguments on all claims relating to the matter referred to the DSB to be set out in a complaining party's first written submission to the panel. It is the panel's terms of reference, governed by Article 7 of the DSU, which set out the claims of the complaining parties relating to the matter referred to the DSB."[43]

---

[40] Reproduced in footnote 35.

[41] WT/DS27/AB/R adopted 25 September 1997, para. 141. Canada also noted that the distinction was reiterated in: WT/DS50/AB/R, para. 91 and WT/DS26/AB/R, and WT/DS48/AB/R para. 156.

[42] WT/DS27/AB/R, para. 143.

[43] Ibid., para. 145.

The question of whether Canada had made "new claims" had therefore to be assessed in the light of Canada's Request for the Establishment of a Panel[44], which established the Panel's terms of reference. In respect of Australia's alleged "new claims" cited above, Canada claimed that these pertained to claims that were set out in Canada's Request for the Establishment of a Panel, namely, that the Australian measure was inconsistent with Articles 2, 3 and 5 of the SPS Agreement.

4.20 Canada argued that Australia's claims of a violation of due process were groundless because (i) Canada had made no new claims, and (ii) the arguments that Australia characterized as "new claims" could be found in the various submissions that Canada had made throughout the proceedings and for which Australia had the opportunity to respond. Canada's arguments had been refined in the light of the Appellate Body's Report on *EC - Hormones*. This had been precisely what had been contemplated when the Panel had agreed to the Parties' request to delay the second substantive meeting until after the release of the Appellate Body's Report.

2. Relationship between GATT 1994 and the SPS Agreement

4.21 **Canada** argued, in the first instance, that Australia's measure was an illegal import prohibition under Article XI:1 of GATT 1994. Although Australia's measure was a sanitary measure which affected international trade within the meaning of Article 1.1 of the SPS Agreement, it was not "developed and applied according to the provisions of the Agreement" (Article 1.1) and was thus inconsistent with the SPS Agreement. Since there was no presumption that the measure was consistent with the SPS Agreement, Article 2.4 of the SPS Agreement could not be used to justify Australia's violation of Article XI of GATT 1994.

4.22 **Australia** agreed that the measure was a sanitary measure which affected international trade within the meaning of Article 1.1 of the SPS Agreement. Thus, Australia observed, the Panel would first have to examine claims in respect of the SPS Agreement in order to avoid a situation where the Panel first found inconsistencies with regard to a Party's obligations under GATT 1994 and subsequently found that party to be in full conformity with its obligations under the SPS Agreement and therefore, within the meaning of Article 2.4 of the SPS Agreement, in conformity with the relevant provisions of GATT 1994. Australia indicated that whereas the parties were in agreement that the measure came within the scope of the SPS Agreement, they did not agree on the identification of the measure at issue.

3. The SPS Agreement

(a) Burden of proof

4.23 **Canada** argued that Australia's measure was inconsistent with Articles 2, 3 and 5 of the SPS Agreement. Canada accepted that it was required to present evidence sufficient to establish a presumption of a *prima facie* case that Australia's measure was inconsistent with its obligations under the SPS Agreement. In this regard, Canada maintained that it had put forward evidence that provided

[44] WT/DS18/2.

legal arguments showing that Australia's measure was inconsistent with the above cited provisions.[45] It was Australia's obligation, in turn, to put forward any alternative scientific evidence to demonstrate the scientific basis for its measure. This Australia had failed to do.

4.24 **Australia** agreed that it was up to the complaining party to, in the first instance, provide *prima facie* evidence to raise a presumption of inconsistency with regard to Australia's measure. However, Australia argued that Canada had not met the evidentiary and legal burden of proof in regard to all provisions cited by Canada. Australia noted that in regard to a *prima facie* case, the Appellate Body in *United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, had stated:

> "In addressing this issue, we find it difficult, indeed, to see how any system of judicial settlement could work if it incorporated the proposition that the mere assertion of a claim might amount to proof. It is, thus, hardly surprising that various international tribunals, including the International Court of Justice, have generally and consistently accepted and applied the rule that the party who asserts a fact, whether the claimant or the respondent, is responsible for providing proof thereof. Also, it is a generally-accepted canon of evidence in civil law, common law and, in fact, most jurisdictions, that the burden of proof rests upon the party, whether complaining or defending, who asserts the affirmative of a particular claim or defence. If that party adduces evidence sufficient to raise a presumption that what is claimed is true, the burden then shifts to the other party, who will fail unless it adduces sufficient evidence to rebut the presumption."[46] (footnotes omitted)

Hence, Australia argued, the mere assertion of a claim did not amount to proof. In the above cited case, Australia recalled that the Appellate Body had ruled that:

> "Since India is the party that initiated the dispute settlement proceedings, we consider that it is for India to put forward factual and legal arguments in order to establish that the US restriction was inconsistent with Article 2 of the ATC and that the US

---

[45] Canada noted that the issues had been exhaustively reviewed in the Appellate Body report in *United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India* (adopted on 23 May 1997, WT/DS33/AB/R). There, the Appellate Body had considered the issue of burden of proof under the Agreement on Textiles and Clothing (the "ATC") respecting the issue of a complaint by India that certain restrictions imposed by the United States did not respect the transitional safeguard provisions of Articles 2.4 and 6 of the ATC. The Appellate Body had stated that:

> "We agree with the Panel that it was up to India to present evidence and argument sufficient to establish a presumption that the transitional safeguard determination made by the United States was inconsistent with its obligations under Article 6 of the *ATC*. With this presumption thus established, it was then up to the United States to bring evidence and argument to rebut the presumption." (p.13)
>
> ...
>
> "[A] party claiming a violation of a provision of the *WTO Agreement* by another Member must assert and prove its claim. In this case, India claimed a violation by the United States of Article 6 of the *ATC*. We agree with the Panel that it, therefore, was up to India to put forward evidence and legal argument sufficient to demonstrate that the transitional safeguard action by the United States was inconsistent with the obligations assumed by the United States under Articles 2 and 6 of the *ATC*. India did so in this case. And, with India having done so, the onus then shifted to the United States to bring forward evidence and argument to disprove the claim. This, the United States was not able to do and, therefore, the Panel found that the transitional safeguard action by the United States "violated the provisions of Articles 2 and 6 of the ATC"." (p.16)

Canada stated that the reasoning in the Appellate Body decision equally applied to the SPS Agreement.

[46] Ibid., p.14.

determination for a safeguard action was inconsistent with the provisions of Article 6 of the ATC".[47]

4.25 In *EC - Hormones*, the Appellate Body had confirmed that the complainant had the burden of establishing a *prima facie* case in respect of all provisions of the SPS Agreement. In its findings and conclusions, the Appellate Body had reversed the panel's general interpretative ruling that the SPS Agreement allocated the evidentiary burden to the Member imposing an SPS measure. The Appellate Body had also reversed the panel's conclusion that when a measure was not based on an international standard in accordance with Article 3.1, the burden was on the Member to show that its SPS measure was consistent with Article 3.3 of the SPS Agreement.[48] It was clear from the Appellate Body's report that the complainant's burden of establishing a *prima facie* case applied across all provision of the SPS Agreement.[49]

(b) The measure at issue

Sanitary or phytosanitary measure – Any measure applied:

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

SPS Agreement, Annex A Definitions

4.26 **Canada** stated that the measure at issue was Quarantine Proclamation 86A (hereafter "QP86A") introduced in February 1975, and published requirements pursuant to QP86A, that together required salmonid product to be heat treated for certain prescribed durations and temperatures prior to importation into Australia. Canada listed the 1983 Guidelines, the 1988 Conditions and the 1996 Requirements as published requirements pursuant to QP86A.[50] The result of Australia's measure, according to Canada, was to prohibit the importation of salmonid products destined for human consumption that had not been subject to such heat treatment. Canada's claim was that the prohibition on the importation of *all* fresh, chilled or frozen Canadian salmon, as a result of the Australian measure that included QP86A and any amendments or modifications to it, violated Australia's obligations under the SPS Agreement and GATT 1994. The products that were the subject of Canada's complaint before the DSU included Tariff Items:

0302.12.00	Fresh or chilled Pacific, Atlantic and Danube salmon
0303.10.10	Frozen Pacific salmon
0303.22.00	Frozen Atlantic and Danube salmon

[47] Ibid., p.12 (the Appellate Body's confirmation of the Panel's findings).
[48] Op. cit., para. 253.
[49] Ibid., para. 108.
[50] Paragraph 2.16.

0304.10.00	Fresh or chilled fish fillets
0304.20.00	Frozen fish fillets
0305.30.00*	Fish fillets, dried, salted or in brine, but not smoked
0305.41.00*	Smoked Pacific, Atlantic and Danube salmon (incl. fillets)
0305.59.00*	Dried fish, not smoked (excl. cod)
0305.69.00*	Other fish salted or in brine but not dried or smoked, nes
1604.20.00*	Other prepared or preserved fish, nes

Note: The products marked "*" fall outside the HS tariff classifications of fresh, chilled and frozen salmon for human consumption.

4.27 Canada argued that Australia's measure (QP86A of 1975 and subsequent published requirements pursuant to QP86A[51] fell within the definition of a sanitary measure in Annex A:1, paragraph (a), as well as within the second part of Annex A.1 ("Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; .... ").

4.28 **Australia** argued that QP86A and any amendments or modifications thereto *did not* represent a prohibition on imports of uncooked salmon. QP86A provided a legal basis for conditions of entry for salmon but did not constitute a prohibition *per se*. It established a system of permit or consent. There had not been any amendments or modifications to QP86A and substantial imports of product coming within the scope of QP86A had in fact entered Australia. QP86A did not operate as an import prohibition, but as a system of permit and consent. The Director of Quarantine had discretion whether to allow importation or not; the condition to be met was that "[t]he Director of Quarantine must be satisfied that prior to importation into Australia the product has been subject to such treatment as in the opinion of the Director of Quarantine is likely to prevent the introduction of any infectious or contagious disease, or disease or pest affecting persons, animals or plants."[52] The conditions to be attached for treatment did not proscribe the entry of fresh, chilled or frozen salmon. It was noted that experts advising the Panel did not consider heat-treated salmon to be the same product as fresh, chilled and frozen salmon and that heat- treated salmon was normally traded in eviscerated form, hence different considerations would apply. In this regard Australia noted that heat-treated salmon had been allowed into Australia since the issuance of QP86A in accordance with the exercise of the delegated authority conferred on the Director of Quarantine by QP86A; for example, substantial quantities of heat-treated salmon, including imports from Canada valued at some $A 10 million in 1996. Fresh, chilled and frozen salmon had been addressed separately, following which a decision had been taken that a permit for this product would not be issued at the present time. Only minuscule, non commercial quantities of frozen uncooked salmon tissue had been imported for scientific purposes and for taxidermy. At the current time, Australia did not permit the commercial importation of fresh, chilled or frozen salmon from any country.

4.29 In common with most other countries, Australia had historically not generally restricted imports of aquatic animal products for reasons of disease risks. Reasons include that by long established practice, aquatic products were primarily sourced from the sea, fishing vessels were free to catch product not subject to private ownership and the significance of aquatic animal disease was not fully appreciated - no ready distinctions could be made between the relevant disease status of fish caught in littoral waters or from other, more remote stocks. The growth of aquaculture and other developments changed this situation, including in relation to the rapid accumulation of evidence on incidents of disease caused damage in aquaculture and wild stocks, in part reflecting the commercial asset value of privately owned stocks.

[51] The 1983 Guidelines, the 1988 Conditions and the 1996 Requirements, paragraph .
[52] Paragraph 2.14.

4.30 Australia stated that the measure at issue was the 13 December 1996 Decision of the Director of Quarantine, which was that quarantine restrictions on imports into Australia of uncooked salmon product from Canada and the United States should not be permitted entry at the present time, following an import risk analysis. This decision derived from the exercise of authority by the Director of Quarantine in accordance with QP86A. In essence, the December 1996 decision meant that a permit would *not* be issued for importation of uncooked salmon for the purposes of free circulation within Australia for commercial consumption. This measure was applied within the meaning of paragraphs 1(a) and (b) of Annex A of the SPS Agreement as a measure applied for the purposes of protection of animal life and health which affected international trade within the meaning of Article 1.1 of the SPS Agreement. The protection of human life or health was not an issue in this dispute.

4.31 **Canada** noted that Australia's claim that the "measure" was the December 1996 decision by the Director of Quarantine limited the scope of the measure to wild, ocean-caught Pacific salmonids from Canada and the United States. However, the Terms of Reference for the current Panel extended to *all* fresh, chilled and frozen salmon from Canada.[53] The Request for the Establishment of a Panel had made it clear that Canada's claim was not limited to wild, ocean-caught Pacific salmon. The matter set out in the Request was "measures prohibiting the importation of fresh, chilled or frozen salmon" through the application of QP86A and any amendments or modifications made thereto. Thus, although the December 1996 decision fell within the Terms of Reference, it did not exhaust them. In other words, while the 1996 Decision dealt only with wild, ocean-caught Pacific salmonids, the Terms of Reference covered all fresh, chilled or frozen salmon.[54] The scope of Canada's complaint covered the following species:

Pacific[55]	*Oncorhynchus gorbuscha*	pink salmon
salmon	*Oncorhynchus keta*	chum salmon
	Oncorhynchus kisutch	coho salmon
	Oncorhynchus nerka	sockeye salmon
	Oncorhynchus tshawytscha	chinook or king salmon
	Oncorhynchus mykiss	steelhead/rainbow trout
	Salmo salar	Atlantic salmon

In Canada, only *adult* salmon is harvested for export. The importation of live salmon was not an issue in this case. Live salmonids and their genetic material had not been approved for importation into Australia since the promulgation of QP86A in 1975.[56]

4.32 However, if the Panel were to find that the measure at issue was the 1996 Decision, Canada argued, in the alternative, that Australia had violated Article XI of GATT for the reasons outlined in paragraph 4.228.

4.33 Furthermore, Canada maintained that paragraph 1(b) of Annex A was not relevant to the measure in question. Canada noted that in the Final Report there had been no mention of assessing risks to salmon from disease-causing organisms in food, nor could it be expected that such an assessment be made when the product in question was intended for human consumption. The first introductory paragraph of the Final Report stated that the main issues discussed were, *inter alia*, "the

[53] WT/DS18/2.
[54] Table 1.
[55] The first five species are known collectively as "Pacific salmon". Most harvested Pacific salmon is wild, ocean-caught. Almost all Atlantic salmon is farmed, including on the Pacific coast.
[56] Final Report, p.5.

likelihood of disease entry and establishment" and "the consequences that may arise from that disease entry and establishment".[57]

(c) The disease agents at issue

4.34 **Australia** stated that the number of disease agents at issue depended on the scope of the dispute and the specific products being addressed. The initial scope of the risk assessment was uncooked salmon from both Canada and the United States. The Final Report identified 24 disease agents at issue, of which at least 20 disease agents exotic to Australia were identified as present or potentially present in adult, wild, ocean-caught Pacific salmon of Canadian and US origin. It was important to put any discussion on the number of disease agents at issue into the context of the specific product, for example whether reference was being made to Pacific, Atlantic or all products.

4.35 The risk at issue was to the health of fish, particularly salmonids and salmoniforms[58], as a potential consequence of the entry or spread of one or more of at least 20 disease agents likely to be present in uncooked wild, ocean-caught Pacific salmon of Canadian (and US) origin. The risk was identified as the potential consequences of entry, establishment or spread of exotic diseases, including biological and economic consequences, for the life and health of live fish in Australia's Territory. This included the economic consequences of the impact of disease entry, establishment or spread in regard to the economic asset value of salmonid aquaculture and recreational fisheries, the biological value in regard to native salmoniforms in the built environment and extended to the quality premiums that were commanded for Australian uncooked salmon in export markets. Australian environmental conditions and the geographical concentration of commercial salmonid aquaculture left Australia significantly exposed to the impact of exotic disease establishment. Salmon had been identified in Australian scientific studies as coming within the "high risk" category in respect of exotic diseases. Salmonid recreational fisheries added significant economic benefit to regions in southern Australia, in addition to the social asset value to the population. Australia confirmed that the diseases were not of concern from a human health perspective, but that they related to the potential consequences associated with the importation of salmon for human consumption, including the pathways by which events might occur. As noted in the Final Report (pages 29 and 30) the product proposed for importation was intended for human consumption. Although most was likely to be consumed by humans the product might be used for purposes other than human consumption. The form of the product could have an impact on its final use; other possible end uses included pet feed, bait and fish feed and disposal as scrap. In this context, Australia noted that Dr. Rodgers had confirmed that salmon were scavengers.

4.36 Australia observed that, as a general rule, salmonids (salmon and trout) would be more likely to carry salmonid diseases than non-salmonids. Due to the commercial importance of salmon, the amount of science documented on salmonid disease was quite extensive when compared to other fish species, but when compared to the knowledge built up over centuries of terrestrial animal production and medicine, this total amount was small and patchy. The gaps in data were compounded by the amount of interaction between disease agents, their hosts and the environment. Australia noted that there was a difference between "known to occur" and "may occur". For many diseases there was scientific data to support the likely presence of the pathogen in salmon, though for a number of reasons the pathogen might not yet have been isolated from adult ocean-caught salmon. There were difficulties associated with growing and identifying pathogens from fish in the carrier state and the presence or absence of monitoring and surveillance programs for the disease agents. The identification of an agent in a particular host would also reflect the intensity of the testing and the sensitivity of the methodology used. When an outbreak of disease occurred, scientific resources

[57] Ibid., "Purpose of Paper", p.3.

[58] Salmoniforms is the common name for the Order Salmoniformes. Salmonids is the common name for the Family Salmonidae within the Order Salmoniformes.

tended to give priority to control and eradication rather than identifying the source of the disease or transmission possibilities.

4.37 Australia noted that, in addition to the identification of disease agents, disease transmission would depend on many factors, including scientific evaluation of the following:

(i) source of product;
(ii) number of different disease agents of quarantine concern that may be found in a species;
(iii) prevalence of the agent in source population (whether naturally present, whether infection recognised under experimental or unusual circumstances;
(iv) relationship between the agent in the host and that found in the salmon in question (whether strains are specific to the host, the species that the strains infect naturally, the circumstances under which the salmonids would be affected);
(v) number of agents present and their tissue distribution;
(vi) impact of processing on viability of agent;
(vii) comparative amount that will be imported (total risk depends on volume imported);
(viii) likely patterns of use in the importing country;
(ix) likely manner of preparation and its impact in regard to the number of infectious agents present (for example, whether more likely to be eaten raw or cooked);
(x) likely means of disposal; and
(xi) consequences that would follow from introduction of the disease.

4.38 **Canada** argued that Australia had not indicated what disease agents/diseases identified in the Final Report were "addressed by" Australia's measure. Canada supported the comment of the United States in its "Third Party Oral Statement" that Australia seemed unable even to make up its mind as to how many disease agents were of concern. Australia first referred to "20 or more diseases under consideration," (paragraph 47 of Australia's first submission), but then in the next sentence referred to "a possibility that up to 20 disease agents exotic to Australia may be present in Pacific salmon products". This would apparently limit the number of disease agents of concern to no more than 20. In the next paragraph, however, Australia listed 21 disease agents without identifying which 20 of these were of concern (paragraph 48 of Australia's First Submission). Australia next referred to "the 23 identified disease agents" that were"'at issue" (paragraph 110 of Australia's First Submission). Australia never identified which 23 agents these were. Thus, even after Australia had done what it purported to be a risk assessment, it could not or would not state which disease agents were the basis of its measure.

4.39 Canada argued that when the Panel asked Australia how many and which diseases were addressed by its measure, Australia presented a list of 24 disease agents "of concern". This list included infectious salmon anaemia virus (ISA), which was never mentioned before, but no longer included Kudoa thyrsites, which was included in the list of diseases set out in the Final Report. Moreover, the list of disease agents of concern did not specify which disease agents were actually *addressed* by Australia's measure. This was due to the failing of the Final Report to assess the likelihood that each of the diseases Australia had identified as being "of concern" would actually establish in Australia as a result of the importation of uncooked Canadian salmon. Thus, Australia had begun its Final Report with the premise that 24 diseases or disease agents might pose a risk and concluded exactly the same way. In Canada's view, this was one of the reasons why the experts advising the Panel considered the Final Report to be nothing more than a "hazard identification".

4.40 Canada maintained that not more than 19 of these disease agents of concern to Australia were known to occur in wild or farmed salmon from Canada. Furthermore, some strains of four of these

disease agents were endemic to aquatic animals in Australia.[59] With respect to *adult, wild ocean-caught Pacific salmon*, for which Australia had performed a risk assessment, Canada argued that only four disease agents were known to occur in that category of salmon (Table 4).

4.41 **Australia** noted that the number of disease agents and the issue of whether they were exotic or non-exotic to Australia needed to be put into context in regard to strains of disease agents, as provided in the OIE Code. Furthermore, as earlier indicated, the precise number of disease agents at issue depended on the product being discussed. In regard to Pacific salmon, there were at least 20 disease agents of concern, but if considering all salmon, the number would be 24. The Final Report addressed 24 disease agents, it did not claim that there were 24 disease agents at issue in regard to wild ocean-caught Pacific salmon.

TABLE 3

Disease Agents of Concern to Australia

#	Disease Agent	Known to occur in any of the five categories of salmon from Canada (Note 1)			Endemic to Australia
		Disease	According to ALA: (Note 2)	According to CAN:	
1	*Aeromonas salmonicida* (typical strain)	furunculosis	YES	YES	
	Aeromonas salmonicida (atypical strain)	various names such as goldfish ulcer disease	YES	YES	X (some strains)
2	*Edwardsiella tarda*	edwardsiellosis	YES	YES	X
3	**Piscirickettsia salmonis*	piscirickettsiosis	YES	YES	
4	**Renibacterium salmoninarum*	bacterial kidney disease (BKD)	YES	YES	
5	*Vibrio ordalii* and *V. anguillarum*	vibriosis	YES	YES	X V. anguillarum (some strains)
6	*Vibrio salmonicida*	Hitra disease or coldwater vibriosis	YES	YES	
7	*Yersinia ruckeri*	enteric redmouth disease (ERM)	YES	YES	X (some strains)
8	erythrocytic necrosis virus	viral erythrocytic necrosis (VEN)	YES	YES	

[59] *Aeromonas salmonicida* (some atypical strains), *Edwardisiella tarda*, *Yersinia ruckeri* (some strains) and *Vibrio anguillarum* (some strains).

TABLE 3

Disease Agents of Concern to Australia

#	Disease Agent	Known to occur in any of the five categories of salmon from Canada (Note 1)			Endemic to Australia
		Disease	According to ALA: (Note 2)	According to CAN:	
9	*Herpesvirus salmonis* type 1	-	NO	NO	
10	†infectious haematopoietic necrosis virus (IHNV)	infectious haematopoietic necrosis (IHN)	YES	YES	
11	*infectious pancreatic necrosis virus (IPNV)	infectious pancreatic necrosis (IPN)	YES	YES	
12	Pacific salmon anaemia virus	erythrocytic inclusion body syndrome (EIBS)	YES	NO	
13	salmon leukaemia virus (SLV)	plasmacytoid leukaemia	YES	YES	
14	salmon pancreas disease virus	pancrease disease	YES	YES	
15	†viral haemorrhagic septicaemia virus (VHSV)	viral haemorrhagic septicaemia (VHS)	NO	YES	
16	*Enterocytozoon salmonis*	-	YES	YES	
17	*Loma salmonae*	-	YES	YES	
18	*Ceratomyxa shasta*	ceratomyxosis	YES	YES	
19	*Henneguya salminicola*	-	YES	YES	
20	*Myxobolus cerebralis*	whirling disease	YES	NO	
21	*Parvicapsula sp.*	parvicapsula disease	YES	YES	

TABLE 3

Disease Agents of Concern to Australia

#	Disease Agent	Known to occur in any of the five categories of salmon from Canada (Note 1)			Endemic to Australia
		Disease	According to ALA: (Note 2)	According to CAN:	
22	proliferative kidney disease agent (sometimes called PKX)	proliferative kidney disease (PKD)	YES	NO	
23	rosette agent		YES	YES	
24	*Infectious salmon anaemia virus (Note 3)		YES	n.a.	

Note 1: See the five categories in Canada's as set out in Table 1 (Canada's response to the Panel's Question 2 of 7 October 1997).

Note 2: In response to the Panel's question. "[w]hich of the identified diseases are known to occur in salmon from Canada? ...", Australia listed those diseases "currently known to occur in different subsets of Canadian salmon". Australia noted, *inter alia*, that the information reflected current knowledge (Australia's 7 October 1997 answer to the Panel's Question 2).

Note 3: This disease was identified after the issuance of the Final Report. Australia indicated that this disease was not brought to its attention until September 1997, following the presumptive diagnosis of the disease in New Brunswick salmon, which was announced by Canadian authorities in late 1997. See Australia's Rebuttal, p.31, p.33 as well as Australia's Responses to the Panel's Questions 1, 2, 11 and 25 of 7 October. It should be noted that this list of diseases does not include *Kudoa thyrsites*, which was one of the 24 diseases of concern in the Final Report (p.133). Canada notes this in their Comments on the experts' responses, of 18 December, p.10.

* OIE - Other Significant Disease (shaded)

† OIE Notifiable Disease (shaded)

n.a. Not addressed

TABLE 4
Disease Agents Known To Occur In:

	Adult , wild ocean-caught Pacific salmon according to **Canada** (4):	Wild caught Pacific salmon according to **Australia** (14)
Disease agents	*Renibacterium salmoninarum*	*Renibacterium salmoninarum*
	Infectious haematopoietic necrosis (IHN)	Infectious haematopoietic necrosis (IHN)
	Salmon leukaemia virus	Salmon leukaemia virus
	Henneguya salminicola	*Henneguya salminicola*
		Vibrio anguillarum and *V. ordalii*
		Yersina ruckeri
		Erythrocytic necrosis virus
		Piscirickettsia salmonis (?)
		Edwardsiella tarda
		Loma salmonae
		Ceratomyxa shasta (affected individuals die as juveniles ?)
		Aeromonas salmonicida (typical and atypical strain)
		Parvicapsula spp.
		Proliferative kidney disease agent (PKX)

Note 1: In Canada, only adult salmon are harvested for export.

Note 2: Australia claimed that the fact that a disease agent present in juvenile fish had not been identified in adult fish did not rule out the presence of that agent in adult fish.

Note 3: While Australia did not explicitly contest Canada's claim that only four diseases (shaded in the table above) are known to occur in adult, wild, ocean-caught Pacific salmon, Australia argued that there was a difference between "known to occur" and "may occur". As Australia had been obliged to make a judgement about risk in a highly uncertain field in the Final Report, it was misleading to imply that only those diseases *known to occur* were relevant.

Source: Parties' response to the Panel's Question 2 of 7 October 1997 (see Note 2 in Table 3).

4.42 Australia indicated that the Final Report (Section 3) included a stochastic assessment of the economic impact in relation to two diseases (Furunculosis and IHN), including the economic and technical feasibility of prevention and control. This demonstrated that Furunculosis (*Aeromonas salmonicida*) and Infectious haematopoetic necrosis virus (IHN) were diseases where the potential impact to Australian waters would be particularly high given that the entire salmon industry would probably cease operation in the event of disease outbreak. In addition, the introduction of Whirling

disease into Australia would substantially raise the costs of production of salmon in Australia and increase mortality.[60] Australia noted that Infectious salmon anaemia (ISA), a disease exotic to Australia, had recently been presumptively diagnosed in Canada (New Brunswick salmon). According to Australia, this disease had previously been thought to occur only in Norway. If the presumptive diagnosis were confirmed in Canada, it would demonstrate that the disease was capable of spreading despite strict controls imposed by importing countries. Australia further noted that Canada had not disagreed that there was a risk of disease spread through product for human consumption.

4.43 Australia stated that the Final Report had been obliged to make a judgment about risk in the face of considerable uncertainties resulting from extensive data gaps. Australia had sought from Canada, but not received directly relevant scientific information on endemic disease agents present in a major resource, pertaining to:

- prevalence of infection in adult, wild, ocean-caught Pacific salmon;
- impact of processing and handling on the infection;
- effectiveness of inspection at detecting infections;
- infectious dose; and
- route of infection.

In view of this dearth of information, the Canadian presentation of those diseases that might be found in adult, wild, ocean-caught Pacific salmon from Canada was a simplification of a very complex issue. Australia contended that, given the disease data gaps together with limitations in surveillance programs and testing protocols, it was misleading to concentrate only on those diseases that were known to occur. Accordingly, Australia pointed out that there was a difference between "known to occur" and "may occur". For example, the fact that a disease agent present in juvenile fish had not been identified in adult fish did not rule out the presence of that agent in adult fish. Equally, Australia contended that the fact that an agent had only been recorded from fresh water did not mean that the agent would not be carried in the same host species under marine conditions.

4.44 Of the total of 24 diseases of concern listed in the Final Report, Australia claimed that 14 of these disease agents might occur in wild caught Pacific salmon from Canada. The remainder had been included in the list as they were either found in US stocks; had been recorded to date only from the Atlantic coast of Canada; or had only been isolated from farmed salmon. For example, while Australia recognized that *Myxobolus cerebralis* (whirling disease) was not present in Canadian salmon, Australia argued that the disease was present in US stocks and could therefore be present in exports from Canada. As such *Myxobolus cerebralis* was considered in the risk assessment on adult, wild, ocean-caught Pacific salmon. Australia noted that Dr. Wooldridge supported the inclusion of any disease in a risk assessment for which there was reason to suspect that it was in the product.[61] In addition to the uncertainty presented by the above, the complexity of the issue had been further heightened by many product-related factors such as the spoilage of flesh, as seen with Henneguya salminicola. This spoilage had the potential for increased wastage of uncooked flesh and consequent increase in the likelihood of such infected product entering the water where susceptible species occur. Australia emphasised that in the context of quarantine, the concern was the dose needed to establish carrier status, which might be considerably lower than that required for actual clinical disease. Australia also noted that Canada had not contested the scientific evidence of the Final Report that all of the agents at issue, other than pancreas disease virus and *Vibrio salmonicida*, had been found in at least one age group of salmonids in the Pacific region.

4.45 Australia argued that although there was no definitive proof of the spread of fish diseases via fish products for human consumption, the potential for introduction of exotic pathogens in this

[60] Final Report, p.48 and pp.251-255.
[61] Wooldridge, Transcript, para. 107.

manner could not be discounted. Australia maintained that this lack of evidence must be viewed in the context of the factors that would minimize the likelihood of detecting the spread of a pathogen, should it occur. These factors included the prevailing situation where most salmon product was traded between countries where salmon diseases were already present. Delay between any incident introducing the agent and the recognition of the presence of the agent would further minimize the chance of relating disease introduction to product movement. The thoroughness and timeliness of disease surveillance and reporting as a factor contributing to the lack of evidence for pathogen spread through fish product for human consumption was also highlighted by Australia.

4.46 To support its argument for transfer of disease agents through product for human consumption, Australia cited examples of other products for human consumption, such as avian and mammalian tissues, known to have spread animal diseases. These included the numerous recordings of international transmission of animal disease through products for human consumption such as foot and mouth disease, African swine fever, classical swine fever (hog cholera), swine vesicular disease and Newcastle disease. Australia noted that the OIE International Animal Health Code included restrictions in respect of these diseases for the same reason. In addition, Australia contended that given both the difficulty of proving the spread of aquatic animal diseases through product and the very short history of aquatic animal medicine in comparison to its terrestrial animal counterpart, it would be prudent to consider that rather than being unlikely, it was probably only a matter of time and attention until there was definitive proof of the spread of aquatic animal disease via product for human consumption. Australia further supported this argument with evidence on previously exotic prawn viruses, responsible for the diseases Taura syndrome, whitespot and yellowhead, that had recently been found in the United States. Though the route of entry of these pathogens was unknown, the importation of farmed prawns for human consumption from South America and Asia where these diseases were endemic had been proposed as the source of the infection

4.47 With respect to Australia's concerns regarding disease surveillance and reporting, **Canada** recalled Dr. Rodgers' comments that:

> "One other aspect to consider [i.e. in assessing the degree of confidence of disease detection] is that regularly tested stocks are normally considered as a lesser risk than occasionally, or untested stocks, or products, since regular monitoring will provide a background database of information over time.
>
> ...
>
> "Unfortunately, this is rarely the case for wild populations of fish because regular monitoring programmes do not normally exist, unless diagnosis is related to the occurrence of large, noticeable mortalities. However, sampling returning anadromous salmonids in their freshwater phase is occasionally the exception."[62]

Canada indicated, however, that over the past 20 years it had developed an extensive programme of disease monitoring of its wild population of Pacific salmon, particularly adults returning to fresh water to spawn. These data had been provided to Australia and were included in Australia's Final Report. For example, between 1972 and 1993, Canada sampled:

- 21,495 returning anadromous salmonids for *Aeromonas Salmonicida* (atypical and typical);
- 21,999 returning anadromous salmonids for *Renibacterium salmoninarum*;
- 21,495 returning anadromous salmonids for *Yersinia ruckeri*;
- 21,495 returning anadromous salmonids for *Vibrio anguillarum* and *Vibrio ordalii*;
- 14,595 returning anadromous salmonids for infectious haematopoietic necrosis;

[62] Paragraph 6.91.

- 14,595 returning anadromous salmonids for infectious pancreatic necrosis; and
- 14,595 returning anadromous salmonids for viral haemorrhagic septicaemia.[63]

4.48 Canada further noted that ISA had been added to the list of diseases of concern to Australia during the Panel process, without a risk assessment. Furthermore, Australia had acknowledged that the disease had only been identified in adult *Atlantic* salmon farmed in New Brunswick.

4.49 In regard to the New Brunswick salmon, **Australia** noted that Canada's comments were valid only insofar as the product at issue in the dispute were limited to the Pacific product addressed in the Final Report. However, Canada claimed that the dispute extended to New Brunswick salmon.

(d) Article 1.1

> This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.
>
> *SPS Agreement, Article 1.1*

4.50 **Canada** observed that Australia's measure directly or indirectly affected international trade within the meaning of Article 1.1 of the SPS Agreement, however, Canada maintained that the measure was not "developed and applied" in accordance with the SPS Agreement and that it was therefore in violation thereof.

4.51 **Australia** agreed that the measure taken, as identified by Australia, was a sanitary measure for the protection of animal life and health within Australia's Territory and within the meaning of Article 1.1 of the SPS Agreement, but did not agree that the measure at issue was as described by Canada. Australia claimed that the Panel was not required to examine whether there had been a violation of Article 1 of the SPS Agreement, as Canada had not claimed a violation of this provision. As stated above, the measure was applied for the purposes of protection of animal life and health and affected international trade within the meaning of Article 1.1 of the SPS Agreement.

(e) Article 2.2

> Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.
>
> *SPS Agreement, Article 2.2*

4.52 **Canada** claimed that Australia was required to ensure that its ban on the importation of uncooked salmon was sustained by sufficient, relevant, scientific evidence, reflecting the risks Australia claimed would arise from the entry of salmonid diseases through the importation of uncooked salmon. There was a substantial body of relevant scientific evidence which made it clear that Australia had failed to ensure that its measure was "not maintained without sufficient scientific evidence". Therefore, Canada contended, Australia had failed to meet the fundamental obligations on the application of SPS measures, as set out in Article 2.2.

4.53 Canada recalled that the Appellate Body in *EC - Hormones* had considered that Article 2.2 and Article 5.1 of the SPS Agreement had constantly to be read together and that elements which

[63] Final Report pp. 137, 157, 175, 165, 191, 197, and May 1995 Draft Report, p.196.

defined Article 2.2 imparted meaning to 5.1.[64] The Appellate Body had concluded that the result of a risk assessment had to sufficiently warrant or reasonably support the sanitary measure at issue. There had to be a rational relationship between the scientific evidence disclosed in a risk assessment and the sanitary measure.[65] Canada argued that the foundation of any sanitary measure must be science, not protectionism or politics. Article 5.1 of the SPS Agreement required that a sanitary measure must be based on a risk assessment. Article 5.2 provided that Members must take into account available scientific evidence in assessing this risk. Thus, the heat treatment conditions set out in Australia's measure and the consequent ban on the importation of uncooked salmon had to be rationally supported by the available scientific evidence to achieve Australia's appropriate level of protection. Canada stated that there was no sound scientific reason for Australia to continue to maintain a heat-treatment policy that had the effect of banning the importation of uncooked Canadian salmonid products into Australia. In Canada's view, Australia's measure violated Articles 2.2, 5.1 and 5.2 of the SPS Agreement.

4.54 **Australia** argued that Article 2 of the SPS Agreement accorded basic rights and obligations to Members in respect of the application of sanitary measures referred to under Article 1 of the SPS Agreement. Article 2.1 enabled Australia to take sanitary measures which might be necessary for the protection of animal life and health, provided that the measures were not inconsistent with the provisions of the SPS Agreement.[66] Article 2 conferred a *basic right,* and Canada had therefore a higher burden of proof to establish a *prima facie* case that the conditions attached to Article 2.1 had not been met. Nevertheless, without prejudice to the question of burden of proof, Australia's contended that the measure was necessary and was not inconsistent with the SPS Agreement.

4.55 Australia noted that Canada's claims of violation of Article 2.2 were limited to the measure not being based on sufficient evidence. In the context of Article 2.2, Canada had *not* claimed that the measure was being applied beyond what was necessary to protect animal life. As had been noted by the Appellate Body in *EC - Hormones*, Articles 2.2 and 5.1 had constantly to be read together.[67] The Appellate Body had also noted:

> "... a panel charged with determining, for instance, whether "sufficient scientific evidence" exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks are irreversible ...." [68]

Australia maintained that there was sufficient scientific evidence to maintain the measure, which reflected Australia's appropriate level of protection. Canada's evidence related to opinions expressed about the absence of conclusive scientific evidence; this did not contradict the evidence on which Australia had based its measure.

Sufficient scientific evidence

4.56 **Canada** noted that in addition to Australia's alleged import risk analysis (paragraphs 2.27-2.30 refer), various studies and reports have considered issues relevant to the matter in dispute. In December 1992 the Working Group on Aquaculture, a Commonwealth/State/Territory Group commissioned background documents for discussion by the Australian and New Zealand Fisheries and Aquaculture Council. Technical Paper No.2, "Relationship Between Wild Fisheries and Aquaculture", studied the major positive and negative interactions between wild-fisheries and

[64] Op. cit, para. 180.
[65] Ibid., para. 193.
[66] Article 2.1 of the SPS Agreement: "Members have the right to take sanitary and phytosantiary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement."
[67] Op. cit., para. 180.
[68] Ibid., para. 124.

aquaculture. Possible objectives and recommendations were made, including in the areas of marketing, co-operation, education, environment, government and management. Technical Paper No.3, "Quarantine, Health and Movement", examined *inter alia*, the importation of fish and fish products (including salmonid products), interstate movement and disease control. The Paper set up a list of priorities which included the principles for the development of appropriate protocols for the importation of fish and fish products from overseas. The technical papers were prepared by consultants as background papers for the Draft National Strategy on Aquaculture.

4.57 In September 1994, the New Zealand Ministry of Agriculture and Fisheries Regulatory Authority published a report on "The Risk of Introducing Exotic Diseases of Fish into New Zealand through the Importation of Ocean-caught Pacific Salmon from Canada". The "1994 New Zealand Risk Assessment" on imports of wild, ocean-caught Pacific salmon from Canada concluded that "the overall risk of introducing diseases of salmon through the vehicle of headless, eviscerated, wild, ocean-caught Pacific salmon, appropriately certified by the Canadian Government authorities as to origin and grade, is negligible and poses no threat to either New Zealand's wild and farmed salmonid stocks or to non-salmonid fish stocks".

4.58 The Australian Quarantine and Inspection Service (AQIS) in 1992 commissioned a review of Australia's aquatic animal quarantine policies as a basis for a review by AQIS of its quarantine policies and procedures. The review was conducted by a scientific working party led by M.J. Nunn of the Bureau of Resource Sciences. Its report, "Aquatic Animal Quarantine in Australia - Report of the Scientific Working Party on Aquatic Animal Quarantine" (the "BRS Report") was released in 1995. This report concluded, *inter alia*, that the present restrictions on the importation of salmonid flesh for human consumption could not be justified and should be revised. The report also made a number of recommendations for AQIS to consider, including that: salmonid fish should be individually inspected for evidence of muscle, skin, visceral lesions or abnormalities, and should be certified as free of such by a competent government authority; unless other safeguards are taken to minimize possible risks, salmonid fish should be imported as eviscerated, filleted flesh to minimise possible contamination by exotic pathogens; databases on several aspects of aquatic animal health and disease should be developed; and that research was needed, for example, in regard to the inactivation of pathogens (by heat).

4.59 In order to facilitate the above-mentioned BRS Report, a consultant was commissioned to produce a detailed independent review of the scientific literature and Australian quarantine policies and practices for aquatic animals and their products. "Australian Quarantine Policies and Practices for Aquatic Animals and their Products: a review for the Scientific Working Party on Aquatic Animal Quarantine", by J.D. Humphrey, Bureau of Resource Sciences, was distributed in 1995 (the "1995 Humphrey Report"). This report concluded that there was little evidence to support a case that the importation of products derived from aquatic animals destined for human consumption presented a risk of establishment of exotic pathogens in the aquatic environment. It concluded that an inconsistency currently existed whereby fresh or frozen products derived from finfish other than salmonids might be imported without specific quarantine restrictions, whereas salmonid flesh was prohibited unless treated in a manner to inactivate potential pathogens. It also concluded that the current process of heating salmonid fish to inactivate potential exotic pathogens did not have a rational basis in view of the thermal stability of a number of pathogens of high quarantine importance, especially at the lower temperature ranges.

4.60 In response to requests for market access for salmon from Australia and the United States, New Zealand undertook an analysis of disease risks from wild and aquacultured salmonid products from a wide range of countries, issued in September 1997. The "1997 New Zealand Risk Analysis" considered in particular headed, gilled and eviscerated salmon, and included both a qualitative and a quantitative assessment. One conclusion of the quantitative assessment was that the upper 95 per cent confidence limits for the probability of Aeromonas salmonicida introduction per tonne of head-off, eviscerated, commercially-harvested, wild Pacific salmon from North America was 2.27×10^{-9} and for

farmed Atlantic salmon from Norway is. 5.48 x 10^{-8}. New Zealand concluded "[c]onsidering that the probability of an aquatic animal disease being introduced into New Zealand through imports of the commodity is likely to be negligible for most diseases and very low for others, continuing a prohibition on imports is inappropriate."[69] (emphasis in the original)

4.61 **Australia** observed that the studies referred to by Canada did not reflect official government policy. In December 1988, Australian government policy objectives on quarantine were set out in "Australian Quarantine - Looking to the Future: a Government policy statement", known as the "Cook Statement". This statement sets out Australia's long-term quarantine policy fundamentals and organization.

4.62 In October 1996, a report on "Australian Quarantine - A shared responsibility" was published by the Department of Primary Industries and Energy. This document (the "Nairn Report") set out a series of recommendations to the Australian Government. Following these recommendations, a program of aquatic quarantine reviews was established. A National Task Force on Imported Fish and Fish Products was commissioned by the Australian Government to prepare a paper that would enable a coordinated response to several current aquatic animal health issues. The "Task Force" had representatives from the Federal and State levels of the Government, industry, recreational fisheries, conservation groups and the scientific community. "A Report into the implications arising from aquatic animal imports", also called the "Report of the National Task Force", was published in December 1996. In August 1997, the Government's response to the Nairn Report and the Report of the National Task Force was published as "Australian Quarantine: A Shared Responsibility - The Government Response". This document set out current Australian quarantine policy.

4.63 Australia also contended that the economic study by the Industry Commission on "Australian Atlantic Salmon - Effects of Import Competition", dated 20 December 1996, was highly pertinent.

4.64 More importantly, Australia indicated that it was the practice of the Australian government to commission studies by consultants at the policy formulation stage. It was also the practice of the Australian government, at the policy development stage, to commission draft reports containing recommendations designed to stimulate public response. These reports often made proposals for change, which resulted in public responses by all stakeholders. However, official decision makers often rejected the draft recommendations or accepted them only partially or in modified form. The various studies and reports cited by Canada, and the recommendations they contained, had to be seen in this light. Furthermore, Canada had selectively quoted from these reports, giving an inaccurate rendition of factual and scientific circumstances. Nor had these reports been subject to the same scientific scrutiny as the Final Report.

4.65 **Canada** argued that the Humphrey Report, the BRS Report, and Technical Paper No. 3, all commissioned by Australia, represented thorough scientific analysis and opinion that together constituted significant evidentiary material before the Panel. These reports concluded that there were no confirmed examples of diseases that had been established in aquatic animal populations as the result of the introduction of fresh or frozen product from aquatic animals including salmonids; that there was little scientific evidence to support a case that the importation of products derived from aquatic animals including salmonids destined for human consumption presented a risk of establishment of exotic pathogens in the aquatic environment; that evisceration of fish was a reliable means of preventing the spread of aquatic animal pathogens through the international trade in aquatic animals; and that a continued ban on the importation of uncooked salmonid products was scientifically difficult to justify. The reports showed that Australia's measure was without scientific foundation. Australia had not questioned the credibility of the scientific analysis and conclusions contained in the reports. Nor had Australia presented any alternative scientific evidence that

[69] M. Stone, S. MacDiarmid, and H. Pharo, "Import Health Risk Analysis: Salmonids for Human Consumption", New Zealand Ministry of Agriculture Regulatory Authority, 1997, p. 6.

contradicted the conclusions contained in the reports. Rather, Australia discredited these reports only because they did not represent official government policy.

4.66 **Australia** argued that Technical Paper No. 3 was commissioned as a discussion paper for the purpose of assisting an Australian aquaculture working group to identify potential issues and options for developing policies and measures to address potential concerns in relation to aquaculture in general. It did not have the purpose of a comprehensive examination of salmonid issues and did not include comprehensive detail on salmonid health. Australia noted that the purpose of the BRS Report was to identify issues and possible options as part of a review of Australia's aquatic quarantine policies. Again, the authors did not have the mandate to undertake a risk assessment, nor to limit the scope of the study to salmon. The Humphrey Report was commissioned to assist the authors preparing the BRS Report, hence it formed part of the BRS Report. To the extent that these papers and reports contained relevant, valid and uncontradicted scientific data, it was drawn upon in the salmon risk assessment process.

4.67 **Canada** observed further that Australia had acknowledged in the Final Report that there was no evidence to link trade in salmon products for human consumption to spread of diseases.[70] Hence, Canada argued there was substantial epidemiological evidence in respect of the lack of spread of the diseases through international trade in uncooked salmon.[71] The Final Report had asserted that:

> "The potential for pathogenic exotic organisms to enter Australia via imports of salmon from Canada and the United States is a risk and for some of the disease agents under consideration it is *probable* that if commercial quantities of product were imported *some* of the exotic agents would be introduced with the product. This must be considered against the background that there is *no epidemiological evidence recorded in the literature* of disease having been spread via trade in salmon products for human consumption although it must be acknowledged that in practice the occurrence of such events would be difficult to determine."
>
> ...
>
> "Although *there is no scientific evidence for the spread of the disease agents under consideration* via product for human consumption, it is possible that such events, if they have occurred, would be relatively uncommon and extremely difficult to recognise."[72]

4.68 Canada noted that the Final Report acknowledged that, since the May 1995 Draft Report, despite further inquiries, no reports had been found in the scientific literature of transmission of disease via salmon product for human consumption[73] and that the scientific evidence did not sustain the conclusion that disease agents were spread through trade in eviscerated fish.[74] On the contrary, there was ample scientific evidence, consistent with a substantial body of epidemiological data, to show that Australia had not ensured that its ban on the importation of uncooked salmon was maintained on the basis of sufficient scientific evidence.

4.69 Canada stated that in both the Final Report and the May 1995 Draft Report, the importance of the sequence of events that had to be met for an exotic disease to become established in Australia had

---

[70] Final Report, p.364. ("There is no evidence to link trade ...").

[71] Canada cited a number of reports, including: the 1994 New Zealand Risk Assessment, pp.5-6; May 1995 Report, p.i, p.iii, p.218; Humphrey Report, pp. 89, 117; Nunn Report, p.34; P. de Kinkelin and R.P. Hedrick, "Dilemmas of Disease Control Policies" (1991), 11, *Bulletin of the European Association of Fish Pathologists 3;* Technical Paper No.3.

[72] Final Report, p.66 and p. 67.

[73] Ibid., p.67, 37, p.349 "Despite further inquiries no reports ...".

[74] Ibid., p. 47 for *Ceratomyxa shasta* and *Henneguya salminicola*; p.44 for IHNV. See also New Zealand Import Risk Assessment, p. 20 for IHNV.

been noted.[75] For the first step in the sequence of events, "the source fish must contain exotic pathogens", Australia had acknowledged in the Final Report that there was no evidence that several of the pathogens at issue had ever been found in wild, ocean-caught Pacific salmon (Table 5). In its response to the Panel's additional questions (Question 3)[76], Australia had also acknowledged that "the 'known' presence of an agent with a particular host by itself is not an accurate indicator of the likelihood of disease introduction, establishment or spread".

4.70 Canada argued that in examining the likelihood that every step in the sequence of events would occur, in light of the scientific evidence on the health status of North American salmonids, the May 1995 Draft Report had concluded that importation under specified conditions of wild, ocean-caught Pacific salmon from Canada and the United States for human consumption did not present a significant risk of the introduction and establishment of an exotic disease or strain of a disease to Australia.[77] This conclusion was consistent with the 1994 New Zealand Risk Assessment [78] and had been supported by comments from peer reviewers.[79] Canada noted, furthermore, that both Drs. Wooldridge and Rodgers had stated that the May 1995 Draft Report was a qualitative risk analysis. Australia had acknowledged this, stating that the 1995 Draft Report fulfilled the requirements under Article 5. Yet the Final Report had rejected these two conclusions, reached independently of each other. Moreover, the Final Report did not show that the scientific evidence in the May 1995 Draft Report was incorrect or not appropriate. Neither did the additional scientific references included in the Final Report provide evidence that importations of uncooked salmon would result in the introduction of each or any one of the pathogens of concern. Further aggravating the situation, Australia had left out data in the Final Report which was present in the May 1995 Draft Report; a fact that both Drs. Wooldridge and Rodgers noted in their submissions to the Panel. Nonetheless Australia's Final Report had come to exactly the opposite conclusion of the May 1995 Draft Report in prohibiting the importation of uncooked salmon under any condition. In Canada's view the only conclusion that could be drawn was that extraneous factors, other than scientific evidence, were at the root of Australia's measure.

4.71 Canada refuted Australia's demand that Canada provide scientific proof that disease would not be transmitted through eviscerated product. Canada countered that it would never be able to meet the scientific burden Australia was imposing; as Dr. Burmaster had noted, "one can never prove the negative in science".[80]

---

[75] Ibid., p.51; May 1995 Draft Report, p.215.

[76] The Panel's Additional Questions to the Parties of 8 December 1997.

> Question 3: Which aquatic animals other than salmonids, that are known to be carriers of any, several or all of the 24 diseases of concern to Australia, does Australia import? For such imports, please indicate (i) the purpose(s) and subsequent use thereof (e.g. for human consumption, bait), (ii) the approximate volume currently imported and that imported over the last 20 years (iii) the form of the product allowed for importation (i.e. eviscerated, frozen) and (iv) the specific sanitary measures applied to these non-salmonids, other than those identified in your response to Question 4 (c) and (d) of 7 October (under what specific conditions can, for example, Pacific herring be imported as bait fish).

[77] May 1995 Draft Report, p.223 (Conclusions), see also paragraph 4.172.

[78] 1994 New Zealand Risk Assessment, p.2.

[79] Tore Håstein (July 1995) and A.H. Mc.Vicar (August 1995).

[80] Burmaster, Transcript, para. 250.

TABLE 5
Occurrence Of Diseases In Wild, Ocean-Caught Pacific Salmon
(Excerpts from the Final Report)

Disease Agent	Final Report
Aeromonas salmonicida (typical strain) *Aeromonas salmonicida* (atypical strain)	p.38 . "Its presence has not been reported in wild, adult, marine Pacific salmon in North America, nor elsewhere in the North Pacific Ocean."
Yersinia ruckeri	p.42. "Disease due to *Y. ruckeri* infection has not been reported in adult, wild, marine Pacific salmon ... "
Piscirickettsia salmonis	p.40. "*P. salmonis* has not been observed in adult, wild, marine Pacific salmon, but it has been seen in captive Pacific salmon stock held in sea water in the region."
Salmon pancreas disease virus	p.45. "Although pancreas disease has not been reported in wild, adult, marine Pacific salmon, as the causal agent has only recently been identified as a virus the likelihood that Pacific salmon could be infected cannot be predicted with any certainty."
Viral haemorrhagic septicaemia virus (VHSV)	p.45. "The virus has not been identified in adult, wild, marine Pacific salmon, but has been identified in spawning salmon, perhaps as a result of contact with cod and/or herring in marine waters."
Enterocytozoon salmonis	p.46. "Of the species currently under consideration, natural infection has only been identified in chinook salmon and has not been reported in adult, wild marine Pacific salmon."
Loma salmonae	p.46. "Infection may occur at sea, but has not been reported in adult, wild, marine Pacific salmon."
Herpesvirus salmonis type 1	p.43. "Infection has not been detected in the Pacific salmon species under consideration, nor has it been detected in salmon in British Columbia or Alaska."
Infectious haematopoietic necrosis virus (IHNV)	p.43. "IHNV has been recovered on one occasion from a group of fish returning to spawn, and this was regarded as an unusual event ... All other attempts to isolate the virus in adult, wild, marine Pacific salmon have been unsuccessful."
Infectious pancreatic necrosis virus (IPNV)	p.44. "Extensive sampling of wild adult Pacific salmon in British Columbia and Alaska failed to detect the presence of IPNV."
Pacific salmon anaemia virus	p.44. "Infection with PSAV has not been reported in adult, wild, marine Pacific salmon."
Myxobolus cerebralis	p.48. "Infection has not been reported in Canada or Alaska. ... Very few if any adult marine salmonids in the Pacific rim of North America would be expected to be infected with *M. cerebralis*."
Rosette agent	p.49. "It has been recognised in farmed salmonids, but not, to date, in adult, wild, marine Pacific salmon."

Source: First submission of Canada, pp.96-97; Final Report, pp.38-49.

4.72 In order to determine what conclusions Australia might have reached had it used the data available to it, Canada had commissioned David Vose, an expert with considerable experience in animal import risk assessments, to prepare an assessment of the likelihood that imports of uncooked Canadian salmon would result in the establishment of the two disease agents identified by the May 1995 Draft Report as posing the greatest risk of introduction, *Aeromonas salmonicida* and *Renibacterium salmoninarum*. Canada instructed Mr. Vose to consider only information cited in the May 1995 Draft Report or the Final Report or that was otherwise available to Australia when it was preparing its reports. Canada observed that both Drs. Wooldridge and Burmaster considered the Vose Report to be "very relevant"[81] to the case at hand. The Vose Report concluded that [82]:

- a salmonid would need to consume 400,000 kg. of Canadian salmon scraps to be 50 per cent certain of receiving an infective dose of *Aeromonas salmonicida* or 7,800 kg. of Canadian salmon scraps to be 50 per cent certain of receiving an infective dose of *Renibacterium salmoninarum*;

- the dilution rates in dumps containing Canadian salmon scraps which might carry the two disease agents would be so high as to make the risk associated with water run-off negligibly small;

- the maximum average levels of the two disease agents in waste water due to imports of Canadian salmon would be billions of times lower than the levels necessary to cause an infection; and

- one would have to wait hundreds of thousands or even millions of years to be 50 per cent sure of at least one lesion containing the disease agents entering Australia in imported Canadian salmon and that lesion would then have to complete intact all of the remaining post-entry steps in order to lead to possible disease establishment.

4.73 **Australia** drew attention to its request that the Vose Report be excluded as evidence.[83] The Vose Report had been amended overnight and the revised version was not communicated to Australia until 6 February 1998. Australia had subsequently provided initial written comment which contested some of the science, but Canada had contested the admissibility of this comment as evidence. Australia had noted that the Vose Report and other studies had not been subjected to the same WTO legal scrutiny as the Final Report, nor did they purport to be risk assessments in the sense of the SPS Agreement. Canada was ignoring requirements of due deference and was requesting the Panel to undertake a *de novo* review.

4.74 Nonetheless, without prejudice to Australia's concerns about its admissibility as evidence - and also without prejudice to Australia's concerns that this paper had not been subject to the same scientific scrutiny (including scientific peer review) as the Final Report, Australia argued that the Vose Report attempted to assess only the risk of introduction and establishment of only two of the 24 agents of concern and did not attempt to assess the consequences of introduction. Australia agreed that it provided a reasonable approach to developing a quantitative model of the risk of *introduction* of these two agents, if sufficient relevant date were available. However, Australia stressed that the paper's attempt at a quantitative assessment of the risk of disease *establishment* was incomplete in that it attempted to assess for only two of the 24 agents of concern only one of a potentially large number

[81] Wooldridge, Transcript, para. 255, and Burmaster, para. 257.

[82] "Quantitative analysis of the risk of establishment of *Aeromonas salmonicida* and *Renibacterium salmoninarum* in Australia as a result of importing Canadian ocean-caught salmon", David Vose, (the "Vose Report"), December 1997.

[83] Paragraph 4.4.

of pathways by which contaminated or diseased imported product could reach susceptible host fish in Australia. The particular post-entry exposure pathway that the Vose Report attempted to model (i.e. exposure via contaminated groundwater from garbage containing contaminated or diseased imported product) ignored other higher risk pathways associated with the disposal of scraps as waste (e.g. the risk of spread via excess run-off and floods, scavenging birds such as seagulls, or the entry of raw or poorly cooked scraps to waterways by other means, including restaurant scraps, picnickers, or people deliberately feeding scraps to birds or fish). Australia also raised concerns regarding the paper's omission of consideration of the risk of introduction and establishment of *Aeromonas salmonicida*, the causative agent of furunculosis, through skin mucus of salmon. What the Vose Report *did not* attempt to model was of considerably more importance than the details of what it did attempt, and it confirmed Australia's view that a fully quantitative approach for evaluating the likelihood of establishment and spread of exotic pathogens imported with the product at issue was not feasible or appropriate. Australia noted again that it was under no obligation to attempt a quantitative risk assessment and reiterated concerns it had previously expressed about the difficulty and limitations of a quantitative approach in complex scenarios where there were significant gaps in information.

4.75 Australia contended that much of what Canada claimed to be substantial scientific evidence simply related to an absence of reports. It did not relate to directed scientific work aimed at detecting whether something occurred or not. Spread, if occurring through product, in countries where the disease agent existed was unlikely to be attributed to the movement of product, frequently because of the delay between any incident introducing the agent and the recognition of the presence of the agent. Also, once a presumptive diagnosis was made of a newly identified disease agent, the bulk of scientific work was concentrated on control and eradication. Canada's evidence was in the realm of assertion, drawing on a statement in a New Zealand risk assessment and selective quotations from various Australian studies, which did not contradict the science of the Final Report. The "substantial epidemiological evidence" cited by Canada related solely to opinions expressed in reports and studies, much of this relating to levels of risk. Some of this opinion had since stood corrected in relation to the recent presumptive diagnosis of ISA in New Brunswick salmon, which had led to stock eradication and other quarantine measures, at significant financial cost.

4.76 Australia argued that in order to establish whether a measure was "necessary", reference had to be made to the appropriate level of protection and whether there was a risk that the appropriate level of protection would not be achieved if the product (uncooked salmon) were to be imported in any form. Australia had not claimed that there needed to be irrefutable scientific evidence that an event would not occur, rather that "sufficient scientific evidence" was relevant to the appropriate level of protection. Australia had identified through scientific research that there was a potential for a number of disease agents exotic to Australia to be present in uncooked Canadian salmon. If product entered, disease agents would enter. This was not in dispute. On the basis of available scientific information, it had been determined that there was a likelihood that those disease agents could be present in the product on arrival in Australia even if the product had been subject to certain forms of treatment other than heat treatment. In addition it had been established that the entry, establishment or spread of those disease agents could occur through certain identified pathways. Options for managing the risk by means other than restrictions on imports had been addressed but had not been considered to be adequate to achieve the appropriate level of protection. It had been concluded that there was an unacceptable level of risk associated with the importation of the product in question. For these reasons, Australia argued that it determined that the measure was necessary to achieve its appropriate level of protection.

4.77 Australia argued that "sufficient scientific evidence" did not require a demonstration of conclusive scientific evidence. Australia was entitled to adopt a cautious approach. There was sufficient scientific evidence of a risk of disease entry, spread or establishment to maintain its measure.[84] The SPS Agreement did not set value or volume thresholds nor categorize obligations

[84] Final Report, pp. 7-10 outlines the process used to gather information.

according to trade or economic concerns. There were no limits to the type or scope of a measure used by a Member; the SPS Agreement did not preclude Members from maintaining import prohibitions if such measures were necessary for the protection of life and health. The evidence presented by Australia was sufficient for the purposes of determining that the appropriate level of protection could not be achieved if uncooked salmon from Canada were permitted entry.[85] Australia was not obliged to demonstrate that there was conclusive evidence. Canada's arguments were based on opinions expressed about the absence of conclusive evidence. Australia had pointed out the significant gaps in scientific research in salmon and other aquatic animals compared to the work undertaken on terrestrial animals, where products for human consumption were known to have spread disease. In terms of "sufficient scientific evidence", the Appellate Body in *EC - Hormones* made it clear that a risk assessment did not necessarily have to embody only the view of the majority of the relevant scientific community and Members were entitled to take decisions notwithstanding scientific uncertainty.[86]

4.78 Australia summarized that the available scientific evidence indicated that:

- at least 20 disease agents, exotic to Australia were potentially present in adult, wild, ocean-caught Pacific salmon which might be imported into Australia from Canada;

- some or all of these disease agents, together with some other disease agents present in other Canadian salmon populations, could enter, establish or spread in Australia through the importation of uncooked salmon of Canadian (or United States) origin; and

- if established, the disease or strains of disease agent were unlikely to be amenable to eradication, with serious economic and environmental impact.

4.79 Australia argued that for most of the disease agents, the information necessary to establish the likelihood of their entry through the importation of uncooked Canadian salmon was lacking. The data that was available was often fragmentary or incomplete.[87] The gaps in information were significant to quarantine decision making. This had not been challenged by Canada and the gaps in data had been acknowledged by the experts advising the Panel. The experts referred to the contribution of the Final Report in this regard. Improved epidemiological evidence was particularly needed to support assertions of the safety of uncooked products. Neither had Canada provided any alternative or supplementary scientific evidence which would refute the conclusion, based on available scientific evidence, that there was a risk of entry, spread or establishment of the diseases at issue. This had furthermore been confirmed by the experts advising the Panel. Canada's evidence did not relate to science, but to level of risk. Gaps in scientific knowledge did not equate to insufficient scientific evidence. If those gaps were filled and provided evidence which might modify the basis for conclusions, Australia would be prepared to review the information, as made clear in the Final Report. To date, Canada had been unable to provide directly relevant scientific evidence on endemic disease agents present in a major resource, including information pertaining to: prevalence of infection in adult, wild, ocean-caught Pacific salmon; impact of processing and handling on the infection; effectiveness of inspection at detecting infections; infectious dose; or route of infection.

4.80 Australia contended that the absence of evidence of spread was not equivalent to evidence that spread did not occur.[88] In this regard, Australia claimed that the recent introduction of prawn diseases, yellowhead, whitespot and Taura syndrome into North America provided strong evidence that products destined for human consumption could be responsible for the spread of aquatic animal

[85] References cited in the Final Report.
[86] Op. cit., paras. 193 and 194.
[87] Final Report, pp.VIII-IX.
[88] Humphrey Report, p.117.

diseases. These diseases had a substantial impact on the American prawn industry. In regard to evidence presented in Table 5, Canada had not included all disease agents considered in the Final Report, thus the information was not a reliable indicator for the totality of the risk being addressed. Finally, Canada had not disagreed that there was a risk of disease spread through product for human consumption.

4.81 Australia noted that it was a misrepresentation of the conclusions reached in the Final Report to state that they were the opposite of those reached in May 1995. The recommendation from the May 1995 Draft Report had been among the five options which had been considered in the Final Report. The recommendations of the May 1995 Draft Report represented the next greatest level of risk when compared to recommendations in the Final Report. The Final Report incorporated the science of the May 1995 Draft Report but could not be described as a reversal of a policy position. Rather, it had been decided to adopt the next more conservative option, consistent with Australia's appropriate level of risk.

4.82 **Canada** refuted Australia's reference to "advances in scientific knowledge" in respect of new pathogens, prawn viruses, biofilms and the identification in Australia of the alternate host of whirling disease pathogen. When questioned by the Panel, Dr. Rogers had said that all experts advising the Panel agreed that they were not aware of any information advances in scientific knowledge that would justify a change in the conclusions from the May 1995 Draft Report to the Final Report.

4.83 According to Canada, none of the cited information constituted advances in scientific knowledge that would justify a change in the conclusions. Regarding pathogen identification, Australia had acknowledged that the information about ISA, Erythrocytic necrosis virus and VHS came *after* the Final Report. The apparent identification of these pathogens in Atlantic salmon had no relevance to Australia's Final Report, which examined only wild, ocean-caught Pacific salmon.

4.84 Canada noted that with regard to prawn viruses, Australia had acknowledged in the Final Report that the route of entry of the virus into the United States was unknown and that the relevance of this example was limited.[89] Australia, in attempting to explain why non-salmonids hosting several of the same disease agents common to salmon were permitted entry into Australia (while salmon was not), had argued that with regard to the carriage of organisms by species of fish other than salmonid, it was difficult to draw any conclusions without having first undertaken any risk analysis. Yet Australia was more than willing to use the purported spread of prawn viruses as evidence of the risk of entry, establishment or spread of disease agents to justify its prohibition on the importation of uncooked salmon products. In terms of biofilms, Australia had acknowledged in the Final Report that biofilms had minimal if any relevance to Australia's measure and had showed that the information on biofilms could not be used to justify the prohibition on uncooked salmon.

4.85 Last, Canada argued that the identification in Australia of the alternate host for *M. cerebralis*, was not enough to justify a complete reversal of the May 1995 Draft Report's conclusion. Australia had acknowledged in the Final Report that whirling disease was not present in Canada at all, and, in any event, the disease was associated with young salmonids in freshwater. Hence, the Final Report did not contain advances in scientific evidence sufficient to justify the reversal of the recommendations in the May 1995 Draft Report.

4.86 The heat treatment conditions set out in Australia's measure and the consequent ban on the importation of uncooked salmon product had to be rationally supported by the available scientific evidence to achieve Australia's appropriate level of protection. In Canada's view, there was no sound scientific reason for Australia to continue to maintain a heat treatment policy that had the effect of banning the importation of uncooked Canadian salmonid products into Australia. Canada noted that Australia had stated that "[w]hat is certain is that applied heat will *reduce* the number of viable

[89] Final Report, p.38.

disease agents that may be present" (emphasis added). Australia had furthermore stated that the scientific basis for its heat treatment policy was based on information available in 1983. Canada claimed that in 1988, when the heat treatment requirements were last amended, the scientific information then available about the effectiveness of heat treatment in inactivating the 24 pathogens listed in the Final Report was at best sparse and continued to be limited. Australia continued not to have scientific evidence of the inactivation of any of the disease agents listed in the Final Report when the fish host was heated.[90] Australia had acknowledged that existing heat treatment requirements had to be reviewed. In the BRS Report, it had been stated that:

> "The current process of heating salmonid finfish to inactivate potential exotic pathogens does not have a rational basis in view of the thermal stability of a number of pathogens of high quarantine importance, especially at the lower temperature ranges."[91]

4.87 Canada noted that Australia was not aware of any studies that had examined the heat inactivation of many of these pathogens when grown in artificial medium (i.e. outside the host fish). Thus, in Canada's view, it was clear that for a number of pathogens listed in the Final Report there was no "certainty" that heat treatment would reduce the number of viable pathogens.[92] To the contrary, Canada claimed that Australia had been aware, since 1991, that especially at the lower temperature range of its heat treatment requirements several pathogens not only survived but actually would grow.[93]

4.88 **Australia** contended its assessment of the 24 salmonid disease agents was based on relevant scientific data. It had evaluated:

- the presence of the disease in Australia (disease status, testing methodology and reliability, control measures);
- exporting country factors (population susceptible to infection by agent, prevalence of infection, effectiveness of the diagnostic tests applied to the agent, disease control policies of the exporting country, disease zoning);
- commodity factors (whether agent found in host, whether there is change of prevalence with the time of year/life cycle);
- pathogenesis factors (disease agent predilection sites, the number of disease agents likely to be found in the commodity, ease of disease agent contamination and the sequence of events for an exotic disease to become established in Australia);
- agent factors (pH lability of the agent, agent's liability to cooling, freezing and heating in the product, whether the agent survives free in the environment);
- exposure factors (what hosts are infected naturally, distribution of known primary, secondary and intermediate hosts, mode of transmission and infectious dose);
- risk reduction factors (restricting zone of origin, species of origin, life cycle stage, pre- and post-shipping quarantine, product testing with tests having high sensitivity,

[90] Final Report, Chapter 2.
[91] BRS Report, p.37.
[92] Final Report, pp. 262, 257, 244, 238, 233, 227, 216, 206, 182, 166, 138.
[93] Pathogens in the Final Report known to survive included *Aeromonas salmonicida* (typical), *Renibacterium salmoninarum*, *Edwardsiella tarda*, *Yersinia ruck*eri, and infectious pancreatic necrosis virus. Pathogens known to grow at the lower temperature range included *Edwardsiella tarda* and *Yersinia ruckeri*.

processing, maturation and storage for specified time and temperature, treating such as heating or disinfection, restricting the destination, vaccination, certification); and

- consequences (consequence of disease introduction on native and introduced species, ability to control or eradicate if disease were introduced).

The risk assessment had also included a study of the economic impact of two salmonid diseases, furunculosis and infectious haematopoietic necrosis (IHN).

4.89 In regard to heat-treated product, Australia recalled that heat-treated product was not within the scope of Canada's initial complaint (paragraph 4.8). Nonetheless, Australia referred to its statements under the relevant provisions of Article 5 (paragraphs 4.194-4.213), including that heat-treated product was scheduled to be reassessed as part of the aquatic review. The current measures for heat-treated product were based on science available in 1982 and there had been some views expressed that the measures might not be sufficiently restrictive in terms of Australia's appropriate level of protection. In regard to Canada's arguments of "refutations" of Australia's claims, Australia reiterated the different status of various studies and reports cited by Canada , including the difference between opinions on levels of protection and judgments on the basis of a detailed risk assessment. Australia also referred to its statements in paragraphs 4.152-4.154 that it was not claiming that the difference between the recommendations of the Final and draft reports was for reasons of new science

(f) Article 2.3

> Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.
>
> *SPS Agreement, Article 2.3*

4.90 **Canada** argued that Australia's ban on the importation of uncooked salmon violated the first sentence of Article 2.3. This sentence provided that where identical or similar conditions existed between Australia and any other WTO Member, Australia was under a positive obligation to ensure that any of its sanitary measures applied to protect salmonid life or health in its territory did not arbitrarily or unjustifiably discriminate against any other WTO Member.

4.91 **Australia** noted that Canada's claim in respect of Article 2.3 was limited to the measure being discriminatory contrary to Article 2.3. In the context of Article 2.3, Canada had not claimed that the measure constituted a disguised restriction on international trade.

4.92 Australia argued that Article 2.3 represented a basic obligation, elaborated under the provisions of Article 5. The basic obligation set out in Article 2.3 needed to be read in the context of the use of the same terms in Article 5.5. The Appellate Body in *EC - Hormones*, had affirmed that Articles 2.3 and 5.5 had to be read in context and that Article 5.5 marked out and elaborated a particular route leading to the same destination as Article 2.3. In particular, Articles 5.2 and 5.3 needed to be taken into account in determining whether there were similar conditions in the sense of Article 2.3 in the same way as when examining Article 5.5.[94] The basic obligation under Article 2.3 was: (i) that the measure (the quarantine prohibition on uncooked salmon from Canada) did not arbitrarily or unjustifiably discriminate between Canada and Australia or between Canada and other Members, under circumstances where identical or similar conditions prevailed, and (ii) that the measure was not applied in a way which could constitute a disguised restriction on trade.

[94] Op. cit., para. 212.

4.93 Australia claimed that there was no situation in existence which imposed different conditions on different Members in respect of the importation of uncooked salmon. In addition, Australia argued that under circumstances where a number of disease agents exotic to Australia had the potential to enter, establish or spread subsequent to imports of uncooked salmon of Canadian origin, it could not be claimed that there were identical or similar conditions prevailing between Australia and Canada in respect of the same product and the same diseases.

4.94 In regard to other products which might host the same diseases or disease agents exotic to Australia, Australia argued that it would have to be necessary to establish whether there would be identical or similar adverse health effects or consequences of the kind listed in Article 5.3, in the event that such a product were permitted entry. A simple comparison of trade restrictions on those products did not constitute evidence of "identical or similar conditions". A *prima facie* case could not be established solely by identifying that different measures applied to other products which might host one or more of the diseases present in uncooked salmon. It was Australia's contention that there were no prevailing conditions which were identical or similar to the risks and consequences associated with the 24 disease agents of concern potentially present in uncooked salmon of Canadian origin.

4.95 **Canada** argued that in Australia there were disease agents of serious pathogenicity not examined in the Final Report that were exotic to some of Australia's States with salmonid aquaculture or recreational fisheries. Australia did not control the movement of salmonid products from infected States to disease free States or Territories to protect its salmonid populations from these salmonid disease agents. An example was epizootic haematopoietic necrosis virus (EHNV), a disease notifiable to the OIE.[95] EHNV had been recorded in Australia, and was found in Victoria where salmonid populations of rainbow trout and Atlantic salmon were substantial. EHNV had not been reported in Western Australia where rainbow trout was commercially cultured and provided an important sport fishery. Yet the Final Report had made it clear that Australian State and Territory governments had not placed any controls on the movement of salmonid products from areas where EHNV was found to areas where EHNV was exotic:

> "Control measures have been placed on the movement of live salmonids from EHNV infected areas to free areas, but as infection of salmonids is rare it has not been necessary to place controls on the movement of salmonid product." [96]

4.96 Canada argued that this constituted an arbitrary and unjustifiable distinction. In the case of the interstate movement of salmonid products from a State where an OIE Notifiable salmonid disease was detected to a State that was free of the disease, Australia had claimed that there was a *possibility* of disease establishment in salmonids via salmonid products, but this was "rare" and thus it had not been necessary to place controls on the movement of the salmonid products. However, in the case of the movement of salmonid products from a Member into Australia, the existence of any one of a number of diseases that Australia claimed were exotic raised for Australia the *possibility* of disease establishment in salmonids via salmonid products. Regardless of the degree of pathogenicity of the diseases or the likelihood of disease establishment, this possibility was the basis for Australia's prohibition on the importation of uncooked salmon. In this sense, Canada argued that Australia violated the first sentence of Article 2.3 of the SPS Agreement.

4.97 **Australia** argued that Canada's assertion that identical or similar conditions prevailed were based in part on the fact that EHNV was an OIE notifiable disease, and as such would be at least as serious a health concern as the exotic salmonid disease or strains of disease agents. In this respect, Australia argued that status as a Notifiable disease did not constitute evidence of "identical or similar conditions". There remained a question whether the classification of EHNV as a notifiable disease was appropriate in the light of it being a disease that caused little environmental or commercial

[95] OIE Code, p.67.
[96] Final Report, p.379.

damage within Australia.[97] The OIE list of notifiable diseases did not include those diseases which were serious, but had a broad geographic distribution, nor did it reflect the severity of the disease in terms of risk of occurrence or consequences.[98] It did not list some serious salmonid diseases of quarantine concern to Australia.[99] EHN was not considered a significant disease of salmonid fish compared to redfin perch. Nor could EHN be compared to some of the more serious diseases of salmonid such as BKD, ISA and typical *A. salmonicida*. Furthermore, it was also noted that the OIE Fish Diseases Commission (FDC) did not have the capacity to undertake detailed risk analysis in considering individual diseases for categorization and listing, nor did the OIE Code contain any guidelines specific to salmonids. Australia also referred to its comments with respect to EHNV in paragraphs 4.99, 4.102, 4.208 and 4.214(v).

4.98 The Australian measure was directed against the totality of the risk of diseases (cumulative effect of identified disease agents potentially present in Canadian salmon), not against a single disease agent. Yet Canada, in Australia's view, appeared to be basing its claims on a like product concept, inferring that the existence of any disease in a comparable product equated to "similar conditions". Consideration of similar conditions under the SPS Agreement involved similar adverse health effects and similar biological and economic consequences, together with the feasibility of employing a similar measure to address the similar risk and consequences. Even if there were evidence of similar conditions and measures, there would have to be evidence that the non-application of a technically and economically feasible similar measure arbitrarily or unjustifiably discriminated between Australia and Canada.

4.99 The factors Members were required to take into account, as detailed in Article 5.3, included the potential damage in terms of loss of production or sales. These factors might not necessarily be comparable; by reason of climatic and topographical factors the salmonid populations of Western Australia did not have the same significance in terms of commercial or recreational fisheries as in south eastern Australia. Hence, the controls on internal movement of aquatic animals in regard to diseases which were not exotic to certain regions of Australia could not be equated to controls on the import of products which might carry disease which were exotic to all regions. The consequences from exotic pathogen introduction would be far greater than those associated, for example, with EHN alone. In addition, other factors being equal, controlling a disease was easier than attempting to eradicate or control one that was already endemic. It was Australia's view that there was no identified, endemic aquatic disease in Australia for which it was warranted, feasible and cost effective to place internal movement restrictions on product. Australia noted that: (i) there was no significant trade of fresh salmonid product into Tasmania[100] from the mainland and local demand in Tasmania was met by local product[101]; (ii) if EHNV were to enter Western Australia, the consequences for salmonids would be minimal; (iii) if EHNV were to enter Queensland and the Northern Territory, the consequences for salmonids would be highly marginal due to climatic factors unsuited to salmonid life (there were no salmonid populations in the Northern Territory, and in Queensland they were restricted to a few isolated mountain areas). Where it was present in Australia, EHNV it did not cause major problems to salmonids.

4.100 Australia maintained that Canada had not provided evidence that identical or similar conditions existed, only that controls on introduction within Australia of one disease which was not exotic to certain regions of Australia differed from the controls on introduction within the whole of Australia's Territory of diseases which were exotic to Australia. Canada had therefore not made a

[97] Australia refers to Resolution No. XII "Amendments to the International Aquatic Animal Health Code and Diagnostic Manual for Aquatic Animal Diseases", adopted by the OIE International Committee on 29 May 1997.

[98] OIE Code, p.109.

[99] Final Report, p.12.

[100] EHNV had not been reported in the Northern Territory, Queensland, Tasmania or Western Australia.

[101] Although demand was met by local product, Australia pointed out that Canadian and Tasmanian product would fill different markets. Thus, local production could not be relied upon to prevent Canadian salmon from entering Tasmania.

prima facie case that identical or similar conditions prevailed. Furthermore, Australia argued that there was no element of arbitrary or unjustifiable discrimination against Canadian uncooked salmon arising from different measures applying to internal quarantine on salmonids and other fish in relation to a different disease which was not exotic to certain regions of Australia. Establishing that there was a difference in a measure in regard to different diseases did not imply that there was arbitrary or unjustifiable discrimination.

4.101 Canada refuted Australia's claim that the consequences from exotic pathogen introduction would be far greater than those associated with EHNV alone. In spite of the fact that the Final Report had shown that EHNV could cause mortalities in several native salmoniforms including the threatened *Maquaria australasica* (Macquarie perch)[102], Australia imposed no controls on the movement of salmonid product that might contain EHNV into EHNV-free States. Australia's attempt to justify its "no controls policy" for EHNV by claiming that there were no salmonids in the Northern Territory and isolated salmonid production in Queensland stood in stark contrast to the fact that Canadian salmonid product was not allowed into the Northern Territory or Queensland. Australia had first claimed that for Western Australia the consequences for salmonids would be minimal. Yet, in its response to a question from the Panel regarding the importance of salmonid culture Australia had acknowledged that in Western Australia and other States salmonid fisheries had a *significant* local economic impact. Canada stated that it was clear, in light of the above, that for uncooked salmonid products Australia had violated the non-discrimination requirement of the first sentence of Article 2.3.

4.102 **Australia** noted that EHN was well understood in Australia and that effective management practices had been developed appropriate to unique circumstances. Australia referred to the facts of salmonid production and distribution in Australia, including the concentration of salmonid production in the south east of Australia because of favourable biological conditions. In States and Territories other than Tasmania, New South Wales and Victoria, salmonid aquaculture operations range from minor (for recreational purposes) to zero. In Western Australia for example, there was little salmonid culture. Total aquaculture trout production in that State was 41 tons, valued at $A 455,000 per year. The hatcheries which provided trout for stocking several rivers in the south west of that State for recreational purposes were routinely monitored for EHN so that, if needed, control measures could be quickly instituted with a view to avoiding any extremely localised economic impact . The disease was endemic in Victoria, New South Wales and South Australia. It was endemic to redfin perch populations and hence the potential for eradication would be very low. It would be relatively more difficult and far less practicable to control the spread of pathogens into regions where salmonids were present, than to prevent the entry of an exotic pathogen into Australia through imported product. What also needed to be considered were the economic and technical feasibility of controlling endemic disease through internal controls. This required a case-by-case approach and Australia had in place emergency preparedness plans for such incidents. In regard to Tasmania, there was no significant interstate trade in fresh salmonid products, but it could not be concluded that consumption in that State would be fully met by local production in the event that imports were permitted entry. Australia had considered the possibility of limiting fish distribution in Australia, but concluded that such a measure would not be economically or technically feasible and would not meet Australia's appropriate level of protection. Australia noted also that, in relation to its federal structure, operational control of aquatic animal diseases rested with the States and Territories. Coordination of policy was achieved through a committee structure, with members drawn from State and Commonwealth Government.

[102] Final Report, p.98 and p.345.

(g) Article 3.1

> To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.
>
> *SPS Agreement, Article 3.1*
>
> *Harmonization* – The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.
>
> *SPS Agreement, Annex A.2*

4.103 **Canada** argued that Article 3.1 of the SPS Agreement imposed an obligation on Australia to base its sanitary measures on the standards, guidelines or recommendations developed under the OIE. With regard to the disease agents at issue (Table 3), Canada noted that infectious haematopoietic necrosis (IHN) and viral haemorrhagic septicaemia (VHS) were OIE Notifiable Diseases. For these diseases, the OIE Code stipulated that relevant competent authorities[103] in countries officially declared to be free from the respective diseases, should demand that dead fish for importation from countries not free from the respective diseases be eviscerated before transit.[104] That is, the OIE Code for these two diseases recommended certification only for imports of live fish or dead, *uneviscerated* fish. Hence, Canada argued, Australia's prohibition on the importation of uncooked salmon was not based on the relevant OIE Code standards for IHN and VHS.

4.104 **Australia** claimed that Article 3 did not have application to the dispute. Notwithstanding Canada's claims of the existence of certain OIE guidelines in respect of two OIE Notifiable disease agents, it was not possible to apply these two standards in respect of a product-based measure. The risk to Australia related to the presence or potential presence of up to 24 disease agents in a product which might be imported into Australia. The OIE guidelines did not extend to all the diseases at issue. The fact that the OIE did not have guidelines for all of the disease agents at issue meant that there was no relevant OIE guideline on which Australia might base its measure. Nor could the practice of other countries be taken as an OIE standard, particularly in light of the sovereignty accorded WTO Members to determine their own appropriate levels of protection.

4.105 Australia further claimed that Canada had not met its burden of proof in regard to the existence of relevant international standards, guidelines or recommendations on which Australia might base a measure in respect of a number of disease agents present or potentially present in a product and for which there were no OIE guidelines in existence. There could be no presumption that an OIE guideline existed on the basis that the OIE had not addressed certain disease agents. Canada had not demonstrated the applicability of Article 3 of the SPS Agreement to the measure. Furthermore, Australia contended that the OIE Code did not state that evisceration was adequate for the two Notifiable Diseases in question. It did not go beyond recommending, as part of a *minimum* worldwide standard for the control of aquatic diseases, that authorities of countries free of IHN and VHS should demand evisceration in regard to fish from countries not free from those diseases.[105] More importantly, Australia argued that the OIE did not provide relevant guidelines on which a product specific measure could be based for the purposes of achieving the appropriate level of protection in regard to the totality of the disease agents of concern to Australia. To assert that WTO Members could apply no more than the OIE minimum standard was in effect imposing on Members a set level of protection, irrespective of the likelihood of disease introduction and the consequences that would arise from such an introduction. This was in contradiction to each Member's sovereign right to

[103] See footnote .
[104] OIE Code, Articles 2.1.2.4 and 2.1.5.4 referring to IHN and VHS, pp. 74 and 86, respectively.
[105] OIE Code, pp.74 and 86.

determine its own appropriate level of protection. Hence, Australia argued that the guidelines had to be seen as minimum recommendations and not as a firm set of standards.

4.106 Without prejudice to Australia's claims in respect of the non application of Article 3 Australia cited the Appellate Body Report on *EC - Hormones* in support of its claim that the existence of an international standard did not raise a presumption of inconsistency with Article 3.1. Australia argued that Canada had the burden of proof in regard to all aspects of Article 3, including evidence that it would be possible to base the measure on existing international standards.

4.107 Australia stressed that OIE recommendations were characterised as minimum standards and that the listing or otherwise could not be taken as an indicator of the seriousness of disease agent in terms of adverse health effect, management or consequences. The diseases listed were those of primary concern to Northern Hemisphere countries, in many cases where the disease was endemic and hence the focus was more on disease management. Australia also noted that evisceration reflected commercial trading practice of those countries. The potential biological and economic consequences of disease agents exotic to Australia was an entirely different matter than the management of non-exotic diseases. As confirmed by scientific disease experts advising the Panel, evisceration, while assisting in the reduction of risk in some instances, would not eliminate the risk. In the case of some of the disease agents at issue, evisceration would not have any effect in situations where the disease agent for instance was blood borne. Australia also noted that OIE standards were not based on an assessment of risks, and that compared to terrestrial animals, OIE work on aquatic diseases was in its infancy. In this context, Australia noted the comments by the experts advising the Panel that the Final Report and the present dispute had enhanced their understanding about salmon diseases.

4.108 **Canada** noted that piscirickettsiosis, bacterial kidney disease (BKD), and infectious pancreatic necrosis (IPN) were classified as "Other Diseases" under the OIE Code. With respect to these disease agents, the OIE recommendations were limited to live fish or uneviscerated fish. As the OIE made no recommendation in respect of importation of dead eviscerated fish, by implication, the importation of such fish raised minimal risk for transmitting these three diseases. Consequently, Canada argued that Australia's measure was not based on OIE recommendations and was in violation of Article 3.1.

4.109 In addition, Australia's measure was not "based on" the relevant OIE Code recommendation. The Appellate Body Report in *EC - Hormones* examined the meaning of "based on" in Article 3.1 and concluded that to be based on an international standard, a sanitary measure had to adopt some though not necessarily all of the elements of the international standard.[106] For finfish, including salmonids, evisceration was the existing OIE recommendation to prevent the transmission of Notifiable or Other Significant Diseases. Dr. Winton, in advising the Panel, had stated that evisceration had attained the status of a *de facto* standard and that FDC considered eviscerated fish to represent a minimal, i.e., negligible risk that did not warrant restriction of trade, and, accordingly, fell outside the concern of the FDC. Dr. Winton further noted that there was no evidence of transmission of disease from eviscerated product and until scientific evidence showed otherwise, the level of risk of disease transmission from trade in eviscerated products was such that it was not of concern to the FDC.

4.110 In regard to the effectiveness of evisceration, Canada noted that neither Drs. Winton nor Rodgers knew of any specific case of disease transmission from eviscerated fish, including salmonids. Dr. Winton had noted two scientific studies in this respect that had not been published simply because the virus had not been found in the flesh of the tested fish. Canada argued that the scientific community was concerned with carrier fish in the epizootiology of several diseases, but only in

[106] Op cit., para. 171, pp.68-69.

respect of *live* fish. Scientific research did not focus on dead eviscerated aquatic animals because it was irrelevant.[107] In respect of evisceration, Dr. Winton noted that:

> "The FDC has considered this point carefully and is unanimous in the opinion that evisceration of fin fish (e.g., salmonids in this case) provides a very high level of safety against transmission of disease and that none of the notifiable or other significant diseases are likely to be transported with such products. Thus, the FDC has judged that eviscerated products fall outside the concern of the FDC. In fact, a paragraph in the first edition of the Aquatic Animal Code (Article 1.5.5.2 paragraph 3) was specifically deleted in the current edition to clarify this point because the former language provided an option for countries to require inspections of any fish products (even eviscerated fish) that were, in the opinion of the importing country capable of introducing a disease of concern. Members of the FDC have reviewed the scientific evidence and are not aware of a known expansion of range for a fish pathogen due to the movement of eviscerated fish; conversely, there are many cases of disease transmission associated with shipment of infected live fish, live eggs, or even uneviscerated fish used to feed other aquatic animals that are documented in the scientific literature." (paragraph 6.144)
>
> ...
>
> "As stated above, the FDC currently regards eviscerated fish to represent a minimal risk that does not warrant restriction of trade." (paragraph 6.145)

Dr. Rogers stated that:

> "It is probably true to say that for a given disease agent, the likelihood of disease establishment is higher for imports of whole, non-eviscerated bait fish and for live fish than it is from imports of uncooked salmon for human consumption." (paragraph 6.100).

4.111 In addition, Canada noted that Dr. Winton went on to suggest that the mere presence of pathogens in the flesh was not synonymous with the establishment or spread of fish disease. There had been examples where fish that potentially contained high levels of an infectious agent had not resulted in transmission of disease if eviscerated.

4.112 **Australia** noted that Dr. Winton's comments in regard to a "de facto standard" referred only to the United States, Canada and the European Communities and that he had qualified this comment to the effect that it was hard to say that there was an international standard in existence. The relevance of unpublished studies referred to by Dr. Winton was difficult to judge because the methodology of the studies had not been provided, nor had the studies apparently been subject to peer review. Australia stated that, from a scientific perspective, it had doubts about the conclusions from these unpublished studies or in relation to extending the information provided to the wide range of different agents of different taxonomic groups involved and the different circumstances that may exist.

4.113 Australia considered that evisceration might serve to reduce the risk in regard to some of the disease agents at issue, in particular in regard to VHS, but that it would not serve to reduce the risk in accordance with Australia's appropriate level of protection. With regard to many of the diseases at issue, including IHN, *Aeromonas salmonicida*, *Renibacterium salmoniarum* and *Piscirickettsia*

[107] Canada noted that in a recent book entitled Furunculosis: Multidisciplinary Fish Disease Research, an entire chapter was devoted to the specific issue of carriers of *Aeromonas salmonicida*. Yet the chapter did not even consider the role of dead eviscerated fish in the epidemiology of the disease because it was irrelevant. The publication was mentioned in the Final Report on pp.353-354.

salmonis, evisceration was not effective. Furthermore, although evisceration could reduce the level of risk from some diseases as the process physically removed tissues that could carry the disease agents, this would not *substantially* reduce the risk because the disease agent could be present in other tissues, or it could be mechanically transferred from an infected tissue to a tissue that was free of the disease agent. It was clear from the view of the experts advising the Panel that there was no scientific basis for assertions that evisceration was an effective means of reducing the risk to what some experts might consider to be a "negligible" level. This was without prejudice to Australia's views on the legal relevance of an expert's views of what might constitute a "negligible" level, within the context of a Member's sovereignty in regard to levels of protection and bearing in mind that the views put forward by experts advising the Panel had not been formed on the basis of a risk assessment, including the biological and economic consequences of disease entry, establishment or spread.

4.114 Australia acknowledged that the movement of fish and their genetic materials for stocking purposes and uneviscerated fish had been identified as causes of spread of disease. Nevertheless, the fact that disease spread was more commonly identified with these situations did not eliminate eviscerated fish as means of spread. Dr. Winton had not claimed that evisceration eliminated risk. Hence, although Australia noted that evisceration would reduce the risk, it did not do so to the extent that it achieved the level of protection required by Australia since it did not fully address Australia's concerns in regard to the disease agents which could be found in skin, bone, muscle and blood. It was evident that not permitting the importation of salmon provided a higher level of protection than allowing the import of eviscerated product. Dr. Winton had not described what level of risk was implicit in the OIE recommendations, nor had he been able to refer to any detailed scientific data to support the FDC's opinion on the alleged safety of eviscerated product. Furthermore, it could not be demonstrated that evisceration was as effective, or more effective than heat treatment, given in particular that heat-treated product was eviscerated. Australia contended that eviscerated fish had to be regarded as a risk product capable of spreading disease. Nor were Dr. Winton's comments made in the context of a situation of low risk and high consequences.

4.115 Australia argued that the OIE recommended that product be imported in uneviscerated form only from countries where Piscirickettsiosis, BKD, and IPN were not present.[108] As Piscirickettsiosis, BKD and IPN were present in Canadian fish, the OIE standard was not relevant to Australia's measure and did not have application. The Code was irrelevant in regard to eviscerated fish for such diseases as it did not provide guidelines regarding importation of dead, eviscerated fish. Hence, Australia noted, the relevant OIE standards, guidelines or recommendations covered only 2 of the 24 diseases of concern (IHN and VHS). These guidelines were disease-specific and, as Australia's measure related to the risk of introduction of a number of diseases which the product potentially could host, there were no OIE guidelines in existence on which Australia could base its measure. The measure could not, in this regard, be broken down into components for the individual disease agents; it was a measure which dealt with the totality of the disease risk. Australia maintained that Canada had not submitted evidence of the existence of a relevant international standard applicable to the totality of the entry, establishment or spread of the 24 diseases of concern.

4.116 Australia noted that there were no detailed criteria for diseases to be listed in the OIE Code; these were listed as a result of discretionary decision making and not necessarily as a result of considered scientific analysis. Australia recalled Dr. Winton's statement to the effect that there was no formal method for evaluation of disease risk and that the FDC decisions were not based on any scientific risk assessments process. Hence, Australia argued, the FDC itself did not make decisions based on the risk analysis process that the OIE advocated, and on which Australia had modelled its Final Report. Australia noted that the FDC did not base its recommendations on detailed examination of risks. The matter was not helped by the fact that the FDC did not keep any detailed minutes from the meetings of the FDC. Regarding the diseases examined by the OIE, Dr. Winton had noted that a lack of a listing (as a Notifiable Disease) did not mean that the FDC considered the disease to be of

[108] Australia noted that ISA was included in the OIE list of Other Diseases.

low priority. Given that many serious salmonid diseases were endemic in the northern hemisphere, it was probable that this had influenced the FDC's consideration of salmonid diseases. In other words, Australia had every right to be concerned about diseases that occurred in adult, wild, ocean-caught Pacific salmon from North America but that did not occur in Australia - regardless of whether or not they appeared on the current FDC list of Notifiable Diseases. In this respect, Australia noted that the five Members of the FDC were from a restricted geographical distribution, with no member being from a country in the southern hemisphere. None of the FDC members could be expected to have a deep understanding of the health or production of salmonids in the southern hemisphere - in particular of Australia's favourable health status and its freedom from the diseases that caused production problems in countries of the northern hemisphere. Hence, Australia argued that the OIE recommendations did not reflect the significance to Australia of certain diseases which might be exotic to Australia but endemic in major aquaculture fishing nations. In light of the above, Australia reiterated that there was no relevant OIE standard on which it would be possible to base a measure in respect of a large number of exotic salmonid diseases.

4.117 **Canada** refuted Australia's argument that relevant OIE Code recommendations did not exist because the OIE did not provide a recommendation for each and every pathogen covered by Australia's measure. Canada recalled that Australia had acknowledged in the Final Report[109] that: (i) there were international standards applicable to the importation of uncooked salmon, (ii) the standard was evisceration, but that (iii) this standard was inappropriate to Australia's circumstances. This position was consistent with Australia's past reasoning at the October 1996 meeting of the SPS Committee where Australia, addressing the salmon import ban, had announced to the Committee that the relevant OIE standard did not meet Australia's acceptable level of protection.[110] According to Canada, these two facts were sufficient to show that Australia's position before the Panel was a matter of "after the fact" reasoning.

4.118 Furthermore, the Appellate Body in *EC - Hormones*, had noted that there were international standards, guidelines or recommendations for five of the six hormones that were covered by the EC directives at issue. In other words, the Appellate Body had not concluded that there were no international standards applicable to the five hormones at issue. Rather, the Appellate Body had concluded that the European Communities was entitled to deviate from these standards provided the EC measures for these five hormones complied with the conditions set out in Article 3.3 (e.g., based on a risk assessment in accordance with Article 5.1).[111] In this case the reasoning by the Appellate Body meant that just because Australia's sanitary measure applied to more pathogens than were identified in the OIE Code did not mean that there was no relevant OIE recommendation applicable to the measure. Rather, it meant that for the pathogens identified in the OIE Code, Australia's measure had to be based on the relevant OIE recommendation or comply with the provisions of Article 3.3 of the SPS Agreement. Canada stated that if Australia's argument were accepted, it would also mean that so long as a Member claimed that a measure applied to just one disease agent not listed in the OIE Code, all of its other standards, guidelines or recommendations would not apply to the measure. According to Canada, this would mean that the importance of Article 3.1 to the SPS Agreement would depend on a Member willing to forego the temptation of saying that its sanitary measure addressed just one other pathogen. The consequence of accepting Australia's argument was that the importance of internationals standards, guidelines or recommendation to the SPS Agreement would be critically weakened.

4.119 **Australia** noted that, while it might be possible to consider application of individual standards in regard to additives, it was not possible to base a measure on an international standard in circumstances of diseases present or potentially present in a single product and for which there were few disease-based international standards in existence.

[109] Final Report, p.66.
[110] G/SPS/R/6, "Summary Report of SPS Committee meeting on 8-9 October 1996", p.4.
[111] Op. cit., para. 209, p.86.

(h) Article 3.3

> Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.[2] Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.
>
> Footnote 2:
> For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.
>
> *SPS Agreement, Article 3.3*

4.120 Prior to the Appellate Body Report in *EC - Hormones*, **Canada** argued that the last phrase of Article 3.1 was phrased as an "exception to the positive obligation contained in Article 3.1". Hence, Australia had the burden of proving that non-use of OIE standards, guidelines or recommendations was justified under Article 3.3 and met the conditions set out therein. Canada claimed that Australia's measure (i) did not result in a higher level of sanitary protection than would have been achieved by a measure based on the OIE standards, guidelines or recommendations, (ii) was not scientifically justifiable and, (iii) was inconsistent with other Articles of the SPS Agreement, including Articles 5.1, 5.5, 5.6 as well as Article 2. Therefore the conditions of Article 3.3 were not met and the measure was inconsistent with Article 3.1. Canada thus argued that Australia had failed to comply with its obligations under Article 3.3.

4.121 Canada further noted that the Appellate Body Report in *EC - Hormones*, stated that under Article 3.3 a Member could choose to set for itself a level of protection that was different from that implicit in an international standard and to implement that level of protection in a measure that was "not based on" the international standard. However, in implementing that measure, the Member had to comply with the provisions of Article 5.[112] However Australia's measure had (i) failed to specify its appropriate level of protection for its sanitary measure, (ii) assuming that the level of protection implemented by Australia's measure was a negligible level of risk, Australia's measure did not provide a higher level of protection than a measure based on the OIE Code recommendation of evisceration, and (iii) Australia's measure was inconsistent with the provisions of Articles 2.2, 2.3 and Article 5, in particular 5.1, 5.2, 5.5 and 5.6. As a result, Australia's measure was inconsistent with Article 3 of the SPS Agreement.

4.122 Without prejudice to the application of Article 3, **Australia** stressed that Members were not required to change their appropriate level of protection in regard to the objective of furthering the use of harmonized international standards. This was emphasized in the preamble to the SPS Agreement, the basic rights and obligations in Article 2, as well as in Article 3.3 itself.[113] There could be no presumption of inconsistency simply on the basis of evidence that a measure had not been based on a relevant existing international standard. In light of this, the last sentence in Article 3.3 could not be read as an exception but as a conditional right. Australia further noted that although Canada had

[112] Ibid., para. 172, p.69.

[113] The sixth indent of the Preamble states:

> "*Desiring* to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including ... the International Office of Epizootics, ... , without requiring Members to change their appropriate level of protection of human, animal or plant life or health; ..."

claimed that Article 3.3 represented an exceptional right and that Australia had the burden of proof to demonstrate consistency with Article 3.3, Canada had *not* claimed that Australia's measure was in violation of Article 3.3.

4.123 Australia contended that the Appellate Body in *EC - Hormones*, had confirmed Australia's interpretation of Article 3 obligations, including in regard to the burden of proof on the complainant.[114] The Appellate Body had also confirmed that international standards, guidelines and recommendations did not have obligatory force and effect and that a Member was not required to conform or comply with such standards. Nor did Article 3.3 represent an exceptional right.[115]

4.124 Australia argued that Canada had not presented any evidence to establish a presumption that Australia was acting in violation of Article 3.3, particularly in respect of the "special meaning" given to the term "scientific justification" in footnote 2 to Article 3.3. Canada's mere reference to inconsistency with other provisions of the SPS Agreement in the context of Article 3.3 was furthermore not sufficient to establish a *prima facie* case of violation of the provisions of Article 3.3. Without prejudice to Australia's claims that Article 3 did not have application to the dispute at issue, Australia had, as a result of its risk assessment and in conformity with its rights under the SPS Agreement, applied a measure different from the international standard and which resulted in a higher level of protection than would have been achieved if it were based on the international standard. Australia stressed that OIE standards, guidelines or recommendations were minimum guidelines, specifically recognized as such by the OIE:

> "Realising that the Code represents a *worldwide standard* for the control of the listed aquatic animal diseases, Member Countries may use risk assessment approaches to include other diseases of particular concern in their national regulations."[116] (emphasis added)

4.125 Australia further argued that claims about the practices of other Members (which appeared to be limited to the United States, Canada and the European Communities) did not constitute scientific justification that those practices would achieve Australia's desired level of protection. Canada had not provided alternative scientific evidence about how a measure based on a standard expressed as a minimal worldwide standard could achieve the level of protection Australia considered appropriate for the diseases at issue. The OIE standards, guidelines or recommendations provided for guidance and did not impede a country's sovereign right to determine its acceptable level of risk, provided there was scientific basis for the decision.

4.126 Australia contended that the OIE's International Aquatic Animal Health Code did not provide a single appropriate level of protection. It noted that none of the experts advising the Panel appeared to have responded to the part of Question 26 dealing with the implicit level of risk in OIE recommendations (see paragraphs 6.146-6.148). Dr. Winton had stated that, because of the differing health conditions in various OIE member countries, it was impractical to have different recommendations for each country. Australia stated that, in fact, the OIE recommendations provide a minimal level of protection against disease entry. The associated implicit level of risk could not be considered to be the same for all OIE recommendations regarding fish. This was because risk had two components, the likelihood of disease introduction, establishment and spread; and the consequence (or harm) that would result because of disease introduction, establishment or spread.

4.127 In the event that the Panel were to find that OIE's standards, guidelines or recommendations were relevant to the dispute, Australia argued, in the alternative and without prejudice to the above,

---

[114] Op. cit., paras. 102, 165 and 171.
[115] Ibid., para. 165.
[116] OIE Code, Introduction, p.vi.

that, contrary to Canada's claims, (i) its own measure would result in a higher level of protection than would be achieved by measures based on OIE guidelines, and that (ii) on the basis of examination and evaluation of available scientific information in conformity with the relevant provisions of the Agreement (Articles 5.1, 5.2 and 5.3), there was scientific justification that a higher level of sanitary protection would be achieved by Australia's measure. Australia recalled that the text of Article 3.3 provided two options for compliance with the conditions attached to the exercise of the right not to base the measure on an international standard. In accordance with footnote 2, the condition of scientific justification was met if a Member determined that the relevant international standard was insufficient to meet the appropriate level of protection and provided also that the determination had been made on the basis of an examination and evaluation of available scientific information. The other option was compliance with the provisions of Article 5.

(i) Article 5.1

> Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.
>
> SPS Agreement, Article 5.1
>
> Risk assessment - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.
>
> SPS Agreement, Annex A, paragraph 4

4.128 Australia argued that Canada confused scientific justification with opinions about a level of risk. It had not provided alternative evidence to the detailed science of the Final Report, including the examination of options which might reduce the risk. Canada could not claim, for instance, that evisceration would achieve a higher level of protection than controls on the importation of a product. If product entered, disease agents would enter. This was not contested. Nor could there be any presumption that an international standard was necessarily based on scientific justification. It also noted that consideration of appropriate levels of protection included consequences as well as disease transmission and that the two factors could not be divorced from each other. Australia maintained that Canada's arguments in respect of the contention that the measure did not result in a higher level of protection rested on a quotation from the Final Report in regard to the difficulty in distinguishing levels of risk in regard to each option presented by a continuum of risks. Australia had provided clear scientific evidence, supported by the fish disease experts, that evisceration would not result in a higher level of protection than the measure applied by Australia. None of the reports cited by Canada concluded that basing measures on an international standard would be sufficient to achieve Australia's appropriate level of protection. In contrast, the Final Report, on which the measure was based, contained a detailed and exhaustive evaluation and examination of available scientific information, on which basis it was concluded that the OIE guidelines would not be a sufficient basis to achieve the appropriate level of protection.

4.129 **Canada** recalled the requirement of Article 5.1 that a sanitary measure be based on an appropriate assessment of the risks. Canada argued that the Final Report did not meet this criteria as it did not (i) evaluate the likelihood of disease introduction but merely identified the possibility; (ii) examine the risks on a disease-by-disease basis; and (iii) evaluate the risk on the basis of the various risk mitigation measures that might be applied.

4.130 In Canada's view, the term "as appropriate to the circumstances" referred to the circumstances in which a risk assessment was being undertaken. Referring to Annex A.1 and Annex A.4 of the SPS Agreement, Canada claimed that these circumstances concerned (i) the source of risk (i.e. whether it was posed by an animal pathogen or a chemical contaminant); and (ii) the subject of risk (i.e. whether it was to human, animal or plant life or health). The risk assessment and risk assessment techniques that are appropriate in the circumstances for one type of measure, such as a measure in respect of risks to human health from chemicals in food, may well be different from that for another, such as a measure in respect of risks from the entry, establishment or spread of disease from an imported product.

4.131 **Australia** advised that, in accordance with the Vienna Convention, it interpreted the term "as appropriate to the circumstances" as requiring a risk assessment based on product, country of origin and country of destination. In other words, it conferred a right and obligation on a Member to include country-specific information in a product-based assessment of risk, and to assess the need for sanitary and phytosanitary measures on a case-by-case basis. Australia drew attention to the relevant negotiating texts of the SPS Agreement, from which it was evident that a "one model fits all" approach to risk assessment had been rejected. The term "as appropriate to the circumstances" was first introduced into the draft text in 1991, in preference to earlier drafts of "risk assessment when appropriate", "based on adequate risk assessment procedures" and "based on an assessment of actual risks entailed". It was considered that those terms, while indicating a high degree of flexibility in making a sovereign judgment as to the level of detail of any risk assessment, did not address concerns regarding specific or unique situations or a Member's right to take them into consideration. During the course of the negotiations of the SPS Agreement, it was Australia's view that the risk assessment policies and practices as detailed in its 1988 policy statement (paragraph (iv) refers) represented prevailing international risk assessment methodology incorporating the need to address specific or unique situations appropriate to the circumstances. This had been the basis for Australia's acceptance of the term "as appropriate to the circumstances" for incorporation in the final text of Article 5.1 of the SPS Agreement. Australia further argued that the non prescriptive approach of the SPS Agreement to risk assessment was consistent with the approach adopted in WTO Agreements relating to subsidies and countervailing measures, anti-dumping and safeguards. Those Agreements provided the envelope of disciplines while allowing for significant differences in approach for assessing key issues, including the need to deal with a wide variety of different circumstances.

4.132 Hence, in Australia's view "appropriate to the circumstances" with regard to risk assessment included (i) that the approach had to include, but not be limited to, the risk assessment techniques which were still being developed and refined by the relevant international organizations, such as the OIE; and, (ii) the approach had also to recognize that there was no single model for risk assessment and that recent developments in the field might have to be taken into account. Australia drew attention to the discussions with the experts advising the Panel, from which it was clear that risk assessment techniques were in constant evolution and that the views of experts, in respect of desirable risk assessment methodology and techniques, could not provide a basis for interpretation of WTO treaty obligations. Australia noted that Article 5.1 did not require that a risk assessment be based on risk assessment techniques developed by the relevant international organisation, rather that they should be taken into account.

4.133 Australia argued that what constituted an appropriate risk assessment could differ from one case to another. In view of the gaps in information on many aquatic animal diseases and the relative stage of development of work on aquatic disease compared to that on terrestrial animals (in part due to historical circumstances), it was Australia's opinion that the qualitative approach taken in the Final Report was the most appropriate to the circumstances. Nothing in the SPS Agreement imposed an obligation on a Member to quantify its level of risk. Australia considered that a quantitative risk assessment might be appropriate when there was a single chain of events in an import pathway. However, there was no contemporary quantitative methodology that could provide a mathematically rigorous, stochastic approach for a quantitative risk assessment of a multiple pathway scenario as

posed by the salmon example (multiple disease agents and more than one route by which the agent could establish in the susceptible population). The feasibility of a quantitative risk assessment would be further limited by (i) insufficient volume of detailed scientific information; (ii) insufficient knowledge of likely volumes to be imported each year and (iii) the absence, in Australia, of a policy judgement to determine what final level of risk was acceptable, including in regard to consequences. According to Australia, a qualitative risk analysis was the most appropriate approach in this case. Hence, Australia maintained that its measure was based on a risk assessment as appropriate to the circumstances and that the risk assessment took into account the risk assessment techniques developed by the relevant international organizations. Canada has not met the burden of proof in regard to its claim that Australia had not undertaken an appropriate risk assessment.

4.134 Australia drew attention to the following excerpts from the Final Report in this context[117]:

> "A qualitative approach has been taken in this risk analysis as there are major impediments to performing a quantitative analysis. These include the lack of reliable quantitative data with which to perform the analysis. Further difficulties are posed by the multiple, complex, and - in some scenarios - the long, indirect potential pathways through which susceptible animals could be exposed to the disease agent in imported product. These pathways are difficult to define - and there is virtually no reliable quantitative data to use in calculating the likely prevalence of agents in product or the likelihood of susceptible animals being exposed to imported product. The scenarios of exposure involve unpredictable and unusual events which are difficult to model.
>
> It is noted that New Zealand MAF attempted a quantitative risk analysis using only *Aeromonas salmonicida* with other agents assessed on a qualitative basis. New Zealand MAF concluded that, as a result of the importation of chilled, headless, eviscerated salmon from Canada, there is a 95 per cent probability that there would be fewer than one disease introduction of *Aeromonas salmonicida* per ten million tons of salmon imported. However some have argued that the statistical reliability of that analysis, including the assumptions used, is open to question. Australia believes the importation of salmon from Canada and the United States falls into this category where it is inappropriate to undertake a quantitative analysis."

4.135 Regarding the scope of the Final Report, Australia argued that it had acceded to a request in late 1994 from Canada and the United States that priority be accorded to a risk assessment on wild, adult, ocean-caught Pacific salmon. There had been no request from Canada to proceed with a risk analysis for the other categories of salmon product from Canada.

4.136 In respect of the scope of the Final Report, **Canada** noted that in order to proceed more quickly and in light of the magnitude of the task, Canada had suggested that Australia proceed *first* with an assessment of wild, adult, ocean-caught Pacific salmon, on the understanding that an assessment of other salmon products would follow thereafter. The scope of the task had been narrowed with a view to facilitating the task so as to achieve progress. According to Article 5.1, it was for Members taking measures to base those measure on an assessment of risks. The obligation was not limited to those instances where another Member requested that a measure be based on a risk assessment. Canada had not excused Australia from its obligations under Article 5.1.

Evaluation of likelihood

4.137 **Canada** argued that the Final Report did not focus on the probability, but rather on the *possibility* of the risk event occurring. The risk event, in this case, was the establishment of exotic diseases through the importation of uncooked, wild, ocean-caught Pacific salmon. In line with Annex

[117] Final Report, p.24.

A.4 and Article 5.1, a risk assessment had to assess the likelihood of the occurrence of the event that the measure in question was designed to prevent by the making of probabilistic estimates. Probability, in Canada's view, could be expressed qualitatively as well as quantitatively. The OIE guidelines focused on the "estimation of the probability of an adverse event".[118] This view was supported by Dr. Wooldridge:

> "In my opinion, the requirement of a risk assessment is to evaluate the *probability* of risk. Given the existence of a particular disease agent, one can *always* construct a *possible* infection transmission scenario, however improbable, and therefore demonstration of the possibility of successful transmission and disease is not adequate. (paragraph 6.59)
>
> "The OIE code does require an evaluation of probability (either qualitatively or quantitatively) rather than merely possibility of a given outcome or consequence even if, given current knowledge levels, the confidence limits on that probability are wide." (paragraph 6.152)

4.138 Canada noted that in the earlier Australian risk analysis, the May 1995 Draft Report, it had been stated that in order for uncooked Pacific salmon to cause exotic diseases to become established in Australia, each step in a sequence of events had to occur. The risk, according to the May 1995 Draft Report, would be reduced to negligible values if one or more events in the sequence was extremely unlikely to occur, or if a number of events in the sequence had a relatively low probability. These events were listed in the May 1995 Draft Report:

> "For imported salmon products to cause an exotic disease to become established in Australia, the following sequence of events must take place:
>
> (i) the product must contain exotic pathogens;
> (ii) the pathogens must survive processing;
> (iii) the fish must be visibly normal (to pass inspection);
> (iv) the pathogens must survive physical/chemical treatments, (such as freezing) in biologically significant numbers;
> (v) the edible product and/or waste products must enter natural water courses;
> (vi) the water must contain susceptible aquatic animals;
> (vii) the pathogens must survive for sufficient time and in significant numbers;
> (viii) the pathogens must be exposed to a susceptible host by a route that allows infection;
> (ix) the pathogens must be present in sufficient numbers to initiate infection in the host; and
> (x) the host must transmit infection to other susceptible animals."[119]

4.139 Canada observed that New Zealand had also undertaken an assessment of the risks of importing wild, ocean-caught Pacific salmon from Canada. The 1994 New Zealand Risk Assessment, like the May 1995 Draft Report, had demonstrated that it was possible to provide a clear statement of probability (whether quantitative or qualitative) by considering the full sequence of events required for disease establishment. Although Canada did not contend that the 1994 New Zealand Risk Assessment was conclusive of the issue of risk posed by importation of uncooked, wild, ocean-caught Pacific salmon to Australia, it was important to note that the 1994 New Zealand Risk Assessment had concluded that, when certain sanitary measures were applied, the probability of disease introduction in respect of each of the diseases in question was negligible.

[118] OIE Code, Chapter 1.4.2 (See the title of the Article 1.4.2.1), p. 33.
[119] May 1995 Draft Report, p. ii (Executive Summary), see also p.218, para. 7.

4.140 Canada maintained that the Final Report was not a risk assessment because it did not assess probability. Canada noted that this was made clear in the reasons given in the Final Report for maintaining the measure, which included "the possibility of diseases establishing in Australia". While it was recognized that probability could be expressed qualitatively as well as quantitatively, all of the experts advising the Panel agreed that a minimum requirement of a risk assessment was that it assessed probability. The experts advising the Panel agreed that the Final Report did not do so and therefore did not meet that minimum requirement. The Appellate Body in *EC -Hormones*, had noted that "probability" referred to "likelihood"[120], hence, it was clear that a risk assessment, in the sense of the first definition in Annex A:4, which refers to the "[t]he evaluation of the likelihood of entry, establishment or spread of a pest or disease...", must evaluate probability. A mere evaluation of the possibility was not enough.

4.141 Furthermore, Article 1.4.2.1 of the OIE Code provided that "[t]he number of aquatic animal import units being imported significantly influences the risk assessment". "Aquatic animal import units" was defined in Section 1.1 of the OIE Code as "a specified weight of a product of aquatic origin". Yet the Final Report had made no attempt to estimate the volume or weight of salmon product that would be imported, despite the fact that quantitative data directly relevant to such an estimate was included in the May 1995 Draft Report.[121] Hence, the Final Report did not conform to the OIE Guidelines for Risk Assessment.

4.142 Even if the Final Report had constituted a risk assessment, Canada argued that Australia's *measure* was not based on a risk assessment. The requirement in the SPS Agreement was not to *do* a risk assessment, but to *base* its measure on one. Yet Australia's measure operated to prohibit the entry of all five categories[122] of uncooked salmonids from Canada while the Final Report considered only adult, wild, ocean-caught Pacific salmon. The measure was hence maintained against the other four categories of salmon without a risk assessment.

4.143 Finally, Australia's measure operated to allow entry into Australia only for salmon product that had been heat treated according to certain time/temperature requirements. Heat treatment was thus part of Australia's measure. However, Australia itself had stated that the Final Report did not cover heat-treated product and that it would in the future undertake a risk assessment for heat-treated salmon. As the Appellate Body had stated in *EC - Hormones*, there needed to be a rational relationship between the measure and available scientific evidence contained in the Final Report.[123] Australia's current measure was not based on a risk assessment and was in violation of Article 5.1.

4.144 **Australia** noted that Canada's claims of violation under Article 5.1 were based on a reading of Annex A of the Agreement, rather than on the terms of Article 5.1. Canada's claim represented a selective interpretation of risk assessment. Canada had read requirements into paragraph 4 of Annex A for which there was no textual basis. Attempts to assign a probabilistic interpretation rested on a quote from a single dictionary definition. Reference to other dictionary sources, including dictionaries of legal usage, revealed that Canada's interpretation of "likelihood" as equating to "probability" was not a universally shared view which would be capable of application as a legal definition, even within national jurisdictions. Contrary to Canada's assertion that the Appellate Body Report on *EC - Hormones* supported this interpretation, the Appellate Body in that case did not address definitions of "likelihood".

4.145 Australia drew attention to the views of the experts advising the Panel in regard to the confusions associated with the use of terms such as probability, which they were clearly using in the sense of statistical risk assessment techniques and methodology which, they noted, were evolving

[120] Op. cit., para. 184.
[121] May 1995 Draft Report, p.23.
[122] Table 1.
[123] Op. cit., para. 193, p.78.

over time. Australia argued that an expert's preference for a statistical probability based methodology or techniques in risk assessment could not be used to define a constant legal obligation. Experts advising the Panel had pointed to the linguistic difficulties and confusions associated with definitions of "probability", which may not adequately describe a range of possible situations, hence the preference of some experts for a quantitative approach as a desirable future goal (although they recognised that a quantitative approach might not be possible where there were gaps in data).

4.146 Australia further argued that "likelihood" could not be interpreted in a way which would restrict the sovereign right of a Member to determine its appropriate level of protection, and that interpretations of "likelihood" could not be constructed in a context divorced from considerations of the appropriate level of protection, including in circumstances of low risk of occurrence and high consequences. Australia noted that "likelihood" had formed part of the SPS draft text in 1990, but on the basis of legal claims advanced by Canada, the Panel was now being requested to interpret "likelihood" in the context of the 1998 views of experts on appropriate methodology, which experts did not view as static. Australia stated that in terms of "likelihood", it did not require scientific certainty, rather that there should be sufficient information to allow reasonable judgments to be made in assessing whether the risk met Australia's appropriate level of protection. Australia referred to the comments of a risk assessment expert advising the Panel in regard to the need for a judgment to be made.

4.147 Australia argued that in interpreting the SPS Agreement, a distinction had to be made between the definition of "risk assessment" set out in Annex A paragraph 4, and the substantive provisions including those set out in Article 5. To do otherwise, according to Australia, would be to fail to give effect to all the terms of the Agreement in their context. Australia pointed out that the definition of risk assessment as set out in Annex A paragraph 4, contained two parts joined by the word "or". This clearly indicated that there was no requirement for a risk assessment to meet all the terms in paragraph 4; compliance with either of the two parts of the definition was sufficient. In this sense, according to Australia, Canada had not put forward any claims that the risk assessment (in the Final Report) did not fall within the definition contained in the second part of the sentence in paragraph 4. Hence, Australia contended that the risk assessment contained in the Final Report had been undertaken as defined in paragraph 4 of Annex A and that it met the requirements of Article 5, of which paragraphs 2 and 3 thereof elaborated the factors to be taken into account in a risk assessment, and as such provided further definition to what constituted a risk assessment. There was furthermore no limitation on the form that an "evaluation of likelihood" might take, except that is should consider the possible risk management measures and the consequences. The SPS Agreement was not prescriptive about the methodology of risk assessment.

4.148 Australia observed that both Drs. Rodgers and Wooldridge accepted that quantitative assessment (i.e. numerical probabilities) could not always be done in such a subject as fish diseases where there were often gaps in relevant data. Dr. Rodgers noted that:

> "The possibility and the probability of an event occurring both embody elements of likelihood and risk. However, as far as I am aware there is currently no pre-requisite to use the quantitative method, particularly in view of the lack of data in certain key areas of aquatic animal health. This applies equally when dealing with more than one disease agent, since, although many risk factors are common between different diseases, each disease may have unique factor to consider and each of these will have a variable quantity and quality of useable data." (paragraph 6.58)

In situation where all the scientific information significant to a risk assessment could not be obtained, it was necessary to apply expert judgement with suitable allowance for uncertainty. The application of such judgement in the present case had led to the conclusion that no set of technically feasible measures met Australia's appropriate level of protection.

4.149 Also, the Appellate Body in *EC - Hormones* had rejected the interpretations of the requirements of the SPS Agreement to the effect that there was a requirement that a risk assessment "establish a minimum magnitude of risk". The Appellate Body noted that[124]:

> "the ordinary meaning of "potential" relates to "possibility" and is different from the ordinary meaning of "probability". "Probability" implies a higher degree or a threshold of potentiality or possibility. It thus appears that here the Panel introduces a quantitative dimension to the notion of risk."
>
> "... We must note that imposition of such a quantitative requirement [in regard to a minimum magnitude of risk] finds no basis in the SPS Agreement."

4.150 Notwithstanding the above, Australia did not agree that the Final Report assessed only the *possibility* of an event. Australia contended that the possibility of an event occurring (i.e. possible pathways) had been evaluated as a first step in the risk analysis process. This was supported in Dr. Wooldridge's advice to the Panel. The Final Report had concluded that the risk of introduction of unwanted exotic diseases from imported salmon meat of adult, wild, ocean-caught Pacific salmon from North America was likely to be small.[125] This conclusion was repeated in the Executive Summary in the Final Report, although the term "low" was used.[126] However, given the potential consequences, and the uncertainty inherent in the assessment, this was judged not to be sufficiently so low as to meet Australia's appropriate level of protection. Australia drew attention to the absence of argumentation from Canada in respect of the factors to be taken into account as enumerated in Articles 5.2 and 5.3 of the SPS Agreement. Canada's arguments addressed only entry, establishment or spread and not biological or economic consequences. The SPS Agreement accorded Members the right to take into account consequences in regard to animal health measures and consideration of the risk of transmission could not be separated from consequences in the context of determining which measure might achieve the appropriate level of protection. The present circumstances related to low risk and high consequences. It was conceivable that in circumstances of a high risk/low consequence a Member might decide that a particular quarantine restriction might not be warranted in the context of achieving an appropriate level of protection, by reason of the capacity to manage or eradicate the risk or by reason of the minor economic or biological consequences, including the low economic or social value that a community might attach to consequences. This illustrated that the appropriate level of protection might still be the same in circumstances of widely varying levels of risk of entry, establishment or spread.

4.151 In respect of the sequence of events set out above (in paragraph 4.138), Australia argued that although the cumulative probability of the 10 events would be low, there were (i) multiple and complex pathways of disease introduction and establishment[127], (ii) a significant number of diseases of concern, (iii) large uncertainties in any estimates of probabilities, and (iv) considerable debate on the number of actual "steps" or "events" in each chain or branch in the possible scenario tree.

4.152 Australia stressed that a comparison of the conclusions between the May 1995 Draft Report and Final Report was not valid. The May 1995 Draft Report was a *draft* import risk analysis intended as a public discussion paper and designed to elicit public comment; as such it had no official status. It represented the risk communication stage of a risk analysis, including recommendations designed to encourage public debate. There had been two opportunities for comment: the May 1995 Draft Report and the "Revised Draft IRA", released in May 1996.[128] In addition, this information had been

[124] Op. cit., paras. 184 and 186.
[125] Final Report, p.70.
[126] Ibid., p xi
[127] Ibid., pp.366-371.
[128] The 1996 Revised Draft Import Risk Analysis took into account the comments made on the May 1995 Draft IRA. Final Report, p.318.

documented and made available for peer review.[129] The May 1995 Draft Report was part of a process leading to the Final Report, which was submitted to the Director of Quarantine for decision. The format of the Revised Draft IRA differed from that of the 1995 Draft Report to ensure it was presented in accordance with OIE guidelines. As no adverse comments had been received on the change in the format, the Final Report was structured in the same fashion. No inferences of motive could be attached to the differences in recommendations. Australia was not seeking to explain the differences between the draft and final recommendations as due to new scientific data as such. The Final Report was an independent document that should be considered on its merits and should not be compared to other studies which had been undertaken for different purposes and which had not been subject to the same level of scientific or legal scrutiny. The May 1995 draft was evaluated following public comment and included a re-evaluation of the scientific data in light of Australia's appropriate level of protection. The conclusion was reached that the level of risk had been underestimated in the draft report.

4.153 Australia noted that some information had been included in the Final Report which was not in the May 1995 Draft Report. This included the spread of prawn viruses in the United States, the biofilms issue and the presence of the whirling disease alternate host in Australia. Furthermore, since the release of the Final Report, infectious salmon anaemia had been identified in Canada, erythrocytic necrosis virus had apparently been identified in Atlantic salmon in British Columbia and there was apparently strain differences in the IHN virus affecting wild and aquaculture salmonids in British Columbia. Australia noted that Dr. Rodgers had also pointed at the presence of VHS in Canadian Atlantic salmon, a fact of which Australia had not been previously aware.

4.154 Although the vast majority of the information in the May 1995 Draft Report was included in the Final Report, some information was no longer required as a result of the re-formatting of the document or was not relevant to the decision making process. For example, the information on the percentage breakdown of a salmon into its various tissues was omitted as it did not add to the decision-making process in a qualitative risk analysis; also, the usage of water and waste disposal in Sydney and Melbourne did not address waste disposal in a number of other regions which were potentially of a higher risk (Tasmania and regional areas). The technical content and the evaluations made in the Final Report and the May 1995 Draft Report were similar. The recommendation of the 1996 Final Report differed from the draft recommendation because after evaluating the almost 200 comments submitted and re-evaluating the May 1995 Draft Report, the conclusion was reached that the level of risk of exotic disease entry, the potential for their spread and establishment and the economic and environmental impacts, including on recreational fishing, had been *underestimated* in the May 1995 Draft Report. Australia stressed that the risk assessment at issue was the Final Report of December 1996 and that there was no other risk assessment on uncooked salmon from Canada. There was thus no other risk assessment on which the existing measure was based.

4.155 Australia also argued that the New Zealand import risk analysis was not relevant to the present dispute as (i) Australia believed that New Zealand's use of a quantitative risk analysis technique was not appropriate in the circumstances; (ii) post entry factors including species at risk, industry practices, population distribution, waste disposal practices, environmental conditions, and disease status were different between Australia and New Zealand; (iii) the New Zealand risk analysis did not consider the consequences arising from the introduction of diseases and pests; (iv) the assumptions made by New Zealand scientists and decision-makers did not necessarily reflect Australia's approach to risk and its appropriate level of protection, and, (v) the New Zealand report had several shortcomings in its modelling techniques. The relevance of the New Zealand risk assessment was valid solely in regard to scientific evidence and whether undisputed scientific evidence in the New Zealand risk assessment was taken account as part of relevant "available

[129] Canada submitted the peer reviews of the May 1995 Draft Report by Dr. Tore Hästein of the Norwegian Central Veterinay Laboratory and Dr. A.H. McVicar of the Scottish Marine Laboratory.

scientific evidence". Australia noted further that the New Zealand risk assessment, together with other relevant studies, had not been subject to the same WTO legal scrutiny as the Final Report.

4.156 Australia noted that Members of the WTO were not limited to the consideration of the risk of transmission of a disease in determining the measure which might be applied, but had in principle the right to introduce or maintain trade restrictive measures in circumstances where the likelihood of entry or establishment might be small, but the consequences were of an unacceptable magnitude. In line with Articles 5.2 and 5.3 of the SPS Agreement, the consequences of occurrence also required an evaluation for the purposes of determining the measure which might be applied. The Appellate Body had clarified in *EC - Hormones* that the SPS Agreement did not distinguish between "risk assessment" and "risk management" and that definitions of "risk assessment" did not stop at scientific evaluation of risk.[130] Experts advising the Panel had, in this context, stressed that once a level of risk of occurrence had been defined, it was by far more difficult to decide how to determine an *acceptable* level of risk. This was, at the end of the day, a judgement for individual countries. In this regard, Australian salmon was internationally competitive and in addition received a premium based, at least to some extent, on its quality and disease free status, both of which could be threatened by disease introduction. As Australian product already competed effectively with product from North America, it was unlikely to suffer any adverse economic impact from competition in the Australian market. However, the costs of disease introduction were substantial enough to threaten the very viability of the industry. Disease introduction could affect not only the commercial salmonid industry and its local and export markets, but also have serious implication for recreational and native fisheries.

Disease-by-disease basis

4.157 **Canada** argued that Australia, having identified 24 disease agents of concern, was obliged in its risk assessment to make an evaluation of the likelihood of establishment for each one of the diseases. As Australia had not done this, it was impossible to determine the risk, if any, posed by a particular disease agent. Canada pointed out that the May 1995 Draft Report had contained a substantial amount of information that had not been included in the Final Report. The May 1995 Draft Report had examined the risk of the same 24 diseases and had reached conclusions as to the risk for individual diseases. The May 1995 Draft Report had stated that the risk was so small as to not merit continuation of the present quarantine restrictions.[131] The Final Report had begun with the premise that 24 disease agents posed a risk and had concluded in exactly the same way. In other words, it reached no conclusions as to which of the diseases or disease agents of concern did in fact pose a risk that required the particular measure to ensure that Australia's appropriate level of protection was met. In Canada's view this was one of the reasons why the experts advising the Panel had considered the Final Report to be nothing more than a "hazard identification".[132] Hence, the Final Report did not fulfil the requirements of a risk assessment as set out in Article 5.1 and did not meet the definition of a risk assessment in Annex A of the SPS Agreement.

4.158 Canada noted that Article 1.4.2.1 of the OIE Code provided that the factors listed needed to be considered "in constructing a scenario by which *a disease agent* might be introduced into the importing country" (emphasis added). Further, in referring to country, commodity, exposure and risk reduction factors, the Guidelines provided that: "*Depending on* the commodity and *the disease agent*, any number of these factors may be used to estimate the probability of an adverse event for the importing country" (emphasis added).

4.159 **Australia** noted that there was no textual basis for Canada's claim that a risk assessment must separately evaluate risk of occurrence for each disease and for each measure which might be applied. Australia did not exclude that such an approach might be feasible in certain circumstances, for

[130] Op. cit., para. 181.
[131] May 1995 Draft Report, p.218.
[132] Burmaster, Transcript, para. 322.

instance where an individual measure might prove capable of reducing or eliminating a single risk from an individual disease, pest or substance in regard to a human health matter addressing the risk of occurrence and consequences of different additives. But such an approach was not feasible in circumstances of the potential risk of multiple diseases carried by a product. As exemplified in Articles 5.2 and 5.3, the consequences also required evaluation. Risk of occurrence and risk of consequences could not be considered in isolation.

4.160 Australia drew attention to its arguments that the SPS Agreement was not prescriptive about the methodology of a risk assessment (see paragraph 4.132). In terms of conformity with the provisions of the SPS Agreement, a risk assessment needed to be examined in regard to the factors enumerated in Articles 5.2 and 5.3, as well as the provisions of Article 2 of the Agreement, including in regard to scientific evidence and scientific principles. Australia considered that, as an initial step, each disease had to be considered individually, where appropriate and where information was available; and collectively in the light of the fact that the measure was applied for all agents collectively. This had been done in Section 1.4 and Section 2 of the Final Report. Australia argued that the OIE recommendations did not require an assessment for *each* disease or an evaluation of possible introduction scenarios. Rather, the risk assessment technique recommended by the OIE was based on the *elaboration* of introductory scenarios according to the components stipulated. Australia noted that the OIE risk assessment guidelines referred to "the risk associated with one or more disease agents". Hence, Australia maintained that its measure was based on a risk assessment as appropriate to the circumstances[133] which took full account of OIE techniques, including assessment of the risk associated with one or more exotic disease agents and the scenarios that might be involved in their introduction, together with subsequent exposure and transmission to aquatic animals. Australia's risk assessment was based on existing, accepted international guidelines contained in Section 1.4 of the OIE Code in line with Article 5.1.[134] Australia noted that the OIE Code indicated:

> "Risk analysis must be able to deal with the complexities of reallife situations and no single method is applicable in all cases. For this reason, countries wanting to conduct import risk analyses may find it necessary to design their own process for carrying out the exercise."[135]

4.161 Australia argued that Canada's interpretations of OIE methodology requirements were not relevant. Australia was not required to conform with or base its requirements on OIE techniques. OIE techniques were in the process of constant change and could not be used to define "risk assessment" in the context of the SPS Agreement. Yet, in Australia's view, this seemed to be Canada's main evidence of the need for a disease-by-disease evaluation.

Evaluation of risk in light of measures which might be applied

4.162 **Canada** argued that Australia failed to evaluate the likelihood of the establishment of the disease (the risk event occurring) according to each sanitary measure which might be applied (as set out in Annex A.4). If a Member did not do so, it would not be able to identify the least trade restrictive measure that would achieve its appropriate level of protection. The Final Report was largely a descriptive document. It described scenarios by which a disease establishment might occur, and it described a number of the factors that were relevant to an estimation of the probability of such an occurrence, but it avoided making the necessary probability assertions for the scenarios it had postulated. Although the Final Report did identify five quarantine policy options, it did not evaluate the likelihood that each option would lead to the establishment of any of the diseases of concern.[136]

[133] Paragraph 4.129 and following.
[134] Final Report, p.37 (Risk Analysis Considerations).
[135] OIE Code, Section 1.4.1.3, p.30.
[136] Final Report, p.69.

4.163 **Australia** argued that a decision on which measure to take in a particular case would be made on the basis of a risk assessment against the level of protection which a Member had "deemed" to be generally appropriate, in accordance with paragraph 5 of Annex A. In this sense, the risk assessment in the Final Report had evaluated the likelihood of risk according to the range of possible measure that might be applied. Australia noted that there was no limitation as to the form that this evaluation had to take except that it had to consider the possible risk management measures and the consequences.

4.164 Australia drew attention to the options identified in the Final Report. Options for pre- and post-entry quarantine conditions on imported product were built into all stages of the risk analysis and could not be separated out. The Report contained a technical review of data which examined, for each disease, control measures, exporting country factors, pathogenic factors, agent factors, exposure factors and risk reduction factors and consequences. In regard to risk reduction factors, the following issues were addressed:

- restricting the zone of origin, species of origin, life cycle stage;
- pre and post shipping quarantine;
- product testing with tests having high sensitivity;
- processing, maturation and storage for specified time and temperature;
- treatments such as heating and disinfection;
- restricting the destination;
- vaccination; and
- certification.

As noted elsewhere, the Final Report included an evaluation of the costs of control or eradication in respect of furunculosis and IHN, including the relative cost effectiveness of alternative approaches to limiting the risk. In regard to consequences, consideration was given, for each disease, to the ability to control or eradicate if the disease were introduced into Australia.

4.165 The Final Report also addressed the following options as part of the risk analysis:

- heat treatment of pathogens of concern, pre- and post-entry (but Australia noted that this was outside the scope of the access request by Canada and United States);
- implement the findings of the BRS report in part or in full;
- permit the importation of retail ready fillets, for distribution in raw form under specified conditions;
- permit the importation of headless, gilled, eviscerated product under specified conditions; and
- permit the import of product that complies with current international standards of evisceration.

4.166 In regard to the options identified in the Final Report, Australia noted that for each option there was a distinct level of protection and it had been established that only the option chosen would achieve the appropriate level of protection. Australia noted that in regard to the continuum of risks, it was true that it was difficult to quantify the differences in the level of risk afforded by each option, but, nevertheless, the fact that differences prevailed was evident. The Final Report stated that " [t]he difference in level of risk between each option is incremental and cannot be quantified".[137] However, the Final Report had clearly stated that Option 1 represented the lowest level of risk (highest degree of security) of any option considered.[138] Options 2, 3 and 4 were not ranked other than that these fell between Option 1 (lowest risk) and Option 5 (highest risk).[139]

[137] Ibid., p.62.
[138] Ibid., pp. 62 and 69.
[139] Australia noted that on page ix of the Final Report "lowest" was an editorial error, and should read "lower".

(j) Articles 5.2, 5.3 and 5.4

> 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.
>
> *SPS Agreement, Article 5.2*
>
> In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.
>
> *SPS Agreement, Article 5.3*
>
> Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.
>
> *SPS Agreement, Article 5.4*

4.167 **Canada** claimed that Australia's measure was contrary to Article 5.2 of the SPS Agreement. Canada argued that according to Articles 5.1 and 5.2 a sanitary measure must be based on an assessment of risks to animal life or health taking into account scientific evidence of the likelihood of the entry, establishment or spread of a disease. Canada noted that the Final Report came to the opposite conclusion of the May 1995 Draft Report without calling into question the scientific credibility of the May 1995 Draft Report, and without presenting additional scientific evidence that warranted a wholesale reexamination of the conclusions of the May 1995 Draft Report.

4.168 Canada argued that the heat treatment conditions set out in Australia's measure and consequent ban on the importation of uncooked salmon were not rationally supported by the available scientific evidence, and were therefore in violation of Article 5.2.

4.169 **Australia** drew attention to its due process concerns, which included concerns in relation to Canada's claim of inconsistency with Article 5.2 (paragraph 4.10). Australia argued that the Panel was thus not required to make findings in respect of the consistency of Australia's measure with respect to that provision. Nonetheless, without prejudice to its due process concerns, Australia noted that Canada's claims rested on a new specific claim that there was no rational relationship between the measure and the scientific evidence. The basis for that claim was new, in regard to heat-treated product. However, Canada had not clearly identified the basis for its claim in the text of the SPS Agreement. It had cited the Appellate Body Report in *EC - Hormones,* but its characterisation of legal issues differed markedly from the language used by the Appellate Body.

4.170 Australia observed that Articles 5.2 and 5.3, together with Article 5.5, imparted meaning to the scope of a risk assessment, as defined in paragraph 4 of Annex A. The Final Report had extensively considered the factors set out in Article 5.2. This had been done in regard to the source of the product and the receiving environment in considering each disease agent. Furthermore, in assessing the risk and determining the measure to be applied for achieving the appropriate level of protection, Australia had taken into account all relevant factors listed in Article 5.3. Australia argued that although Article 5.4 did not contain any substantive obligations, it did impart meaning to the substantive obligations in Article 2.2 (in regard to "necessary") and Article 5, in particular Article 5.5. The fact that Australia had previously determined, *inter alia*, that canned and heat-treated, uncanned salmon would be permitted entry, was evidence that Australia had taken into account the objective of minimizing negative trade effects.

4.171 Australia noted also that Canada had never addressed the May 1995 Draft Report in terms of legal consistency, but presumably its endorsement of that draft report related to the conclusions rather than the content. Australia maintained that SPS legal obligations were not about ascribing motive or

intent, but it would be highly misleading to believe that there had been a change in Australia's policy on an appropriate level of protection between 1995 and 1996.

(k) Article 5.5

> With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade ....
>
> *SPS Agreement, Article 5.5*
>
> *Appropriate level of sanitary or phytosanitary protection* – 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.
>
> *SPS Agreement,Annex A, paragraph 5*

Determination of the acceptable level of risk

4.172 **Canada** noted that a fundamental problem in accepting Australia's contention that only heat-treated product would achieve its appropriate level of protection was Australia's failure to adequately express its appropriate level of protection. While a Member had a sovereign right to choose its own appropriate level of protection, Australia had failed to determine its "appropriate level of sanitary protection" in maintaining the measure at issue. In not doing so, Australia had, on this ground alone, violated its obligations under Article 5.5 of the SPS Agreement. Canada noted that among the conclusions in the May 1995 Draft Report, Australia had stated:

> "In light of the substantial information considered on the health status of North American salmonids, it is AQIS's judgement the importation of salmonid product derived from wild, ocean-caught Pacific salmon from Canada and the USA under specified conditions for the purposes of human consumption does not present a *significant risk* of the introduction and establishment of an exotic disease or strain of disease to Australia. Accordingly, AQIS recommends that importation be permitted under the draft conditions described in Appendix 6.
>
> "It has concluded that the risk of disease introduction is acceptably low, having regard to the potentially serious consequences of such an event."[140] (emphasis added)

4.173 Canada observed that in the Final Report, Australia had indicated:

> "As a practical matter, the concept of "acceptable risk" is applied in most circumstances in a qualitative manner, as is the practice in comparable countries. Because of its favourable animal health status, Australia has traditionally maintained a *consistently conservative approach to the management of risk* in accordance with the broad policy position of government.
>
> ...
>
> "Where Australia has a great deal to lose from the entry and establishment of exotic diseases, controls on imports are set so as to reduce risk to *very low* levels."[141] (emphasis added)

[140] May 1995 Draft Report, Conclusion, p. 223.
[141] May 1995 Draft Report, Conclusion, p. 223.

Furthermore, the final paragraph of the conclusion in the Final Report stated:

> "On the basis of the large number of disease agents in question; *the many unknowns about them*; the impossibility of detecting covertly infected animals at inspection; the multiple, complex pathways through which imported product could enter Australian waterways; the presence of potential host species in Australian waterways; *the possibility of diseases establishing in Australia*; the substantial economic impacts that could result to the salmonid aquaculture industry from disease establishment; the potential loss of amenity and economic impact on recreational fishing and associated business; the potential environmental impacts on listed endangered and vulnerable species; and the ineradicability of disease, it is recommended that the present quarantine policies for uncooked salmon products remain in place."[142] (emphasis added)

4.174 Thus, in Canada's view, Australia had gone from apparently using the standard of "no significant risk" (May 1995 Draft Report), to "very low risk" and "possibility" of risk in the Final Report. Canada argued that to use the *possibility* of disease establishment as a basis for refusing access for uncooked salmon was tantamount to a "zero-risk" policy. In its Rebuttal Submission, Australia had stated that Canada had not put forth evidence "that spread could not occur" and that "Canada is unable to say that there is no risk or that none of the disease agents in question will be found in Pacific salmon in the Pacific region". It appeared to confirm this when it indicated in response to a question from the Panel (Question 24)[143] that it required freedom of a product from pests or diseases of concern as the basis for access to its markets. Thus, Australia appeared to be demanding zero risk that a disease agent would even enter its territory through the importation of Canadian salmon. Canada also noted that Australia appeared to admit explicitly in its First Submission (at paragraph 382) that it had not determined its acceptable level of risk at all:

> "Use of a quantitative approach implies that there is agreement on what level of risk is acceptable. A policy judgement is needed to determine whether or not such a risk is "acceptable", including in regard to consequence, and to date, no such level of acceptability has been agreed in Australia."

Australia's shifting and contradictory statements in respect of its appropriate level of protection indicated that Australia had either not determined its appropriate level of protection, or that it was using its appropriate level of protection not to protect its fish, but to protect its measure.

4.175 **Australia** argued that the evidence cited by Canada was incorrect or misleading. Australia recalled its arguments in paragraph that inferences of motive or intent belonged in the realm of assertion and did not constitute evidence, and further that there had not been a change in Australia's policy on an appropriate level of protection for salmon between May 1995 and 1996. Rather, the recommendations of the Final Report were made after a full evaluation of comments in response to the draft import risk analysis (whose recommendations were framed with a view to eliciting public comment) and a thorough evaluation of the draft report by experts. Furthermore, Australia argued that claims whether Australia had or had not undertaken a risk assessment needed to be addressed in the context of Article 5.1.

4.176 Without prejudice to the forgoing, Australia had the right to take into account the *consequences* of entry, spread or establishment, including the factors listed in Article 5.3 of the SPS

---

[142] Ibid., Conclusions, p.70.

[143] Panel's Questions to the Parties on 10 September 1997.
Question 24: Is it correct to say that Australia effectively bans all uncooked salmon whether or not it originates from Canada or the United States? What is the status of imports of New Zealand salmon into Australia? What are the possibilities for a country to prove that it is free of the diseases of concern to Australia and thus to get permission to export its salmon to Australia?

Agreement. The appropriate level of protection was determined in regard to risk, including consequences - a likelihood of occurrence might be small, but the consequences were of an unacceptable magnitude. The level of protection deemed appropriate was that of the Member establishing the measure - there were no minimum or maximum thresholds. The issue of the determination of Australia's acceptable level of risk was not relevant to the examination of consistency within the provisions of Article 5.5. Furthermore, Australia claimed that Canada had not met its burden of proof with respect to Article 5.5. Canada's evidence was in the realm of assertion, based on assumptions derived from a comparative analysis of the May 1995 Draft Report, the 1994 New Zealand Assessment and the Final Report. This ignored the standard of review and was tantamount to a *de novo* review.

4.177 The basis for Canada's claim that Australia had not determined its appropriate level of protection appeared to be the non-quantification of the acceptable level of risk. Australia argued that there was nothing in the SPS Agreement which imposed an obligation on a Member to quantify its level of risk. Determination of the appropriate level of protection was a sovereign decision as was evident from the definition of the term (Annex A, paragraph 5), and the preamble to the SPS Agreement. Australia recalled its earlier arguments in this respect (see paragraphs 4.146-4.149).

4.178 Australia argued that the appropriate level of protection reflected community expectations across a range of issues and activities to protect human, animal and plant life, health and safety. The determination of the appropriate level of protection included consideration of, *inter alia*, the benefits of access for imported products as against the costs of pest or disease incursions - in a general sense, not on a case-by-case basis. The decision on which measure to take in a particular case would be made on the basis of a risk assessment against the level of protection which a Member had deemed generally appropriate, in accordance with the definition of risk assessment in Annex A, paragraph 5. According to Australia, the risk assessment evaluated the likelihood of risk according to the range of possible measure that might be applied. Subsequently, in the case of protection from pests and diseases, a quarantine decision, including specific quarantine measures applicable (ranging from free entry to prohibition) and consistent with Australia's appropriate level of protection, was then made. Factors to be considered in the case of protection from pests and diseases included the likelihood of introduction, establishment or spread, the consequences (economic and social) that would result from that event occurring and the weighting that would be applied where uncertainty existed. Australia noted that in the Final Report, explanations or terms to describe the concept of the appropriate level of protection included:

- "very conservative";
- "where Australia has a great deal to lose from the entry and establishment of exotic diseases, controls on imports are set so as to reduce risk to very low levels"; and,
- "Australia develops quarantine measures to provide the appropriate level of quarantine security acceptable to the Australian community".

4.179 Australia argued that successive Australian governments, in the light of Australia being an island State free of many pests and diseases and with a very high economic dependence on agricultural production and exports, had consistently adopted a conservative approach with respect to the appropriate level of protection. Quarantine was seen as a fundamental to the protection of Australia's unique environment and was clearly linked to Australia's export future which depended on Australia's relative freedom from pests and diseases. There was a history in Australia of new agents/pests (for example the cane toad, papaya fruit fly) having a significantly greater impact than in other countries. Australian quarantine policy, while not based on a zero risk approach, was very risk adverse because of the consequences of not maintaining the current pest and disease status. In regard to salmonids, the number and distribution of susceptible salmonid hosts within Australia had increased significantly since the 1970s. This change, combined with greater mobility of people (including recreational boating and ecotourism), as well as dietary changes (including greater consumption of raw fish products) had significantly increased the risk of exposure of salmonids to

imported product since the 1970s. Australia intended to maintain its conservative approach to quarantine policy while ensuring that sufficient resources were available to maintain a science-based quarantine system capable of decision making based on the weight of scientific evidence and judgement. Australia underscored that care had to be used when making comparisons between decisions that had been taken at different times since community expectations on the appropriate level of protection changed with time.

4.180 **Canada** refuted Australia's attempt to justify its measure in part by asserting special ecological circumstances.[144] Australia had offered no evidence for its assertions regarding export price premiums due to a "privileged health status". Moreover, many salmonid diseases were endemic to Australia.[145] Any price premium Australia received was clearly not due to its self-proclaimed "privileged health status", but rather was likely due to commercial and marketing factors such as Australia's ability to supply product from January to March (a low production and export period for northern hemisphere countries), and the freshness of its product due to its proximity to markets such as Japan. While Australia had argued that dead Canadian salmon posed a *potential* threat to its indigenous fish populations[146], Australia had ignored documented threats to those same populations from its live, introduced recreational salmonid populations.[147]

4.181 Canada argued, specifically, that Australia had contravened each of the three distinct elements that the Appellate Body in *EC - Hormones* had indicated were required to make a violation of Article 5.5, namely:

(i) that the Member imposing the measure complained of has adopted appropriate levels of sanitary protection in different situations;

(ii) that those levels of protection exhibit arbitrary or unjustifiable differences or distinctions in their treatment of different situations; and

(iii) that the arbitrary or unjustifiable differences result in discrimination or a disguised restriction on international trade through the measure embodying a particular level of protection.[148]

Different levels of protection in different situations

4.182 **Canada** recalled that Article 5.5 required Australia to "avoid arbitrary or unjustifiable distinctions in the levels it considers appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade". Canada argued that "different situations" in this case were, at minimum, those that involved at least some of the same 24 disease agents that Australia had used as a justification for its measure. Thus, whatever level of protection was reflected in Australia's measure, Australia would have to impose the same restrictions on the importation of all products known to host any of the same 24 disease agents, irrespective of whether the hosts were salmonids or not. The consequences of establishment of the disease would be the same whether a given disease was established via salmonid or non-salmonid imports. However, Canada contended that Australia did not do this. Australia explicitly distinguished between salmonids and

[144] Final Report, p.70.

[145] These included septicaemic and ulcerative disease attributed to *Vibrio anguillarum*; septicaemic diseases caused by *Yersinia ruckeri*, *Enterococcus seriolicida* and *Lactobacillus piscicola*; amoebic gill disease caused by *Paramoeba* sp.; haemorrhagic gill lesions caused by *Ceratothoa* sp.; ulcerative dermatitis caused by *Flexibacter maritimus* and *Cytophaga psychrophila* and various skin and gill diseases caused by the fungi *Saprolegnia* sp. Furthermore, Canada observed that endemic to Australia were diseases of other species which affected salmonids, including *Aeromonas salmonicida* (atypical), *Edwardsiella tarda*, and epizootic haematopoietic necrosis (EHN), an OIE Notifiable disease not found in North America.

[146] Final Report, p.108 (Response to Question 3).

[147] Report of the National Task Force, p.69; Final Report, p.97.

[148] Op. cit., para. 214.

other finfish for sanitary purposes, despite scientific evidence that many of the 24 disease agents of concern to Australia could also occur in a wide range of non-salmonids (Table 6 and Table 7).

4.183 Canada pointed out that the Appellate Body in *EC - Hormones* had taken a broad view on what constituted different situations for the purpose of identifying different levels of protection in different situations, namely some common element or elements that rendered them comparable.[149] The common element for the products Canada had identified was that they all were known to host disease agents that were also found in salmonids, that were exotic to Australia, that might infect salmon and other salmonids in Australia and that Australia had claimed as the basis for its prohibition on uncooked salmon. Canada also noted Australia's failure to control the internal movement of salmonids that might host EHNV as another example. In that case, the common element was that EHNV was another serious disease agent of salmonids, and Australia claimed it was attempting to avoid the introduction of serious diseases of salmonids by its prohibition of uncooked salmon from Canada.

4.184 **Australia** argued that, as supported by the Appellate Body Report on *EC - Hormones*, consistency was not an obligation of Article 5.5. Nevertheless Australia had taken steps towards achieving consistency in regard to aquatic animals as well as in other areas, as evident in the detailed program of scheduled risk analyses (paragraph refers). Different situations needed to be interpreted in the light of the Appellate Body Report on *EC - Hormones*, that is that there must be sufficient elements in common for the purposes of comparison. The concepts of Article III of GATT 1994 in respect of "like" or "directly competitive or substitutable" products was not relevant. Article 2.2 , which was relevant, referred to "conditions", not products. It was Australia's contention that, in regard to the evidence submitted by Canada, there were no common elements sufficient to render comparable the levels of protection on salmonids and non salmonids. There could not be any assumption that the existence of the same disease in another product was an element sufficient to render comparable the treatment of another product which hosted or potentially hosted a significant number of other diseases. Any such assumption did not have scientific validity. Nor as, evidenced by the views of the experts advising the Panel, were there sufficient common elements in regard to heat-treated product.

4.185 Australia had imposed the measure on salmon because of the range of disease agents that potentially might be present in imported salmon. The measure had not been put in place for any one particular disease agent. The only fact in common was that salmon and another fish might have a disease agent in common. However, the existence of different measures for different products where there were one or more diseases in common did not constitute evidence of distinctions in the appropriate level of protection. Canada had not addressed the issue of comparability of (i) the likelihood of entry, establishment or spread of diseases in these different products; (ii) the biological or economic consequences; or (iii) the risk management factors.

4.186 Australia contended that "different situations" might occur in regard to the same product and the same diseases where there might be an identical or similar adverse health effect and identical or similar consequences. Different situations could also involve the same adverse health effects and consequences in respect of different products. In regard to identical or similar adverse health effect and consequences, Australia had permitted the entry of certain cooked products, which had been determined to represent an acceptable level of risk. In regard to the same product and the same diseases, Australia had determined that the same level of protection had to be applied to products from all sources. With respect to EHNV, Australia recalled its response to Canada's arguments given in paragraphs 4.97, 4.99 and 4.102 .

[149] Ibid., para. 217, p.88.

TABLE 6
Salmonid Disease Agents Identified In Australia's Final Report Known To Occur In Non-Salmonid Fish Imported Fresh Or Frozen Into Australia (As Argued By Canada)

Disease Agent	Non-salmonid host species (Number of additional non-salmonid host species)	Australian import
A. BACTERIA		
Aeromonas salmonicida (atypical)	Pacific herring Haddock Atlantic cod Plaice Japanese eel (28)	Herring Haddock Cod Plaice Eel
Aeromonas salmonicida (typical)	Coalfish American eel Atlantic cod (32)	Coalfish Eel Cod
Edwardsiella tarda	Japanese eel (10)	Eel
Vibrio anguillarum	Atlantic cod Coalfish (8)	Cod Coalfish
Vibrio salmonicida	Atlantic cod	Cod
Yersinia ruckeri	European eel Coalfish (9)	Eel Coalfish
B. VIRUSES		
Erythrocytic necrosis virus	Atlantic herring Pacific herring Atlantic cod (15)	Herring Cod
Infectious pancreatic necrosis virus (IPNV)	European eel Japanese eel Dover sole Cod (25)	Eel Sole Cod
Infectious haematopoietic virus (IHNV)	Pacific herring	Herring
Viral haemorrhagic septicaemia virus (VHSV) (N.A. strain)	Pacific herring Pacific cod	Herring Cod
Viral haemorrhagic septicaemia virus (VHSV) (European strain)	Atlantic cod Haddock European eel (3)	Cod Haddock Eel

Source: First submission of Canada, Table 6, p.79-80.

TABLE 7
Australian Imports Of Live Fish Known To Host Disease Agents Identified In Australia's Final Report (As Argued By Canada)

Fish	Disease Agent	Total number of fish Imported 1988-1995
Ornamental: fresh water	IPNV *A. salmonicida* (atypical) *Y. ruckeri* *E. tarda*	57,663,000
Ornamental: salt water	*V. anguillarum*	1,193,000
Carp	*A. salmonicida* (typical) IPNV *A. salmonicida* (atypical) Y. ruckeri	3,814

Source: First submission of Canada, Table 7, p.82.

4.187 In regard to the same diseases which might be present in other products, Australia argued that due to scientific knowledge about the presence of exotic diseases in salmonids and the research which had been undertaken on entry and establishment of the diseases, salmon represented the only finfish on which a species-specific level of protection had been established. As concluded in the Final Report, Australia had determined that there was an unacceptable level of risk associated with the entry of uncooked salmon from Canada and the United States.

4.188 Australia further noted that a Task Force[150] had been established to examine and report on issues relating to the importation of fish and fish products into Australia, including fish health, industry implications and environmental aspects. The Task Force had been concerned about the potential risks inherent in some existing aquatic animal imports. Australia had reaffirmed its commitment to undertake open, transparent, scientifically-based import risk analysis of these imports in order to clearly identify the risks and take appropriate action to ensure the consistent application of quarantine policy in line with Australia's international obligations. Following recommendations by this Task Force, Australia had attached quarantine conditions to imports of uncooked freshwater crayfish products and prawns not fit for human consumption.

4.189 If Article 5.5 were to be interpreted in a way which required Australia to impose the same restrictions on other fish which might host other diseases, Australia would then run the risk of breaching its obligations in regard to the measures on those other products, including Article 5.1 obligations. It was Australia's view that risks associated with other aquatic animals could not be compared in the absence of a risk analysis. This was supported by the experts advising the Panel. The same measure, applied in different circumstances, might not achieve the same level of protection. Consistent with a Member's rights under Article 5.7 of the SPS Agreement, it could not be excluded that, depending on the circumstances, quarantine restrictions be considered on the importation of other aquatic animals and their products prior to the completion of an import risk analysis if it were believed that there was sufficient justification. In fact, there were Australian experts who were of the view that quarantine measures applied to some other fish species might *not* be appropriately

[150] Paragraph 4.62.

restrictive.[151] Nevertheless, in the absence of strong justification, Australia intended to await the completion of an import risk analysis process before revising its import conditions for aquatic animals and their products.

4.190 Import risk analyses were scheduled for the following aquatic products:

- processed aquatic animal feeds;
- table fish;
- other aquatic animals for human consumption (some crustacean species and miscellaneous invertebrates);
- uncanned heat-treated salmon;
- registered premises - standards and guidelines, including the use of live animals for research;
- biologicals, vaccines, fish hormone preparations;
- aquatic microorganisms;
- fomites, fishing gear, wastes, packaging materials;
- processed aquatic animal products and extracts;
- brine shrimp;
- transhipment of live aquatic animal species;
- live aquatic animals for human consumption;
- live aquatic animals for aquaculture, breeding purposes;
- live aquatic animals for ornamental purposes (not fin fish);
- molluscs and bait and feed fish; and
- prawns and freshwater crayfish (commenced).

Australia stated that an import risk analysis process had commenced in 1997 for the importation of ornamental fish, which had been identified as a high-priority area. Australia emphasised that, in a real world, it was not possible to undertake numerous and complex risk assessments in parallel. They had to be programmed and prioritised in the light of resources, including specialist scientific expertise. This was the situation in practice in most countries. In terms of aquatic issues, Australia was more advanced than any other country, including Canada, in regard to working towards the achievement of the objectives of Article 5.5.

4.191 Australia noted its rights under Article 5.7 to take provisional measures and had not excluded that it might be necessary to do so in respect of the products and diseases which were under examination, but Australia was also conscious of the objective of minimizing negative effects on trade in non-salmonids as well as salmonids.

4.192 Quarantine measures for aquatic animals were being developed to reflect the same level of protection as for terrestrial animals. Although some factors might be different, and the interaction between host, pathogen and environment more complex, the same principles applied to the spread of disease for aquatic animals as for terrestrial animals. The main differences between terrestrial and aquatic animals was the longer history of observation, the intensity of the observation, and the different state of knowledge of diseases and disease agents.

4.193 The Final Report identified the import requirements for aquatic animals and their products other than salmonids:

> "All goods entering Australia are subject to quarantine. They may be inspected on arrival and may be sampled and tested at the importer's expense regardless of whether or not prior permission to import is required and granted.

[151] Final Report, pp. 334-335.

"The specific policies applying to the importation of aquatic animals (other than salmonids), their products and related materials, are as follows:

- *Live, freshwater, ornamental fish* may be imported with prior written approval. Approval is restricted to fish on Schedule 6 of the Wildlife Protection (Regulation of Exports and Imports) Act 1982 and there are pre-entry and post-entry requirements including a minimum period of 14 days in post-arrival quarantine premises.

- *Live, marine, ornamental fish* may be imported subject to examination on arrival for species identification, clinical health and presence of other materials of quarantine concern. Approval is restricted to fish on Schedule 6 of the Wildlife Protection (Regulation of Exports and Imports) Act 1982.

- *Animals imported for scientific or display purposes* must be held in premises approved for the purpose under the Quarantine Act 1908. Permission must also be obtained from DEST, under the Wildlife Protection (Regulation of Exports and Imports) Act 1982 for the importation of fish species other than those on Schedule 6 of that Act.

- *Brine-shrimp eggs* may be imported with prior written permission subject to suitable processing, including surface chemical sterilisation and drying.

- *Other live aquatic animals* may be imported subject to risk assessment and approval on a case by case basis. Permission must also be obtained from DEST under the Wildlife Protection (Regulation of Exports and Imports) Act 1982

- *Meals derived from aquatic animals*, for example fish and prawn meal, require prior written permission for importation subject to suitable processing of the product and inspection on arrival.

- *Manufactured aquatic animal feeds* require prior written permission for importation subject to quarantine acceptance that ingredients meet quarantine requirements and have been appropriately treated either before export or before release from quarantine in Australia.

- *Oysters in the full or half shell* are prohibited from all sources, except oysters in the half shell from New Zealand (prior permission is not required). Other oysters in the full or half shell may be imported for scientific purposes with prior written permission. The goods must be held in premises approved for that purpose under the Quarantine Act 1908.

- *Uncooked, freshwater crayfish product*, subject to risk assessment and approval on a case by case basis, requires prior written permission for importation.

- *Uncooked prawns (shrimp) not fit for human consumption*, subject to risk assessment and approval on a case by case basis, requires prior written permission for importation.

- *Other non-viable aquatic animal products*, for example mussels, are allowed entry subject to inspection and confirmation of non-viability and freedom from visible contamination.

- *Clothes, footwear and used fishing gear* that have had contact with fish or fish farms overseas are subject to inspection on arrival and treatment if required."[152] (emphasis added, emphasis in original removed)

4.194 Australia recalled its due process concerns in respect of heat-treated product (paragraph). Australia noted that heat-treated product had not been addressed in the risk assessment for the reason that Canada had not sought a risk assessment on that product, which the experts advising the Panel had stated to be a different product than that considered by the Final Report. An import risk analysis was scheduled as part of the aquatic quarantine review. In Australia's view, Canada's claim in respect of heat-treated product was an entirely different legal claim from allegations of differences between live and bait/feed fish and salmon. It also raised significantly different scientific issues. Canada could not claim that the factors pertaining to heat-treated salmon were the same as those pertaining to live and bait fish, which formed the basis of Canada's legal claims.

4.195 **Canada** observed that in the case of *EC - Hormones*, the fact that the European Communities had not done a risk assessment for either the hormones at issue or for the veterinary drugs carbadox and olaquindox did not prevent the Panel or the Appellate Body from comparing them and finding evidence of an arbitrary or unjustifiable distinction in levels of protection in different situations. Canada suggested that if Australia's position were accepted, Article 5.5 would be critically weakened as it would mean that unless and until Australia did risk assessments for the other pathogen-hosting products identified by Canada, no comparisons would be possible. The scenario would arise whereby a Member might impose a highly trade restrictive measure in one situation in respect of one product but no measure whatsoever in respect of another comparable product, and the Member would be able to do so with impunity.

4.196 **Australia** noted that Canada's characterisation of the legal issues in regard to the Appellate Body report on *EC - Hormones* differed markedly from the language used by the Appellate Body.

4.197 **Canada** argued that there were circumstances where it was valid to compare the risk posed by other aquatic animals or products hosting any or all of the same disease agents with those posed by uncooked salmon, *even in the absence* of a risk assessment for those other aquatic animals or products. This was so in respect of assessing the probability of exposure, transmission and consequences of a given disease post-entry within a country or region; and, it was also relevant in respect of identifying inconsistencies in acceptable level of risk. Canada claimed that its argument that for any given disease agent, the consequences of an introduction would be the same, regardless of the imported product responsible was supported by Drs. Wooldridge, Burmaster and Rodgers. In particular, Dr. Wooldridge noted that:

> "Briefly, in my opinion, the risks from salmonids and non-salmonids can be compared by comparing available data pre-entry plus potential exposure pathways. The decision on whether risk [sic] are acceptable or not depends on many factors but if the risks are assessed as being (or are otherwise believed to be) at a similar level then in my opinion they must be either equally acceptable or equally unacceptable regardless of the source." (paragraph 6.104)

4.198 Canada conceded that if different products were imported into different regions of a country, the consequences could be different due to variability in the presence of susceptible hosts in the regions. However, this qualification was not a function of different consequences arising from the same disease agent in different products. It was a function of different regional environments. The same variation in consequences would exist if the same disease agent were imported into different regions in the *same* product. Canada noted that there was no evidence that Australia had prohibited into any particular region any of the non-salmonid products that Australia imported or allowed to be

[152] Ibid., pp.5-6.

imported that were known to host many of the disease agents which Australia had cited as a basis for excluding salmonid imports. Canada noted Dr. Wooldridge's statement to this effect:

> "Once a given disease is established country-wide in an importing country, then in my opinion the consequences from that point on will be the same whatever the original imported source or manner of establishment." (paragraph 6.81)

4.199 **Australia** refuted Canada's claim that the consequences of the disease being established in an importing country would be the same, regardless of the original imported source. Australia noted that Dr. Wooldridge agreed with this proposition only insofar as a disease became established. Nevertheless, Dr. Wooldridge had pointed out that regional variations might affect consequences in the short to the medium term. In addition, Dr. Rodgers had noted that there were degrees of severity for some disease agents, and consequences could vary depending on the nature of the pathogen and the genetic basis of the indigenous species. The final destination of a particular consignment could have an impact on potential disease establishment.

Arbitrary or unjustifiable differences in levels of protection

4.200 **Canada** noted that Australia had claimed that its appropriate level of protection was conservative for certain pathogens of quarantine concern when these pathogens had not been found in salmon. As a result it excluded uncooked salmon product, on the basis that it was possible that its importation could lead to the establishment or spread of such pathogens. However, when Australia had been faced with the knowledge that many of the same pathogens were found in a wide array of other aquatic animal products, Australia had abandoned its conservative approach.

4.201 Canada identified the following four differences in levels of protection, which it considered to be arbitrary or unjustifiable:

(i) Canada noted that in the Final Report, Australia stated that: "*A. salmonicida* has a wide range of hosts and would present one of the most serious threats to Australian fish".[153] Canada claimed that despite the fact that confirmed hosts of atypical *Aeromonas salmonicida* included Pacific herring, haddock, cod, plaice and Japanese eel, Australia did not ban the importation of fresh and frozen products of these species. However, uncooked Canadian adult, wild, ocean-caught Pacific salmon, which was not know to host *Aeromonas salmonicida*, was not allowed entry on the grounds that it was a potential (possible) host of, *inter alia*, *Aeromonas salmonicida*. In addition, in the Final Report, Australia had conceded that viral haemorrhagic septicaemia virus (VHSV), had not been identified in adult, wild ocean-caught Pacific salmon.[154] Similarly, in regard to Infectious pancreatic necrosis virus (IPNV), the Final Report stated that "[e]xtensive sampling of wild adult Pacific salmon in British Columbia and Alaska failed to detect the presence of IPNV." [155] Yet despite the fact that these two diseases had not been identified in adult, wild, ocean-caught Pacific salmon, Australia banned the importation of uncooked salmon, ostensibly to protect against both VHSV and IPNV. On the other hand, Australia allowed imports of fresh, chilled and frozen Pacific cod and herring (both of which the Final Report admitted were natural hosts for VHSV in North America[156], as well as fresh, chilled and frozen Atlantic cod, haddock and European eel (which Canada contended were also included in the host range of VHSV). Furthermore, Australia did not ban the importation of fresh, chilled and frozen products of the species Atlantic herring, European eel, Japanese eel, Dover sole, or Cod, although IPNV had been identified in these species. Canada drew attention to other disease agents, and corresponding Australian imports, identified in Table 7.

[153] Ibid., pp.38, 138-139.
[154] Ibid., p.45.
[155] Ibid., p.44.
[156] Ibid., p.45.

(ii) Canada further noted that Australia imported herring in whole, frozen form, for use as bait fish in Australian waters. These were imported uneviscerated and deposited directly into the aquatic environment.[157] It was logical that the likelihood of disease establishment arising from imports of bait fish would be greater than for uncooked salmonids because the events sequence (see paragraph 4.138) that had to be completed for disease establishment to occur through bait fish was greatly compressed. Whole bait fish was by definition not eviscerated. Canada claimed that herring was known to host *Aeromonas salmonicida* (atypical strain), erythrocytic necrosis virus, infectious haematopoietic necrosis virus (IHNV) and viral haemorrhagic septicaemia virus (VHSV).[158]

(iii) Canada argued that under the quarantine regime regulating the importation of live finfish, including ornamental freshwater and marine finfish, the Director of Quarantine had permitted the importation into Australia of close to 59 million ornamental finfish between the period 1988 through 1997. Ornamental fish (fresh and saltwater) were known to host the disease agents *Aeromonas salmonicida* (atypical), *Yersinia ruckeri*, *Edwardsiella tarda*, Infectious pancreatic necrosis virus (IPNV) and *Vibrio anguillarum*. In addition, Canada stressed that, unlike dead, eviscerated product, live ornamental finfish were known to have introduced exotic diseases.[159] Referring to the 1995 Humphrey Report, Canada noted that the disease risk in respect of introducing exotic disease for live fish or invertebrates was particularly high.[160] Yet uncooked, Canadian adult, wild, ocean-caught Pacific salmon, not known to host any of the above diseases, was not allowed for importation.

(iv) Finally, Canada noted that EHNV was found in Victoria where salmonid populations of rainbow trout and Atlantic salmon were substantial, but had not been reported in Western Australia where rainbow trout was commercially cultured and provided important sport fishery. Yet the Final Report had made it clear that Australian State and Territory governments had not placed any controls on the movement of salmonid products from areas where EHNV was found to areas where EHNV was exotic. Given the potential for Australian salmonids to introduce EHNV into aquacultured salmon, Australia had failed to explain the differences in levels of protection it had established in respect of those products and uncooked Canadian salmon.

4.202 In respect of both live fish and bait fish, Canada pointed out that Dr. Rodgers had noted that the risks posed by live fish and bait fish imports were probably at least as high or higher than for uncooked salmon from Canada:

> "The importation of several other groups would pose a potential risk of disease introduction that would probably be at least as high, if not higher, than that posed by the importation of uncooked salmon from Canada. These groups would include any live ornamental fish, bait fish and trash fish for feeding aquaculture species ...." (paragraph 6.97)
>
> and,
>
> "It is probably true to say that for a given disease agent, the likelihood of disease establishment is higher for imports of whole, non-eviscerated bait fish and for live fish than it is from imports of uncooked salmon for human consumption." (paragraph 6.100)

[157] Report of the National Task Force, Table 3.8 : "Import usage within the commercial bait sector", p.24.
[158] Final Report, p.45 (for VHSV).
[159] J.S. Langdon, "Diseases of Introduced Australian Fish", *Fish diseases: refresher course for veterinarians*, May 1988, p. 231.
[160] Humphrey Report, p.87.

Dr. Winton had stated that there was a hierarchy of product risk, with live fish posing the greatest risks, bait fish in the second place and dead, eviscerated fish, ranked last of the three. Dr. Winton had noted that it was quite clear that herring, imported as bait, was a major reservoir of VHS, yet Australia imported large quantities of herring as bait.

4.203 In summary, Canada alleged in the first instance that as Australia had not banned the importation of both dead non-salmonid finfish and live ornamental finfish, despite scientific evidence that several of the 24 disease agents of concern to Australia occurred in these products, Australia had chosen distinct levels of protection in different situations. In the second instance, Canada argued that it was not possible to justify these distinction in the levels of protection that Australia had adopted in different situations. This view was supported by Australia's own experts, in particular in the 1995 Humphrey Report, the 1995 BRS Report and Technical Paper No.3 (1992).[161] This latter paper characterized the distinction whereby the Director of Quarantine prohibited the importation of fresh, chilled and frozen salmonids but permitted the entry of live ornamental finfish, as an "arbitrary" separation of aquacultural and recreational species (including ornamental species), which had "little, if any, scientific basis."[162] Hence, these distinctions were arbitrary and unjustifiable.

4.204 In respect of Canada's claim that Australia's alleged distinctions in the level of protection adopted in different situations were arbitrary and unjustifiable, **Australia** argued that Canada had not, in the first place, demonstrated that there were distinctions in the levels of protection considered to be appropriate in different situations. Australia stressed that there could not be any presumption of distinctions in the levels of protection solely on the basis of evidence of a difference in measures applied to the same animal species or according to origin of a product. Nor could there be a presumption of different levels of protection in circumstances of a product hosting one or more of the diseases in question. A comparison of measures applying to different fish, some of which might have a disease in common, was not sufficient to demonstrate that there existed identical or similar conditions or arbitrary or unjustifiable distinctions in the levels of protection in different situations in the sense of Articles 2.3 and 5.5.

4.205 Without prejudice to the above, Australia argued that if the Panel were to find to the contrary, Canada had not put forward relevant evidence that such distinctions amounted to arbitrary or unjustifiable discrimination. The burden of proof could not be satisfied by a mere assertion of a claim, it had to be shown that the distinction was arbitrary and unjustifiable. This had been the conclusion of the Appellate Body Report *United States - Measures Affecting Import of Woven Wool Shirts and Blouses from India*.[163] The arguments were, furthermore, supported by the Appellate Body's ruling in *EC - Hormones*.[164] Nor could the evidentiary standard be met by inferences of motive or intent. In accordance with the Appellate Body Report on *EC - Hormones*, the measure needed to be examined in the context of the architecture and structure of the measure. Australia further noted that, in the context of the comments by the experts advising the Panel on a hierarchy of risks, the experts had stated (paragraph 287 of the transcript) that risk assessments would be needed in each case.

4.206 Australia claimed that several of the reports cited by Canada to substantiate its claim that the measure was arbitrary and unjustifiable were cited out of context and in some cases were out of date. In this regard, Canada had not taken into account the status of the reports it had cited.[165] None of the reports cited had the status of an import risk assessment. The Humphrey Report explicitly noted the privileged position of Australia in regard to "freedom from many serious salmonid pathogens or strains thereof" and identified salmonids as a higher risk species. The Humphrey Report

[161] Humphrey Report, p.120 (A-22); Nunn Report, p.34 (A-21); Technical Paper no.3, p.2 (A-19).
[162] Technical Paper No. 3, p.2 (Present measures).
[163] Op. cit., paragraph 4.24.
[164] Op. cit., paras. 239 and 240.
[165] Paragraphs 4.56-4.60

recommended minimum restrictions and that the importation of all fish be permitted only on a case-by-case basis.[166] The BRS Report had argued along the same lines that a higher level of "surety from exotic pathogens" was justified in regard to non-living salmonid product for human consumption in "view of Australia's relative freedom from exotic disease". The BRS Report had recommended that quarantine restrictions in excess of evisceration were justified and that quarantine restrictions on both salmonid and non-salmonid aquatic animals had to be reviewed and brought into consistency.[167] Australia noted that the separation between recreational and aquaculture species from other species, including ornamental fish, had been made on environmental grounds and used in connection with assessments made under the Wildlife Protection (Regulation of Exports and Imports) Act with regard to the inclusion of fish on Schedule 6.[168] The rationale had been that aquaculture and recreational species would be attractive for release into the wild because of their aquaculture and recreational attributes and could potentially form feral populations leading to environmental damage. This approach was no longer practised and the new assessment procedure could be found in Appendix D of the Report of the National Task Force (December 1996).

4.207 Furthermore, Australia observed that not all live ornamental fish imported into Australia were capable or recognized as harbouring the disease agents that were the subject of the current dispute. All live ornamental fish entering Australia were inspected on arrival to (i) ensure that they were healthy, (ii) confirm the identification of the species and (iii) ensure that no other materials or issues of quarantine concern were present.[169] Even if a species of ornamental fish could carry a disease agent, one could not automatically conclude that Australia's appropriate level of protection had not been met. Further import risk analysis for the importation of bait and feed fish, and for the importation of molluscs were planned for April 1998.

4.208 In terms of Canada's claims concerning EHNV, Australia noted that these had been addressed in respect of Article 2.3 (see paragraphs 4.97, 4.99 and 4.102). Australia argued that the evidence submitted by Canada did not relate to similar conditions or that the measure represented arbitrary or unjustifiable discrimination. Canada's claims rested on the OIE status of EHNV as a notifiable disease. As noted elsewhere, the classification and listing of diseases by the OIE was not evidence of the severity of disease or of the comparability of risk of occurrence or consequences.

Disguised restriction on international trade

4.209 **Canada** argued that there were seven factors which demonstrated that the arbitrary or unjustifiable distinctions in Australia's levels of protection did in fact result in a disguised restriction on international trade:

> (i) *Australia's failure to simply prohibit the importation of other products known to host the same disease agents.* In Canada's view this was not reflective merely of the magnitude of the difference of the levels of protection or the fact that the measure in respect of salmon was significantly more trade restrictive, rather, it went directly at Australia's purported basis for the measure. While Australia was concerned about the *potential* presence of certain exotic disease agents in Canadian salmon and therefore required a ban on the product, Australia was willing to permit the entry of exactly the same disease agents in other products, and even in Canadian salmon that had been heat treated pursuant to the 1988 Conditions. Australia took this position despite its admission in respect of non-salmonids that "the 'known' presence of

[166] Humphrey Report, p.89, p.120.
[167] BRS Report, pp.34-35.
[168] Schedule 6, Wildlife Protection (Regulation of Exports & Imports) Act 1982, "Live animals and live plants the import of which is not prohibited by paragraph 22 (b) and in relation to which section 9 apples", updated 7 May 1996.
[169] Final Report, pp.5-6.

an agent with a particular host by itself is not an accurate indicator of the likelihood of disease introduction, establishment or spread".

(ii) *The circumstances surrounding the abrupt change in conclusions from the May 1995 Draft Report to the Final Report*. Following the release of the May 1995 Draft Report, Tasmanian salmon producers lobbied against it in an effort to reverse the conclusion that uncooked Canadian salmon should be permitted entry, and those conclusions had in fact been reversed. The conclusion for the May 1995 Draft Report had been that for imports of head-off, eviscerated salmon the risk of disease introduction was negligible. This was deemed to be "acceptably low, having regard to the potentially serious consequences of such an event".[170] Yet the Final Report concluded that not only would this not satisfy Australia's appropriate level of protection, but that no imports of uncooked salmon would satisfy it. Only heat treatment would. This conclusion had been reached without an assessment of the risks entailed by heat-treated product, in a document which all three risk assessment experts advising the Panel regarded as opaque and inadequate. Hence, the only reasonable inference was that Australia was hiding the real reason for reversing its conclusions - to protect its domestic salmon not from disease, but from import competition.

(iii) *Australia excluded from the Final Report relevant information that was considered in the May 1995 Report.* Australia had argued, contrary to the conclusions of Drs. Wooldridge and Rodgers, that the information excluded was not relevant to the decision-making process.[171] Australia had also stated that the water and waste disposal statistics from Sydney and Melbourne did not address waste disposal in other regions of potentially higher risk such as Tasmania. Yet, in fact, the May 1995 Draft Risk analysis had provided waste water statistics for Hobart, Tasmania. In addition, Australia offered no explanation why conclusions regarding pathogen dilution rates based on the information in the May 1995 Draft Report were not applicable to other potentially "higher risk" areas. The only convincing explanation for why Australia excluded relevant data in the Final Report was that the data led inexorably to the conclusion that it did not want to reach - the conclusion that had been reached qualitatively in the May 1995 Draft Report - that the likelihood of disease establishment by the pathways identified by Australia were negligible. This conclusion was supported by the quantitative assessment Dr. Vose had undertaken, using the same data which had been available to Australia.[172]

(iv) *Absence of scientific basis for the measure* (Canada's arguments in this regard are contained in paragraphs 4.65-4.72 below).

(v) *Australia's failure, despite professed concerns about the health of its salmonid populations, to control the internal movement of EHNV hosts.*

(vi) *Australia's failure to specify the pathogens addressed by its measure.* As Australia had failed to assess the risks posed by pathogens identified in the hazard identification stage of its risk assessment, Australia had no credible basis for asserting that its measure addressed the risks posed by particular pathogens.

(vii) *Australia's inability to explain consistently or at all the appropriate level of protection, that its measure aimed to achieve.* This inferred that rather than its measure being applied to achieve its appropriate level of protection, Australia was using its "appropriate level of protection" as a shield for a trade-restrictive measure.

---

[170] May 1995 Draft Report, p.223.
[171] Paragraph 4.154.
[172] "Quantitative analysis of the risk of establishment of *Aeromonas salmonicida* and *Renibacterium salmoniarum* in Australia as a result of importing Canadian ocean-caught salmon", David Vose, Canada's Submission of 18 December 1997 ("Vose Report").

4.210 Canada further argued that the reasoning of the Appellate Body in the dispute *United States - Standards for Reformulated and Conventional Gasoline*, on the relationship between arbitrary or unjustifiable distinctions in levels of protection and the resulting disguised restrictions on international trade was equally applicable to Article 5.5 of the SPS Agreement.[173] Hence, the distinction in Australia's levels of protection for uncooked salmonids and non-salmonids, and for uncooked salmonids and live ornamental fish was, in Canada's view, arbitrary and unjustifiable. The resulting import ban on uncooked salmon was a restriction on international trade in the guise of a sanitary measure.

4.211 **Australia** drew attention to its due process concerns regarding Canada's claim that the measure resulted in a disguised restriction on international trade (paragraph 4.12). Moreover, in addition to the measures previously forming the basis of Canada's legal claims, Canada had introduced a new legal claim of inconsistency in regard to the purported differences between heat-treated and other salmon (paragraph 4.16). Australia also argued that the evidentiary standard could not be satisfied by a comparison of measures applying to different fish. Nor could the evidentiary standard be met by ascribing motive to actions. As stated by the Appellate Body in *EC - Hormones*, it was the architecture and structure of a measure which needed to be addressed.[174]

4.212 In regard to Canada's assertions under (ii) above, Australia noted, in reference to Canada's arguments regarding the Appellate Body ruling in *United States - Standards for Reformulated and Conventional Gasoline*, that the Appellate Body findings related to Article XX of GATT 1994 and that the incidence of obligations in that regard may be somewhat different, given that Article XX of GATT 1994 deals with conditions attached to an exceptional right, as compared to Articles 2.3 and 5.5 of the SPS Agreement, which deal with the conditions to be attached to the grant of a basic WTO right. In *EC - Hormones*, the Appellate Body had rejected the interpretation of Article 5 put forward by Canada on the basis of the Appellate Body findings in the reformulated gasoline case. Moreover, it had stated that the three elements under Article 5.5 - (i) the adoption of appropriate level of protection in different situations, (ii) arbitrary or unjustifiable differences in these different situations which (iii) resulted in discrimination or a disguised restriction on international trade - were of a cumulative nature; all had to be demonstrated and in particular both the second and the third element had to be found, the second element alone would not suffice.[175] In this regard, Australia claimed that Canada, in its submissions to the Panel, had equated the element of "discrimination or a disguised restriction on international trade" with "arbitrary and unjustifiable distinction". Canada had furthermore incorrectly assumed that the Appellate Body interpretations of Article XX of GATT 1994 had a direct application to Article 5.5 of the SPS Agreement.

4.213 Furthermore, Australia argued that Canada had not demonstrated that the draft import risk analysis met Australia's appropriate level of protection. The Final Report did not conclude that heat treatment was satisfactory, it stated:

> "... it is recommended that uncooked salmon products should not be permitted entry from Canada and the United States at the present time. Other issues related to salmon, such as current policies for importing heat-treated salmon, should be

[173] WT/DS2/AB/R adopted on 29 April 1996, p.25. "We consider that "disguised restriction", whatever else it covers, may properly be read as embracing restrictions amounting to arbitrary or unjustifiable discrimination in international trade taken under the guise of a measure formally within the terms of an exception listed in Article XX. Put in a somewhat different manner, the kinds of considerations pertinent in deciding whether the application of a particular measure amounts to "arbitrary or unjustifiable discrimination", may also be taken into account in determining the presence of a "disguised restriction" on international trade. The fundamental theme is to be found in the purpose and object of avoiding abuse or illegitimate use of the exceptions to substantive rules available in Article XX."

[174] Op. cit., para. 246.

[175] Op. cit., paras. 214-215.

> considered in the light of priorities recommended by the National Task Force on Imported Fish and Fish Products."[176]

Australia explained that, in regard to salmon, the measures pre-dated the entry into force of the SPS Agreement. Australia had undertaken a risk assessment on Pacific salmon and on the basis of that risk assessment had decided to maintain quarantine restrictions on imported salmon. No Member had the capacity to undertake concurrent risk assessments on all salmonids, let alone all aquatic products. Australia was undertaking a structured program of risk assessments on a range of aquatic animal products. This was relevant to the architecture and structure of Australia's measures.

4.214 Australia contended that Canada had misrepresented a number of statements made by Australia. The seven points listed by Canada were not facts, but assertions and had previously been addressed by Australia. In particular, Australia argued that:

> (i) Canada's claims reiterated the same claims in regard to different levels of protection and arbitrary and unjustifiable differences. Australia's arguments in regard to these matters expressed in paragraphs 4.185-4.189 and paragraphs 4.204-4.207 were valid here.
>
> (ii) Canada's arguments did not go beyond an ascription of motive which was not relevant to the architecture and structure of the Article 5.5 obligation. Furthermore, the assertion was not borne out by the empirical evidence submitted by Australia in rebuttal, including in relation to the status of the draft risk analysis.
>
> (iii) Australia had already explained the reasons for the differences in content between the draft report and the Final Report, as well as the relationship between the reports, which could not be viewed as separate and distinct exercises. Canada's assertion was an attempt to ascribe motive. Australia had not claimed that the difference between the draft and final recommendations was because of new scientific information. The Final Report had reappraised scientific information and the measures that would be required to meet Australia's appropriate level of protection, as well as factoring in new information.
>
> (iv) In regard to the scientific basis for the measure, the Final Report fully evaluated all scientific data and the measure was based on the Final Report. Canada's arguments relate to scientific views (not all shared) about acceptable levels of protection. Australia explained that it did not require conclusive scientific evidence that an event would not occur, but that there was sufficient scientific evidence on which to base its judgment of the likelihood of occurrence. Canada had not disputed Australia's scientific evidence.
>
> (v) In regard to EHNV, Canada's arguments had no legal basis and were a misrepresentation of Australia's evidence in regard to EHNV (addressed in paragraphs 4.97, 4.99 and 4.102). Evidence of the existence of a non-exotic disease in domestic salmonids did not constitute evidence of a situation identical or similar to evidence of a large number of exotic diseases in imported salmonids; evidence of a different measure did not constitute evidence of arbitrary or unjustifiable distinctions and there was no evidence of a disguised restriction on international trade.
>
> (vi) As was clear in the Final Report, Australia had specified the pathogens addressed.
>
> (vii) Australia had consistently explained its appropriate level of protection. Canada could not provide evidence to the contrary.

[176] Final Report, p xi.

4.215 Australia argued that Canada's claims rested on a premise that the test of legal consistency was one of changes between the draft and Final Reports. In particular, most of the seven factors cited by Canada were simply attempts to infer motives. There was a fundamental difference between an attempt to demonstrate a disguised restriction on international trade through inferring motive and a presentation of evidence based on an analysis of the architecture and structure of Australia's measures. Canada had failed to do this, but was requesting the Panel to undertake a *de novo* review. As such, Canada ignored due deference and the standard of review referred to in the Appellate Body Report on *EC - Hormones*.[177]

4.216 Australia also argued that Canada had not met its burden of proof and had not produced any evidence that Australia's measures resulted in a disguised restriction on international trade. Australia was a significant importer of aquatic animal products, including smoked and canned salmon from Canada. Many of these products competed directly with domestic products in the Australian market place. Australia was, in fact, a net importer of fish products. Australia was also a significant producer and exporter of non-salmonid aquatic products. On the basis of Canada's interpretation of Article 5.5 obligations, consistency could only be assured by removal of the restrictions on salmon, whatever the basis for such measure, or by introducing trade-restrictive measures on other aquatic animal products, whatever the basis for sanitary protection in the case of those products. The latter approach would risk inconsistency with other provisions of the SPS Agreement, while the former would deny Australia the right to protect its salmonid populations against an assessed risk.

(l) Article 5.6

> 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.[3]
>
> Footnote 3:
> 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.
>
> *SPS Agreement, Article 5.6 and footnote*

4.217 **Canada** argued that even if the Panel were to conclude that Australia had determined the appropriate level of sanitary protection to be achieved by its measure and that the distinction in the levels of sanitary protection considered to be appropriate in different situations was not arbitrary or unjustified, Australia's measure was nevertheless more trade-restrictive than required to achieve its appropriate level of protection. The footnote to Article 5.6 made it clear that a determination of a measure's consistency with Article 5.6 entailed the assessment of that measure in relation to other potential measures which would also achieve the same appropriate level of protection that the Member could reasonably adopt. Since Australia prohibited the importation of uncooked salmon while permitting the importation of uncooked non-salmonids, including fish for human consumption and whole uneviscerated bait fish, Australia's sanitary measures for non-salmonids were significantly less trade restrictive. Yet, according to Australia, they achieved the same appropriate level of protection. Additionally, Australia permitted the entry of live ornamental fish which, according to Australia's own experts, posed the highest risk of causing the establishment of serious aquatic animal diseases. Thus, in the case of both non-salmonids and live fish, the measures maintained by Australia against the risk of the establishment of exotic diseases were significantly less trade restrictive than the prohibition on the importation of uncooked salmon.

4.218 Canada noted that it was necessary to know what Australia's level of protection was in order to identify alternatives that would meet it. As a matter of principle and logic, a Member could not evade its obligations under Article 5.6 (or any other provision of the SPS Agreement) simply by

[177] Op. cit., paras. 244-245.

failing to determine or disclose its appropriate level of protection. If it could be inferred that Australia's appropriate level of protection was "zero risk", there might be no measure less trade restrictive than the current measure which achieved that level. Australia had argued that there was no scientific evidence that evisceration would eliminate the risk of entry, establishment or spread of disease. But, as Canada had shown, there was no scientific evidence that heat treatment would eliminate this risk either. Thus, if the Panel were to find that Australia's appropriate level of protection were zero risk, Canada submitted that the Panel would have to consider whether the measure currently imposed by Australia actually met its appropriate level of protection.

4.219 Should, on the other hand, Australia's appropriate level of protection be inferred to be something other than zero risk, Canada argued that a complete prohibition on uncooked salmon imports was the most trade restrictive measure available to Australia. The conclusions in the Final Report demonstrated that Australia had maintained this prohibition despite having been unable to distinguish the level of risk presented by other less trade restrictive options.[178] The fact that Australia had not been able to distinguish among the levels of risk in the import options, including the measure which it had chosen in order to achieve its acceptable level of risk, logically meant that each of the measures achieved Australia's acceptable level of risk. Australia had noted that the Final Report had referred to a number of options as "lower risk options" of which only Option 3 had been identified.[179] Thus, according to Canada, there were several options for fresh, chilled or frozen salmon that represented the bottom of the import risk spectrum and therefore, by definition, had to be capable of achieving Australia's acceptable level of protection.

4.220 Although Australia insisted that it was "readily apparent" that there was a difference in the level of risk between the importation of eviscerated fish and that of maintaining restrictions on uncooked salmon, Canada argued that for many of the pathogens there was no evidence of the effectiveness of heat treatment at the lower temperature ranges allowed under Australia's current restrictions. To the contrary, by providing the conditions for certain of the pathogens at issue to flourish, heat treatment might actually increase the risk for certain of the pathogens identified as being of concern. Although Australia claimed to have assessed the risks entailed by the four less trade restrictive options, Australia had acknowledged that the Final Report did not cover heat-treated product. Therefore, it could not possibly have compared the risk of the four less trade-restrictive options with the risk entailed in its current measure, and it could not claim that the current measure achieved its appropriate level of protection. Hence, it was not "readily apparent" that there was a difference in the level of risk between the current restrictions and evisceration. There was no basis in the Final Report for drawing such a conclusion. As Australia had decided that one option achieved its appropriate level of protection, it necessarily followed that the other options would also achieve Australia's appropriate level of protection. All of the four other options identified in the Final Report[180] were significantly less trade restrictive than the heat treatment requirement and were economically and technically achievable. Australia had therefore violated Article 5.6.

4.221 **Australia** argued that Article 5.6 obligations could not be determined on the basis of views of appropriate methodology for risk assessments. Nor could the obligations be determined by an examination of different measures in force between aquatic products. Australia referred to its due process concerns in regard to Canada's claims about heat-treated product (see paragraph 4.8). Australia had not taken the most trade restrictive measure possible for the protection of salmonid life and health, as evidenced by ongoing significant imports of salmon products. Measures in respect of heat-treated product (which the experts advising the Panel had characterised as a product different from uncooked salmon) were significantly less trade restrictive than a total ban on salmon imports. As documented in the Final Report, Australia had evaluated other potential measures which might be

[178] Final Report, p.62. pp.69-70.

[179] Ibid., p.ix-x (last two paragraphs on page ix). Australia noted in its first submission that on page ix of the Final Report "lowest" was an editorial error, and should read "lower".

[180] Ibid., p.69.

less trade restrictive, but had determined as part of a risk assessment that there was no other significantly less trade restrictive measure reasonably available to it that achieved the appropriate level of protection for salmonids. Australia also noted that heat-treated product was traded in eviscerated form, hence disease risk factors could be different.

4.222 Australia noted that the provision in Article 5.6 was an elaboration of the provisions of the basic rights in Article 2.1 that "Members have the right to take sanitary ... measures necessary for the protection of ... animal or plant life or health ... " and the basic obligation in Article 2.2 in regard to "only to the extent necessary ...". The meaning of the term "necessary" could not be fully interpreted with regard to Article XX of GATT 1994, nor with regard to the jurisprudence of Article XX, as that article covered exceptional rights, not basic rights. The term used in the footnote to Article 5.6 "significantly less restrictive to trade" was not the same as "least trade restrictive". Australia argued that through the risk assessment process, it had been established that there was no other measure reasonably available to Australia in regard to the risk and consequences of entry, establishment or spread of the disease agents of concern in Pacific salmon products subject to the Final Report, taking into account technical and economic feasibility, that would achieve the appropriate level of protection and which would be significantly less restrictive to trade. In other words, the measure was necessary. In this context, Australia referred to its arguments in regard to Article 2.2.

4.223 Australia argued that Canada had not come forward with any evidence that would demonstrate that there were significantly less trade restrictive measures available on uncooked salmon which would achieve the appropriate level of protection. Canada's assertion that different measures were applied between live fish and dead uncooked fish did not constitute evidence that there was an alternative and significantly less trade restrictive measure available which was feasible in both technical and economic terms and which was capable of achieving the appropriate level of protection. A generalization that uneviscerated bait fish or live fish posed a greater threat than eviscerated fish of a different species could not be substantiated without reference to a risk analysis including detailed scientific risk assessment, as stated by the experts advising the Panel. It had to be demonstrated that there were comparable situations in a scientific, economic and biological sense in regard to the risk of entry, establishment or spread of the totality of diseases at issue, together with comparable consequences, and that the same measure would be feasible in an economic and technical sense. Canada's claim that Australia's requirements on heat-treated product were not sufficiently restrictive to achieve Australia's level of protection did not represent evidence that a significantly less trade restrictive measure was available to achieve Australia's appropriate level of protection in relation to uncooked salmon. Canada had not put forward documented evidence that the other options identified in the Final Report could achieve Australia's level of protection. Australia drew attention to the detailed evaluation of options in the Final Report (see paragraphs 4.164-4.165).

4.224 In regard to other aquatic products, Australia observed that it would have to conduct a risk assessment in order to establish what measures to adopt *vis-à-vis* these other products. The need for this had been confirmed by the experts advising the Panel. Risk assessments for other aquatic products were scheduled or underway in order to determine the appropriate measure for the particular circumstances, including ornamental fish. Following the risk assessments, the measures to be applied might be more or less trade restrictive than those applying to uncooked salmon, however, that did not mean that they were significantly more or less trade restrictive within the meaning and intent of the SPS Agreement, including Article 5.6. Pending quarantine reviews on other aquatic products, Australia was not in the position to determine whether the measures that applied to uncooked salmon would or would not achieve the appropriate level of protection in relation to animal health and life risks.[181]

4.225 In regard to the options identified in the Final Report, Australia noted that for each option there was a distinct level of protection and it had been established that only the option chosen would

[181] Ibid., pp. 334-335.

achieve the appropriate level of protection. Although the Final Report stated that " [t]he difference in level of risk between each option is incremental and cannot be quantified"[182], it had clearly stated that Option 1 represented the lowest level of risk (highest degree of security) of any option considered.[183] Options 2, 3 and 4 were not ranked other than that these fell between Option 1 (lowest risk) and Option 5 (highest risk).[184]

4.226 Australia maintained that it had applied the only measure available to it that was consistent with its appropriate level of protection - it was not the most trade restrictive measure as was evident from imports of heat-treated salmonids. Australia argued that even if the measures on salmon were the most trade restrictive possible, Canada would need to demonstrate that there was a significantly less trade restrictive measure reasonably available which would protect animal life and health within Australia in accordance with the level of protection deemed to be appropriate. Moreover, even the most trade-restrictive measure available did not constitute evidence of inconsistency with Article 5.6. Canada had not met its burden of proof in regard to its claims that the measure was more trade restrictive than required in the meaning of Article 5.6.

4. Articles XI and XX of GATT 1994

4.227 **Canada** argued that Australia's measure was a quantitative restriction in the meaning of paragraph 1 of Article XI of GATT 1994, which provided that:

> "No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party."[185]

In Canada's view the measure was a restriction on the importation into Australia of fresh, chilled or frozen salmon from Canada and could not be characterized as a "duty, tax or other charges" which would exempt it from paragraph 1 of Article XI. Furthermore, the measure did not qualify for any of the exemptions within the meaning of paragraph 2 of Article XI. The burden of proof that one or more of the exceptions applied was Australia's.

4.228 If the Panel were to find that the measure at issue was the 1996 Decision, Canada argued that measure would be limited to wild, ocean-caught Pacific salmonids. However, Australia had admitted that its prohibition extended to all uncooked salmon as it had stated in the Final Report that "commercial quantities of fresh, frozen and chilled salmon product are not permitted entry into Australia".[186] If the measure were the December 1996 Decision, then Australia would be maintaining a prohibition on farmed Pacific and Atlantic salmon without a measure. As the prohibition in respect of farmed salmon would be maintained without the benefit of a measure, the SPS Agreement, which applies only to "sanitary or phytosanitary measures", would not apply. Thus, with respect to these products, the prohibition was a violation of Article XI:1 of GATT 1994 to which none of the exceptions in Article XI:2 applied.

4.229 In respect of Article XI, **Australia** contended that the measure cited by Canada did not constitute an import prohibition within the meaning of paragraph 1 of Article XI. Australia argued that QP86A did not prohibit the importation of uncooked salmon from Canada; it allowed imports

[182] Ibid., p.62.
[183] Ibid., pp. 62 and 69.
[184] Australia noted in its first submission that on page ix of the Final Report "lowest" was an editorial error, and should read "lower".
[185] GATT 1994, Article XI paragraph 1.
[186] Final Report, p.4.

subject to permit, provided by the Director of Quarantine within the scope of the delegated legal authority accorded under QP86A.

4.230 Nonetheless, with respect to both Article XI and Article XX(b) of GATT 1994, Australia argued that in accordance with Article 2.4 of the SPS Agreement, a sanitary measure which conformed to the relevant provisions of the SPS Agreement was presumed to be in accordance with obligations under GATT 1994 which related to the use of sanitary measures. Furthermore, Canada had not contested that the measure was within the scope of the SPS Agreement. As Canada had not established inconsistency with Articles 2, 3 or 5 of the SPS Agreement, there had to be a presumption that the measure was in conformity with Australia's obligations under Articles XI and XX(b) of GATT 1994. Canada therefore bore the burden of proof to rebut the presumption of conformity.

4.231 **Canada** stated that Australia's measure could not be justified under any of the exceptions under Article XX and that Australia bore the burden of justifying under Article XX its violation of Article XI. Canada recalled that GATT practice dictated that the party invoking Article XX bore the burden of proving it. Furthermore, GATT and WTO Panels had made it clear that a measure could be considered necessary "only if there were no alternative measure consistent with the General Agreement, or less inconsistent with it, which [the member] could reasonably be expected to employ to achieve its ... policy objectives".[187] Since Canada had already demonstrated that Australia had adopted alternative measures (heat treatment) with respect to the importation of pathogens occurring in salmon and had nevertheless been able to achieve its policy objective of protecting animal life and health, Australia's measure had no justification in the "necessity test", set out in Article XX(b). As Australia had failed to meet this "necessity test", it was not necessary to examine the chapeau of Article XX which proscribed the application of measures which "in a manner which would constitute a means of arbitrary or unjustifiable restriction on international trade".

5. Article XXIII of GATT 1994

4.232 **Canada** maintained that the inconsistency of Australia's measure with GATT 1994 and the SPS Agreement established a *prima facie* case of nullification or impairment pursuant to GATT Article XXIII:1(a) and Article 3.8 of the DSU. If the Panel were to find that Australia's measure was not inconsistent with the cited Agreements, Canada requested the Panel to find that the measure otherwise nullified or impaired benefits accruing to Canada under Article XXIII:1(b). Canada noted that in its request for consultations in 1994 under GATT, the Request for Consultations under the WTO, and the Request for the Establishment of a Panel[188], Canada had raised non-violation claims under Article XXIII:1(b) of GATT 1994. Moreover, Article XXIII:1(b) applied to both GATT 1994 and the SPS Agreement[189], and Canada had made it clear in its requests for consultations and for the establishment of a panel that it considered that benefits accruing to it pursuant to the WTO Agreement were being nullified or impaired as a result of Australia's application of its measure. Canada noted that Article 26.1 of the DSU made it clear that complaints concerning non-violation nullification or impairment could be made within the framework of the WTO Agreement.

4.233 Canada argued that the benefits that it reasonably could have expected to accrue as a consequence of Australia's tariff concessions had been nullified or impaired in that: (i) fresh, chilled and frozen salmon were subject to tariff concessions originally made by Australia in 1947, before the introduction of Australia's measure; (ii) as a consequence of Australia's measure, Canada's uncooked salmon had been denied access to Australia's market; and, (iii) the tariff concessions had been carried forward in successive tariff negotiations, such that Canada was entitled to rely on the reasonable

[187] *Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes*, 7 November 1990, BISD 37S/200, para. 75; *United States - Restrictions on Imports of Tuna*, circulated 3 September 1991, BISD 39S/155, para. 5.28; *United States - Standards for Reformulated and Conventional Gasoline*, Panel Report, adopted 20 May 1996, WT/DS2/9, paras. 6.25-6.28.

[188] GATT Doc. DS48/1, WT/DS18/1 and WT/DS18/2, respectively.

[189] Article 11.1 of the SPS Agreement.

expectations it had in 1947 at the time of negotiation of the original tariff concessions. Canadian salmon exporters could reasonably have expected to export significant quantities of fresh and frozen salmon to Australia, commensurate with Canada's increased export potential for this product and with growing demand in Australia. Moreover, while the measure had denied Canadian exporters access to Australia's growing market for fresh, chilled and frozen salmon, it had at the same time enabled domestic producers to benefit from higher domestic prices.

4.234 **Australia** argued that Canada's claims in regard to nullification and impairment were not within the Panel's terms of reference as a claim of non-violation had not been raised in consultations and was not cited in Canada's request for a Panel. Canada's request for the establishment of a Panel identified GATT 1994 and SPS Articles on which it was seeking findings by the Panel, although it did not specify provisions of those articles. Canada did not identify Article XXIII:1(b) of GATT 1994 as a basis for its legal claims. Nor did it identify Article 26 of the DSU. No reference was made to Article II of GATT 1994 as a relevant provision. Australia further contended that the 1994 consultations, which were held under the GATT dispute settlement rules, were not relevant to the terms of reference of the Panel constituted under Article 6 of the DSU. The relevant WTO consultations were those which took place in 1995. Canada's request for a panel did not cite the 1994 GATT consultation and did not incorporate matters discussed at those consultations. The basis for the current panel was Canada's request set out in WT/DS18/2. Australia noted that in *India - Patent Protection for Pharamceutical and Agricultural Chemical Products*, the Appellate Body had reaffirmed that a complainant had to identify the measures and legal basis of its claims in a request for a Panel, in accordance with Article 6.2 of the DSU. The Panel, under the terms of Article 7.2 of the DSU, was only required to address the relevant provisions in any covered agreement or agreements cited by the parties to the dispute. Canada had not previously cited non-violation claims. Nor had Canada fulfilled the requirement set out in Article 6.2 of the DSU to identify the specific measure at issue and to provide a brief summary of the legal basis of the complaint.

4.235 Australia noted that Canada's claims of the application of the doctrine of "reasonable expectations" were limited to the citation of GATT jurisprudence in footnotes in its submissions. Australia noted that it was clear that claims of "reasonable expectations" were valid in the context of non-violation claims relating to the introduction of subsidies subsequent to the negotiation of a GATT bound tariff concession. However, Canada had not come forward with any evidence in the context of the application of a sanitary measure, including in the context of the application of a sanitary measure as a basic right under the SPS Agreement. Canada's claims, if accepted, could become an obstacle to the protection of life and health and might effectively prevent Members from exercising a basic WTO right conferred under the SPS Agreement. Any such construction would upset the balance of rights and obligations as practised by Members and would undermine the attainment of WTO objectives expressed in the preamble to the Marrakesh Agreement Establishing the WTO, including in regard to the objective of protecting and preserving the environment.

4.236 Without prejudice to the above, Australia maintained that if the Panel were to find that Canada's complaint in this regard fell within the scope of its terms of reference, Canada had nonetheless not satisfied its legal and evidentiary burden of proof in regard to claims of non-violation nullification and impairment in accordance with Article 26.1(a) of the DSU. Australia stated that, as a matter of fact, at the time of negotiation of the original tariff concession, the Quarantine Act of 1908 was in place. The Act made it clear that entry into Australia would be subject to quarantine conditions. The relevant legislative provisions remained unchanged. Hence, it was a measure that could have been reasonably anticipated by Canada at the time of the initial tariff bindings. Furthermore, in regard to the rights accorded under the SPS Agreement in 1995, it was within Canada's reasonable expectations that the identification of a number of disease agents exotic to Australia could affect access to Australia and that Australia would have recourse to sanitary measures in the exercise of its basic WTO rights which might have affected international trade within the meaning of Article 1 of the SPS Agreement.

V. SUMMARY OF THIRD PARTY SUBMISSIONS

European Communities

Burden of proof - Articles 3.3 and 5

5.1 The European Communities argued Article 3.3 was not an "exception" to Article 3.1. The SPS Agreement was based on the recognition that Members had the right to choose their appropriate level of protection. Although Article 3.3 laid down specific conditions governing the exercise of that right in cases where an international standard existed, this did not change the nature of Members' rights to choose their own level of protection into an "exceptional" right. Three possible options were available to Members when international standards existed. Those were to take measures which were (i) *based on* the relevant standard (Article 3.1); (ii) which *conformed* to the standard (Article 3.2); or, (iii) which resulted in a higher level of protection (Article 3.3). The SPS Agreement encouraged Members to adopt measures which "conformed" to existing international standards by providing that such measures would be "deemed" to be "necessary" (in the sense of Article 2.2 of the SPS Agreement) and "presumed to be consistent with" the remainder of the SPS Agreement and with GATT. But even this presumption could not be rebutted by a complaining Member. From this, it could not be inferred that a reverse presumption (or negative inference) applied in those cases where a Member chose to depart from the international standard in order to set a higher level of protection. The three options were of equal standing and no one could be qualified as an exception to the others. The SPS Agreement clearly distinguished between measures which were *based on* international standards (Articles 3.1 and 3.3) and those which *conformed* to such standards (Articles 2.4 and 3.2). The complaining party had to bear the burden of showing that the measure of another Member was not based on the international standards, was not based on scientific principles and was maintained without sufficient scientific evidence (Article 2.2).

5.2 The European Communities emphasized that the right to choose a higher level of sanitary protection was explicitly provided for in the SPS Agreement (6th preambular paragraph, Annex A paragraph 5, and Articles 2, 3 and 4.1). A sovereign right could not be undermined by technical and procedural requirements, like the burden of proof, especially in cases where there was scientific uncertainty. Issues of health were so fundamental to the democratic system of government, that sanitary measures had to be given the benefit of conformity with the SPS Agreement until the complaining Member had succeeded in establishing beyond doubt and on the basis of the latest scientific information available that a sanitary measure was not based at all on scientific principles, in the sense of Article 2.2.

5.3 In the view of the European Communities, "burden of proof" was an ambiguous term. It was essential to distinguish between the following concepts: (i) standard of proof; (ii) burden of persuasion; (iii) minimally sufficient evidence; and, (iv) burden of producing evidence. These concepts applied to very different aspects of fact-finding and responded to very different policies. Initially, a complaining party had to "present evidence and argument sufficient to establish a presumption" that a Member had acted inconsistently with its obligations under the SPS Agreement.[190] Evidence had to be produced (i) that was minimally 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 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. Once a complaining party had produced such compelling evidence, the Member against whom the complaint was being brought faced the practical reality that either it had to produce convincing rebuttal evidence or it would be likely to suffer adverse findings. It was misleading, however, to speak of any "shift" in the "burden of proof" in such a case. The burdens of production and persuasion on any issue essential

[190] Appellate Body Report on *United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, WT/DS33/AB/R, p.13.

to proving a violation had to be borne throughout the process by the complaining party. The fact that in the dynamics of the proof process there might come a point when the defending party had to produce convincing evidence or lose did not amount to an additional rule of law that "shifted" those burdens. The European Communities noted that the argument on burden of proof they proposed found clear support also in the almost identical provisions of the NAFTA Agreement on sanitary and phytosanitary measures.

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

5.4 The European Communities argued that the Panel had to decide whether the Australian measure was based on a risk assessment as appropriate to the circumstances (Article 5.1). The Panel had also to judge whether the Australian measure was based on scientific principles and was maintained with sufficient scientific evidence (Article 2.2), as well as whether there was scientific justification for departing from existing international standards (Article 3.3).

5.5 The Panel could not conduct its own risk assessment, nor could the Panel substitute its own scientific judgement or that of individual scientists or experts chosen by it for that of the Member applying an SPS measure. Panels had no authority nor competence to evaluate the weight of scientific evidence used by the government of a Member applying an SPS measure. A panel's mandate, in considering the evidence invoked by a Member maintaining an SPS measure, was not to determine whether it agreed that such evidence constituted *best evidence* available but merely to determine whether that evidence had the minimum external attributes of scientific inquiry and provided a sufficient basis for the Member's own determinations about the risk.

5.6 It followed that if in a particular case the "weight" of available evidence indicated that there was no risk of spread of a certain disease, but another part of available scientific evidence indicated that there was such a risk, the government of the Member concerned would still be entitled, under the SPS Agreement, to take a precautionary or preventive approach and base its measure on the latter part of the available scientific evidence.

5.7 The European Communities disagreed with Canada's claim that a "risk assessment" could not satisfy the obligation imposed by Article 5.1 of the SPS Agreement, unless it estimated the "probability" of a risk rather than its mere "possibility". This implied that Members were required to make a quantitative assessment of the risk, but the use of the term "likelihood" in the definition of "risk assessment" could not be taken to mean that a risk assessment had necessarily to include a quantitative estimate of the risk level. The SPS Agreement qualified the obligation to conduct a risk assessment with the phrase "as appropriate to the circumstances" in Article 5.1. This was an express recognition that what was an appropriate risk assessment might differ from case to case. In many cases, a quantitative assessment of the risk might not be appropriate or indeed feasible at all.

5.8 The European Communities noted that a Member was free under the SPS Agreement to refuse to take any risk, no matter how small its possibility of occurrence might be and irrespective of whether it was considered to be acceptable to other Members. With its submission Canada did not appear to argue that there was no risk at all, but simply that its probability of occurrence was very very small. However, a Member was free under the SPS Agreement to refuse to take any risk, no matter how small its possibility of occurrence may be and irrespective of whether it had been considered to be acceptable to other WTO Members or to international organizations such as the OIE. Canada appeared also to forget that, in basing their measures on a risk assessment, Members could take into account a wide range of reports, studies, publications and individual scientific advice. Because the "information-base" for the analysis of the risk was necessarily very wide and constantly being updated as science progressed, it was not surprising to find sometimes contradictory scientific statements. However, this could not prevent a Member from choosing to base its evaluation of the possibility of the harm arising on the part of available scientific evidence which in its view appeared to be more reasonable.

Article 5.5

5.9 The European Communities agreed with Australia that the text of Article 5.5 did not impose an obligation lending itself to immediate implementation. Article 5.5 required a comparison of the *levels* of protection applied by a Member in different situations and not of the *measures* adopted to enforce those levels of protection. Instead, Canada had compared the measure applied by Australia to different types of fish and then mistakenly assumed that to different measures must necessarily correspond different levels of protection. In order to achieve a given level of protection it was necessary to apply different measures depending on the circumstances of each situation. More restrictive measures were not necessarily equivalent to a higher level of protection and, conversely, less restrictive measures were not necessarily indicative of a lower level of protection. Because there could often be a wide range of sanitary measures available to achieve the same level of protection, the measures employed by Members could differ significantly even where they were designed to achieve the same level of protection. This was, in the EC view, not to be dealt with under Article 5.5 as Canada had done, but rather, under the provisions of equivalency of the SPS Agreement (Article 4).

5.10 The European Communities further argued that a distinction in the levels of protection applied in different "situations" could not be deemed to be "arbitrary" or "unjustified" nor lead to "discrimination" or to a "disguised restriction of international trade" unless those situations were clearly comparable. The mere fact that a disease agent was found in two different species of fish was not sufficient to render "comparable" for the purposes of Article 5.5 the level of protection and the sanitary measure applied by Australia to those species, because there might be other factors which could make the two situations *not* comparable. For instance, the severity of the effects of a disease agent might vary from one type of fish to another, thus justifying both a different level of protection and different sanitary measures. Consistency could not be seen as a static concept, but rather a process that would take years to achieve. The guidelines, which Article 5.5 required before the objective became operational, had been foreseen precisely for that purpose. Canada's interpretation of Article 5.5 was not only unreasonable and unfounded but could also lead to regulatory chaos for Members of WTO.

Arbitrary, unjustifiable or disguised restriction on international trade: proportionality of the Australian measure

5.11 The European Communities noted that in accordance with Articles 2.3 and 5.6 of the SPS Agreement, Canada bore the burden of showing that Australia's measure was arbitrary, unjustifiable or constituted a disguised restriction on international trade. In particular, Canada had to show that there was another reasonably available measure, which was less trade restrictive and which could achieve the level of protection chosen by Australia. Canada did not appear to have established this, because the salmon it was endeavouring to export did not come from regions or zones that had been declared free from certain diseases of concern. The European Communities, on the other hand, claimed to have shown Australia that the Atlantic salmon caught or farmed in Ireland and the United Kingdom was free of the specific salmon diseases mentioned by Australia. EC salmon, therefore, came from regions or zones free of those diseases and to that extent the Australian measures were not, in the view of the European Communities, in conformity with Articles 2.3 and 5.6 of the SPS Agreement.

India

5.12 India agreed that each Member had the right to take such measures which it might feel were necessary for protection of human, animal or plant health or life. It was, however, important for Members to ensure that these measures were applied in an equitable manner, did not constitute a disguised restriction of international trade. In this perspective, even though India recognized Australia's desire to prevent the transmission of some of the diseases of concern to its own fish population, it was important that the measures were not only necessary for attaining these objectives

but were also consistent with the WTO obligations. The sanitary measure had to be applied *only to the extent necessary* to protect human, animal or plant health or life, and had to be based on scientific principles and not maintained without sufficient scientific evidence. As salmon constituted an important ingredient in international trade, it was essential that any measure which was found to be inconsistent with Members' obligations, or which in any way negated the benefits accruing to any country under the WTO Agreement, was removed expeditiously.

Norway

5.13 Norway did not contest Australia's stated policy objective to protect salmonid life or health from the spread of exotic diseases, and accepted that Australia had the right to establish its appropriate level of sanitary or phytosanitary protection, i.e., its acceptable level of risk. Norway did, however, submit that Australia's measure was not necessary to achieve this purpose. Furthermore, a risk assessment as appropriate to the circumstances had not been performed.

5.14 Norway stated that the Australian measure at issue amounted to an effective ban on imports of fresh and frozen salmonid products, in contravention to GATT Article XI. The ban could not be justified either under the general exceptions in GATT Article XX or the SPS Agreement, the latter being an elaboration of relevant provisions of GATT 1994, in particular the provisions of Article XX(b). As Australia had submitted that its measure was being maintained for the purposes of protection of animal life and health from the risks arising from the entry, establishment or spread of diseases, disease-carrying organisms or disease-causing organisms - measures that came within the scope of Article 1 of the SPS Agreement as detailed in paragraph 1(a) of Annex A of that Agreement - Norway considered that the Australian measure had to be first examined against the rights and obligations of the SPS Agreement. If the measure violated the SPS Agreement, there would be no need to discuss Article XX of GATT 1994 separately.

5.15 Norway noted that the Australian measure applied to all salmonid product of whatever subspecies or origin. However, the Australian reports that related to risk assessment only assessed disease risks in connection with potential imports of fresh and frozen adult, wild, caught Pacific salmon from the United States and Canada (the species belonging to the genus *Oncorhynchus*). Imports of farmed salmon and wild caught salmon from other countries would require separate risk analyses. It thus seemed that no risk analysis existed that would cover all the products and origins covered by QP86A (the species belonging to the genus *Salmo* and *Salvelinus*, common to aquaculture). This in itself casts serious doubts as to the conformity of QP86A with the SPS Agreement.

5.16 Norway noted that a distinction had to be made between measures depending on the extent to which they were based on an international standard, guideline or regulation. Of the 24 diseases discussed in the Australian reports, and thus presumably the diseases the measure was supposed to protect against, two diseases had been identified by the OIE as requiring special attention (i.e. notifiable Diseases). For these two diseases, fish had to be eviscerated before sold. Three diseases were labelled Other Diseases (OIE recommended that the importing country require an international aquatic animal health certificate). The other 19 diseases were not subject to any specific recommendation. Only three of these had been considered by the OIE Fish Diseases Commission, which had not considered any specific recommendation necessary for these three diseases. The Australian measure (the import ban) thus did not conform to any international standard, guideline or recommendation.

5.17 Where an international standard, guideline or recommendation existed a measure which did not conform to that standard, was subject to two sets of requirements in Article 3.3, i.e., that it resulted in a *higher* level of sanitary and phytosanitary protection than would be achieved by measures based on the relevant international standards; *and* that there was *either* scientific justification for the deviation from the relevant international standard *or* the measure was a

consequence of the level of sanitary or phytosanitary protection a Member determined to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5. Where no international standard, guideline or recommendation existed, there was no obligation to harmonize with other countries' standards, but the measure had to be developed and applied in accordance with *inter alia*, Articles 2 and 5 of the SPS Agreement.

5.18 The Australian measure, as it related to those diseases covered by OIE recommendations, did not comply with the first requirement in Article 3.3, i.e., it did not result in a *higher* level of sanitary and phytosanitary protection than would have been achieved by measures based on the OIE recommendation. Australia's May 1995 Draft Report listed a number of events that had to take place before an exotic disease could become established in Australia, and had concluded that this outcome was so unlikely that it did not merit the stringent measures in effect. Later Australian reports and submissions had not provided reasons to disprove this conclusion.

5.19 Even if one had assumed that a higher level of protection could be achieved by Australia's measure, the measure did not comply with the second set of requirements in Article 3.3. Footnote 2 to Article 3.3 stated that "there is scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this [SPS] Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection". Norway contended that there were no international scientific studies that supported the contention that headless, eviscerated salmon for human consumption had spread diseases to living salmon.

5.20 Alternatively, if one accepted that Australia's measure could achieve a higher level of sanitary or phytosanitary protection, Australia's right to determine such a higher level of protection - and the measure to implement this decision - had to comply with the relevant provisions of Article 5, as well as Article 2. This meant that the risks from the introduction of diseases had to be related to the importation in question.

5.21 Articles 5.1 and 5.2 required that an appropriate risk assessment be made. Annex A, paragraph 4, explained this as an "... evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, ...; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of ... disease-causing organisms in food, beverages or feedstuffs." Article 5.2 furthermore required that Members had to take into account, *inter alia* scientific evidence, production methods, inspection methods, prevalence of disease and existence of disease free areas. Taken together, this required Australia to perform a thorough evaluation of the different measures which might be applied to achieve its appropriate level of protection. Norway accepted that Australia might come to a different result than the OIE, if its evaluation of the risks and measures, performed in conformity with the elements detailed above, could justify a different approach. The Australian arguments as to why the OIE measures were not sufficient to achieve this level of protection, when other countries applied the OIE measures to achieve, successfully, the same level of protection, were, however, not based on the elements mentioned above. Furthermore, there had been no quantification of likelihood of disease introduction for different measures were discussed.

5.22 Annex A, paragraph 4, defined risk assessment as relating to *a* pest or disease. The requirement to perform separate risk assessment and management decisions for each disease was also inherent in Article 5.2 with respect to disease-free areas. In establishing its measure, Australia had not evaluated the likelihood of entry for each disease. When the OIE had established its two lists of diseases, it had been because some diseases were thought to require more stringent measures than others. Yet Australia's broad measure made no distinctions, thus denying *inter alia*, other Members the right, according to Article 6.2, to demonstrate that its area was free of any or all of the diseases, something which was particularly important with respect to the 5 diseases covered by the OIE recommendations as opposed to the 19 diseases not so covered.

5.23 Norway noted that Australia's right to determine its appropriate level of protection was circumscribed by the obligation to avoid arbitrary or unjustifiable distinctions in the level it considered appropriate in different situations, if such distinctions resulted in discrimination or a disguised restriction on international trade. This Article established a general objective of consistency, unrelated to the level of protection chosen. Consistency was, however, an objective, and did not impose an absolute obligation in all respects. The SPS Committee had so far not developed guidelines for the application of this paragraph. Considering the numerous regulations that currently existed, the differences that might exist between substances and diseases, and the many regulations that were in force before the SPS Agreement came into force, it seemed to Norway that only quite similar circumstances coupled with unjustifiable levels of protection might be considered a violation. This requirement had to be applied with caution, and the limits to unwarranted comparisons would probably have to be decided from case to case. In the present case, the treatment of the same diseases when present in other fish species, and perhaps also the treatment of other exotic diseases in fish, would seem to be relevant.

5.24 Australia did not prohibit importation of fresh or frozen fish of other species which might carry the same diseases, and where the introduction of disease would follow the same pattern. Australia, furthermore, allowed the importation of live ornamental finfish which might be host to various exotic diseases. Norway argued that this indicated different levels of protection. Australia, furthermore, had provided no explanation or justification for these differences, which previous Australian reports had admitted were arbitrary and unjustifiable. As such, they had clearly to be considered a disguised restriction on international trade, and, in this case, contrary not only to Article 5.5, but also to the requirement in the last sentence of Article 2.3.

5.25 Irrespective of what might be considered as Australia's "appropriate level of protection" - which Australia had never defined or quantified - against the spread of the diseases in question, it was evident that Australia applied different measures to different fish species. Australia had not presented evidence that would substantiate that different fish species with the same disease represented different risks. It thus seemed that some of the measures were either unwarranted or ineffective.

5.26 The OIE recommended measures to protect importing countries against various diseases. Australia's measure with respect to salmonids was more trade restrictive than another measure, readily available to Australia and which resulted in the same level of protection, while at the same time its necessity over other measures was unsubstantiated. In this respect, Norway therefore contended that Australia had violated Article 5.6 and Article 2.2 of the SPS Agreement.

United States

5.27 The United States noted that it had a long history of unsuccessfully trying to work with the Government of Australia to permit the importation of wild, ocean-caught salmon. For over 20 years, Australia had prevented the importation of any uncooked salmon by claiming potential fish disease transmission. The industry protected by Australia's ban, the Tasmanian salmon industry, had originated at least in part from the importation of live salmon eggs from the United States.

5.28 The United States noted that Australia's import ban applied to *all* uncooked salmon, no matter whether any salmon products in a shipment carried the disease and no matter whether the stock from which the salmon was harvested was free of disease. Australia's broad arguments in support of its ban disguised the lack of scientific justification. Under the terms of the SPS Agreement, the United States argued that the analysis had to be whether the measure at issue was based on legitimate sanitary concerns for each specific disease on which Australia had based its ban. Instead of analysing each disease, Australia referred generally to a broad number of fish disease agents that it considered could "potentially" be present in Canadian salmon. Yet Australia had declined to address the issues involving each of these disease agents. As Australia had not specified on which disease risk it had based its ban, it was impossible to conduct the necessary analysis. The United States noted that

varying references in the Australian first submission in respect of the disease agents of concern had led to confusion in regard to the actual number of diseases at issue.

5.29 The United States claimed that Australia's analysis did not address some of the basic issues surrounding its claims in support of its ban. First, Australia's claims turned on the assertion that for each of the disease agents there was a risk that the agent might be present in eviscerated, wild, northeast Pacific ocean-caught salmon (the "salmon at issue"). Yet in many cases Australia had presented no scientific evidence of the agent ever having been found in the salmon at issue, let alone in any products from such salmon. Furthermore, Australia had not conducted its own tests to look for the disease agents. Much of the analysis was mere speculation that, because the agent had been found in salmon in freshwater, there might be a chance that the agent would occur in wild, ocean-going salmon. Most of the disease agents which had been listed by Australia had been isolated from stressed Pacific salmon in freshwater, but had never been isolated or detected in wild, ocean-caught Pacific salmon. Pacific salmon returned to freshwater as adults to spawn and then they died. As they returned to freshwater, they became highly stressed, their immune response was compromised, their flesh quality would begin to deteriorate, and they might contract a number of opportunistic infectious diseases which were not found in ocean-caught fish. Thus, Australia's list of 20 or so disease agents would have to be reduced by removing those for which there was no scientific evidence of the agent being present in the salmon at issue.

5.30 Second, according to Australia's own Final Report, an essential link in the chain of events necessary for imported salmon to introduce a disease was that "the pathogens must be present in biologically significant numbers to initiate infection in the host". In other words, Australia claimed that, for each remaining disease, the level of any disease agent that would be present in the salmon at issue was large enough to be an infective dose. Again, there was no scientific evidence to support this claim with respect to each of these disease agents and, in many instances, there was scientific evidence that this claim was not valid. Australia had not provided scientific evidence that all of the disease agents of concern even occurred in the edible muscle, or other tissues which would be imported, at a level which would constitute a risk of infection.

5.31 Third, Australia's claims were based on the assertion that each of the disease agents was exotic to Australia. Australia had not conducted an adequate survey of its waters or domestic stocks of salmonids and native fishes to determine if these diseases were present. Instead, it relied on the fact that the disease had not been reported and that it would turn up in routine testing. However, this approach stood in stark contrast to the approach used to determine if the disease was present in the salmon at issue. For instance, in the United States, the states of Alaska, Oregon and Washington examined salmon submitted to their fisheries laboratories by commercial fishers and processors. The testing by these states was much more extensive than that done by Australia. In fact, only a few of the disease agents listed by Australia had ever been recorded in wild, ocean-caught Pacific salmon in any life stage or in any tissue and might well have not been found had the United States used Australia's testing system. According to Australia's approach, none of the other disease agents existed in the salmon at issue.

5.32 As a result, in the view of the United States, Australia's approach to the evidence was inconsistent. Australia had to either accept that the evidence was sufficient to establish that these other diseases were not present in the salmon at issue (in which case there was no reason to ban their importation in fresh or frozen from) or else that the evidence was no sufficient to establish that these diseases were exotic to Australia.

5.33 The United States noted that many of the disease agents about which Australia claimed to be concerned also occurred in other finfish, and Australia imported large quantities of other marine finfish in a fresh or frozen condition, and imported live ornamental fish, without any sanitary controls. Although Australia claimed that it had commenced, and would commence, risk assessments on some of these other fish, it was doubtful that Australia was really concerned about the introduction of these

diseases or that the risk of disease was the true basis for its ban. For over 20 years Australia banned the importation of salmon without taking any steps to assess risks from, or protect against the introduction of disease from, these other finfish.

5.34 Australia had stated that its appropriate level of protection was that "fish have been subject to such treatment as in the opinion of the Director of Quarantine is likely to prevent the introduction of any infectious or contagious disease." "Likely to prevent" would mean that it was likely that the fish would not introduce an exotic disease. Australia's own characterization of the risks from the salmon at issue made it clear that it was likely that the salmon would not introduce the disease. Accordingly, it was not clear why Australia's ban was necessary. Instead, Australia's ban appeared to be designed to ensure that there was no likelihood of any disease agent being found in imported salmon. "No likelihood of disease" was a different test altogether from "likely to prevent disease," and "no likelihood" was a much higher level of protection than "likely to prevent." The United States did not see how Australia could reconcile its ban with its stated level of protection.

5.35 Finally, the United States noted that it could not endorse all of the arguments put forward by Canada. In particular, the United States did not agree that the SPS Agreement required a "quantitative" risk assessment. Nothing in that agreement specified that the risk assessment had to be quantitative. The term "likelihood" in the definition of "risk assessment" in Annex A to the SPS Agreement did not mean a numerical value of probability. This simply recognized the constraints of scientific knowledge. Ideally the objective of a risk assessment would be to establish, through scientific evidence, a quantitative level of risk whenever this was possible. However, in many if not most cases, this would not be possible due to a lack of evidence that could link an activity quantitatively to any effect on the population covered.

VI. PANEL'S CONSULTATION WITH SCIENTIFIC EXPERTS

Panel procedures with regard to scientific expertise

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."

Noting that this dispute involved scientific or technical issues, the Panel consulted with the parties regarding the need for expert advice. Neither party requested the Panel to seek such advice, however both parties indicated that they had no objection to the Panel seeking advice. The Panel decided 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.

6.2 The parties were invited to submit names of individuals expert in the subject matter before the Panel. At the same time, names of individuals were also sought from the Office international des epizooties (OIE). Brief curricula vitae were solicited from all experts who were prepared to assist the Panel.

6.3 The parties were provided the opportunity to comment on these potential experts on the basis of the curricula vitae, and in particular to state any compelling objections they might have with regard to any individual. The Panel than selected four individuals from the list taking into account the comments of the parties and the need for expertise in a number of areas (eg., risk assessment,

transmission of diseases of fish, and the procedures of the OIE). These experts were requested to serve, in their personal capacities, as individual advisers to the Panel.

6.4 The Panel, in consultation with the parties, prepared specific questions which it submitted to each expert individually. The experts were requested to provide their responses, in writing, to those questions they felt qualified to address. The parties agreed that their written submissions to the Panel, including the written versions of their oral statements, be provided to each of the selected experts. The written responses of the experts were provided to the parties, and the parties were given the opportunity to comment on these.

6.5 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.[191]

6.6 The experts selected to advise the Panel were:

Dr. David E. Burmaster, Alceon Corporation, United States

Dr. Christopher J. Rodgers, fish disease consultant, Spain

Dr. James Winton, National Fisheries and Research Center, US Fish and Wildlife Service, United States

Dr. Marion Wooldridge, Department of Risk Research, Central Veterinary Laboratory, United Kingdom

Questions to the experts - Compiled Responses

6.7 By way of general introductory comments, **Dr. Wooldridge** noted that a number of different terminology systems were still in use even within the veterinary and animal health sphere (including fish). In the terminology system now generally advised for use within this field, *risk analysis* and *risk assessment* had different, distinct meanings although in the past they were often used interchangeably. The term risk analysis as now generally used comprised four components: hazard identification, risk assessment, risk management and risk communication. This terminology was taught in the WTO/OIE sponsored Risk Analysis Training Workshops.

6.8 In the SPS Agreement definitions, hazards were defined as additives, contaminants, toxins or disease-causing organisms which may potentially have an adverse effect. A particular risk analysis might look only at a particular range of hazards, for example disease-causing organisms; and within the scope of that particular risk analysis, hazard identification (HI) was then the process of identifying all potential hazards in the commodity being considered.

6.9 Risk assessment was the process of estimating the risk presented, by the identified hazard or hazards, for the outcomes of interest. The relevant outcomes of interest for import risk assessments were specified in the SPS Agreement. In theory, the assessment could be done either qualitatively or quantitatively. In a qualitative assessment one estimated the risk (that is, the probability) of a particular outcome in words; thus the probability of a particular outcome might be estimated as, for example, high, or low, or negligible. In a quantitative risk assessment the probability was assessed numerically and the resultant probability (P) was given a numerical value; thus, for example, P= 0.99, or $P=1x10^{-6}$, or "there is a 95 per cent probability that P<0.1". In practice a quantitative assessment could only be undertaken where quantitative data allowed.

[191] A transcript of the meeting with the experts is attached as Annex 2 of this document.

6.10 Risk management was the process of deciding whether a particular risk estimated under the pertinent circumstances was acceptable (which was a matter of judgment dependent upon various factors including the results of a risk assessment) and, if not, selecting and implementing measures that could be applied to reduce the level of risk. Risk communication included all the communication relevant to the risk analysis, including communicating results of risk assessments and obtaining information, opinions, and feedback from all interested parties on any relevant factor including scientific data and method, and acceptable risk levels.

6.11 A risk assessment was therefore only part of a risk analysis, but in answering the Panel's questions on risk assessment, it might be necessary to consider the other elements of the risk analysis within the Australian document. In addition, the two Australian documents did not use the two terms in exactly this way. They appeared to call both the whole process, and the risk assessment itself risk analysis, therefore those parts of the document relating specifically to the risk assessment have to be identified by the reader. Also, the qualitative assessment of risk often leads very directly into a risk management recommendation, making separation more difficult.

6.12 Dr. Wooldridge further noted that her main area of competence in this matter was on risk analysis and risk assessment.

Risk assessment procedures

Question 1. When comparing Australia's Draft 1995 risk assessment with the 1996 Final Report, what are the main differences between the two risk assessments? Would you characterize one or the other of these risk assessments as technically or scientifically more sound than the other? If so, on what basis? What, in your view, are the minimum requirements of a risk assessment? Would requirements vary depending on the product and/or diseases addressed? With regard to both the 1995 Draft Report and the 1996 Final Report, do these reports, from a technical/scientific point of view, meet the minimum requirements of a risk assessment generally accepted in the specific area of aquatic animal health?

6.13 **Dr. Burmaster** replied that the two reports used similar methods but came to opposite policy conclusions. He did not consider that one or the other of these risk assessments was technically or scientifically more sound than the other, but that the two reports had similar strengths and limitations. In terms of the minimum requirements for such a risk assessment, Dr. Burmaster indicated that, with some exceptions in some situations (but not in the case of this dispute), a risk assessment must use quantitative methods to estimate the probability and the magnitude of desired and adverse consequences. Neither the draft risk assessment (May 1995) nor the final risk assessment (December 1996) used quantitative methods, so neither met the minimum requirements for this situation. Dr. Burmaster noted that the requirements might possibly vary depending on the product and/or diseases addressed. For example, the minimum requirements for a risk assessment concerning insect pests in fruit orchards might differ in some ways from those for a risk assessment concerning bacterial diseases in fish. However, he believed that each such risk assessment must, at a minimum, use probabilistic methods to distinguish and to quantify the *variability* and the *uncertainty* inherent in the problem. [References to the current thinking in the risk assessment community about distinguishing and quantifying *variability* and *uncertainty* could be found in (i) Burmaster & Thompson, 1997; and (ii) Burmaster & Wilson, 1996, via the Internet from http://www.Alceon.com.]

6.14 **Dr. Rodgers** observed that the 1996 Final Report had been restructured and divided into 4 main sections, which were linked by an overall summary, reflecting the two previous draft reports. The 1995 Draft Report was designed as a draft import risk analysis (IRA) for public comment, which was a valuable additional step for this type of exercise. Unfortunately, this led to the subsequent 1996 reports being less specific, although the sections on disease considerations presented the background information in a more clearly structured format by using recommended risk assessment factor groupings (e.g. country, commodity, agent, etc.). The 1996 Draft Report adopted a more cautious

approach, since the conclusion used expressions such as "... if the importation of product were to be permitted ...", rather than statements such as "... AQIS recommends that importation be permitted under the draft conditions described ...", as occurred in the 1995 Draft Report. On the other hand, the 1996 Final Report went one step further and categorically stated that "... it is recommended that uncooked salmon products should not be permitted entry ...". This could only be as a result of the public consultation exercise and the uncertainty arising from missing or difficult to interpret data. This approach gave the impression that the 1996 Draft Report considered the available options as a technical review but fell short of commitment. The 1996 Final Report fully committed itself.

6.15 In contrast, the 1995 Draft Report, although appearing as a straightforward literature review in some sections, appeared to use the available information to attempt a qualitative risk assessment, which lead to subjective assumptions about the various possibilities for disease introduction. As such, the 1995 Draft Report was a more useful document, in the sense of an internal risk assessment exercise, since it evaluated the data to conclude that a negligible risk existed, while at the same time recognising that the overall risk of disease introduction could not be quantified. The 1996 Final Report gave more weight to the unknown elements of the assessment and as such was more cautious, which resulted in an outcome closer to the "unacceptable" rather than the "negligible but acceptable" end of the scale. Dr. Rodgers indicated that the lack of actual data and disagreement between scientists on likely outcomes probably led to this anomaly, since subjective opinion is usually argued as unrepresentative of the true situation. Unfortunately, qualitative risk assessment contains an element of assumption which is a necessity as a substitute for gaps in the scientific data base. In fact, a range of "scientific expert opinion" could actually be very useful in these circumstances and might even be adapted to create probability distributions for a more accurate quantitative risk assessment. This would be equally true for both the disease agent factors and the unique factors related to Australia, such as the susceptibility of Australian species to exotic salmonid diseases. Only the 1995 Draft Report made an attempt in this direction.

6.16 Dr. Rodgers noted that the reports had been compiled from an Australian perspective and in this respect met the methodology requirements laid down by the OIE, which stated that countries may design their own process. The reports were supported by references to the scientific literature and other sources, as required. The question of the potential volume of trade was addressed in the 1995 Draft Report by listing the Canadian export statistics for salmon to other countries and simply estimating that about 3000 tons would be imported annually. The 1996 Final Report only referred to "commercial quantities of product", even though the number of aquatic animal units being imported significantly influences the risk assessment. The other basic factors required for a risk assessment, namely country factors, commodity factors, exposure factors and reduction factors, were considered on a disease-by-disease basis from a textual technical/scientific point of view. The potential adverse consequences of disease introduction were also outlined in the same way.

6.17 One of the more important necessities for a risk assessment, particularly a quantitative risk assessment, was good scientific data concerning the reported prevalence of infection in the exporting country. For fish or shellfish (and other animals) this generally occurred in one of three ways: data from the OIE annual returns, scientific reports and published peer-reviewed scientific literature. In practice, each of these varied in detail from basic information (OIE returns) to detailed data (scientific literature). However, even the most detailed data varied widely, in both content and usefulness.

6.18 Prior to a consideration of the factors involved in a risk assessment exercise it was necessary to address the basic question that the analysis would be designed to answer. The question needed to be as specific as necessary in order to provide useful information in support of a subsequent decision concerning the importation of a batch of fish or their products. A question usually specified the disease, or diseases, of concern, the fish species to be imported and possibly the time-frame of interest. However, the basic question might need refining and could be divided into more precise questions. Sometimes it was not clear, until the problem was considered in detail, exactly which risks needed to be estimated. As a result, the original question might need to be re-framed. Once the

hazard had been identified, all the events likely to occur during importation needed to be listed in order to represent the expected pathway which would prevent the unwanted event from occurring.

6.19 The potential risk factors could be generally divided into prioritized categories, such as:

- the diseases of concern and their prevalence in the species for export and any closely related species in the exporting country and surrounding areas;

- the epizootiology of the diseases of concern;

- the effectiveness of the disease surveillance and monitoring systems in the exporting zone/country and the powers of the government administration over the movement of fish and fish diseases;

- the sensitivity and specificity of diagnostic tests for detection and identification of the pathogens of concern.

The identified risk factors could also be further broken down into more specific topics as follows:

(a) Country factors concerned with the diseases present in both the exporting and importing country or region and would include factors such as disease prevalence, disease characteristics (methods of spread, clinical signs, carrier state and reservoir species) and the prevalence of residual infection; the establishment/facility factor (the presence of known vectors, presence of anadromous fish to water supplies, means of processing); assessment of monitoring services (import/export policies and legislation) and transportation. Destination factors were also a consideration but would need to include host susceptibility and the end use of the import. These factors would be considered for each disease of concern.

(b) Commodity factors, mainly applicable to the diseases present in the fish or products rather than live animals. These were generally concerns related to whether any infected material was removed after slaughter, the pathogen survival rate after processing (storage and transit temperatures, processing plant waste and disposal practices, elimination during storage) and the volume of any permitted trade (disease introduction is directly proportional to amount imported). Specific exposure factors related to the use of the product could also be considered in this category, or form a separate topic dealing specifically with the probability of a susceptible species being infected and transmission of a disease.

(c) Risk reduction factors could be considered to include options available to reduce the probability of introducing a disease agent. These might include factors such as the origin of the product, selective destination establishments and specified product processing or treatments.

6.20 The risks were identified by drawing up a list of potential diseases of concern that would be associated with the importation of the fish product, followed by an examination of the consequences of their entry and establishment. In addition, it was prudent to identify management options to further reduce the likelihood of disease entry and to consider the socio-economic and environmental impact of disease establishment.

6.21 Dr. Rodgers indicated that actual historical data was required for a quantitative risk assessment, since it was necessary to define the distribution of the probability of a disease introduction. For disease prevalence, this information would come from surveillance and monitoring programmes. In the absence of reliable data, a qualitative risk assessment might need to be performed particularly for factors related to the potential pathogens themselves, such as pathology, epizootiology, control, survival and inactivation. A certain amount of assumption might also be

necessary in these cases, although a worst case scenario could be adopted, even if expert opinion had been included as a short term substitute for actual documented data.

6.22 Dr. Rodgers noted that the current OIE guidelines for undertaking risk assessment were being completely rewritten and a draft should be available shortly. Whilst not specifically referring to fish, the principles would be applicable to aquatic animals and their products in general terms, as in the current version. Consequently, this would probably entail a change in the OIE guidelines for importation of aquatic animals and their products, as detailed in the International Aquatic Animal Health Code.

6.23 **Dr. Wooldridge** identified the following minimum requirements of a risk assessment, providing an explanation for each.

Requirement		Explanation
A.	A risk assessment must be transparent, that is it must be clearly set out, and fully referenced in the risk assessment report produced.	
B.	The risk which the risk assessment evaluates must be defined and clearly set out.	For an import risk assessment this includes the definition of the commodities to be included in the assessment and the definition or description of the outcomes of interest. For an import risk assessment these outcomes will usually be the various identified *unwanted consequences*.
C.	The hazard or hazards to be addressed must be defined and clearly set out. If a particular hazard has not been specified in the request for a risk assessment, this will require a hazard identification of appropriate breadth.	A decision must be made as to which are the hazards of interest. If the decision is that all disease-causing organisms are of interest, then a hazard identification to identify all disease-causing organisms potentially in the commodities of interest must be undertaken.
D.	The potential pathways from the hazards of interest to the outcomes of interest (that is the sequence of events necessary) must be elucidated, and clearly set out. Details of any processes incorporated in this pathway (for example testing for infection) must be fully referenced where appropriate.	These pathways will be based upon the (mainly biological) requirements necessary to arrive at the defined outcomes and are most clearly illustrated as a series of steps in a diagram. Full referencing allows for transparency. For most import risk assessments, there will be (either implicitly or explicitly) a risk release assessment stage, an exposure assessment stage, and a consequences assessment stage, and outcomes will generally be consequences.

E.	For each identified step in the pathway, information (data) must be gathered to evaluate the probability of that step occurring. This may vary from hazard to hazard, and therefore must be hazard specific where necessary. This information must be clearly set out, and the source of this information should be fully referenced.	The information (data) will be either qualitative or quantitative, depending upon availability and the type of assessment being undertaken. The assessors should undertake a search which is as thorough as is practicable to find the most appropriate information for the assessment in hand. Full referencing allows for transparency.
F.	The overall probability of the pathway of events from hazard to defined outcome actually occurring is evaluated either qualitatively or quantitatively for each defined hazard and outcome, using the information obtained. A quantitative assessment also uses appropriate mathematical manipulations. Reasoning, mathematical manipulations (where used) and conclusions must be fully set out. A quantitative assessment must include a time-frame.	This will be a probability given in either qualitative terms (for example high, low, negligible risk), or quantitative terms. A time-frame may be actual time (e.g. risk per year) or quantity based (e.g. risk per batch).

Dr. Wooldridge indicated that these basic requirements did not vary with the product or disease addressed. The specific variations which would occur in each stage of the table, depending upon the assessment required, were allowed for within the defined minimum requirements.

6.24 With regard to the 1995 Draft Report, Dr. Wooldridge observed that the major part of this risk analysis document comprised a very clearly set out and transparent qualitative risk assessment. Included within the document were:

- A short, clear executive summary which summarized all major points.

- An introduction (Section 1) which included a definition of the risk analysis, and thus the risk assessment, being undertaken.

- A background (Section 2) which included a brief overview outline of the risk assessment methodology, including the sequence of events necessary for unwanted consequences to occur (Section 2.2) and an assessment of the current disease status of Australian salmonids, necessary for consequence assessment given a disease incursion by import (Section 2.9).

- A section on risk factors (Section 3) which described the potential pathways from hazard to risk in detail and illustrated diagrammatically with an assessment, where appropriate, of the effect of each of these stages on the probability of viable disease-causing organisms successfully passing through that step.

- A section on diseases (Section 4) which initially gave the results of the hazard identification, which comprises a list of the defined hazards, or diseases, being considered in this assessment. This was followed by a fully referenced section on

each disease hazard including, for each, a consideration of the factors involved in the evaluation of the probability of a disease outbreak due to that hazard.

- A discussion section (Section 5) whose risk assessment part included summaries of the disease considerations, product conclusions, environmental concerns (including the current recorded Australian disease situation and the regulations applied to other imported fish species) and consequence considerations. Also considered was evidence from the experience of fish importation into other countries, and that of Australia before the current regulations were put into force. The discussion initially considered each potential disease hazard and then, taking into account all the relevant factors, qualitatively evaluated the probability of an unwanted outcome from import of the commodities under consideration.

  In addition, risk management issues were discussed, including considerations in setting the level of risk. Dr. Wooldridge specifically noted the following points made on page 217; that the mere possibility of an imported product containing exotic pathogens was not sufficient to prohibit importation; that Australia had rejected the impractical 'zero-risk' approach; and that quarantine decisions must be made based on the best information available and the most likely outcomes given that information. There was therefore emphasis throughout on attempting to estimate probability rather than merely possibility. In conclusion, in this analysis risk management recommendations were given resultant upon the probabilities estimated in the qualitative risk assessment.

The 1995 Draft Report also included a glossary and appendices on draft import conditions, translating the findings into a recommended policy given in Appendix 6.

6.25 Dr. Wooldridge summarized that the 1995 Draft Report was technically and scientifically a clearly and well executed qualitative risk assessment with all essential requirements present, particularly with respect to the clarity of the rationale for the conclusions reached. She noted that she was not competent to comment upon the validity of the fish-related information given.

6.26 With regard to the 1996 final risk analysis report, Dr. Wooldridge noted that this document resulted from the process of risk communication entered into after the publication of the draft document. It was divided into an executive summary and four sections. The first section was described as a risk analysis, the second section contained the data used for the diseases identified as hazards. The first two sections therefore included the final risk assessment for the risk of disease introduction, as well as the risk management conclusions and decisions. These sections had counterparts within the draft document. She expressed the opinion that, for clarity of comparison, the risk assessment layout within related documents should be broadly similar but, noted that here this was not the case.

6.27 The third section of the 1996 Final Report was an economic assessment of the effect of the introduction of two of the diseases, and the final section contained the bulk of the responses to the draft risk assessment; that is, the results of the risk communication process. These sections had no counterparts in the draft document.

6.28 A risk communication process served two major functions; it might identify inaccuracies in the risk assessment process; and it would provide information regarding the acceptable level of risk amongst interested sections of the community. These were two separate types of feedback, with different implications. In Dr. Wooldridge's view, each point in the documentation of such a consultation process should refer specifically, by cross-reference to the place in the initial risk analysis and risk assessment to clearly demonstrate whether, how and exactly where and why the

communication process had modified and altered the initial assessment, conclusions and resultant policy recommendations.

6.29 New or altered 'factual' evidence or methodology incorporated into the hazard identification or risk assessment itself should be clearly indicated, and it should also be immediately possible to see how this related to any altered conclusions reached in the assessment. This allowed the risk assessment, that is the estimation of the risk involved, to be agreed as an issue separate from any considerations of acceptable risk. Any changes in recommended risk management policy due solely to the differing conclusions of the modified risk assessment should also be made clear.

6.30 Any changes in the level of risk considered to be an acceptable risk by the risk manager after consultation during the communication process should be separately discussed and described and any resultant effect on risk management policy should be clearly differentiated from the effects of an altered risk assessment.

6.31 Dr. Wooldridge noted that this was not the case with this document as, although the risk communication responses were documented in the final section, the format of the risk analysis and risk assessment were very different from the draft. This made it more difficult than it otherwise would be to identify differences, particularly of detail, between the two risk assessments and exactly how they came about. Nevertheless some highly significant differences were present.

6.32 In comparing the 1995 Draft Report and the 1996 Final Report, Dr. Wooldridge noted that there were differences in format, clarity and transparency. The first major difference was that the processes involved and conclusions reached in the actual risk assessment were much less clearly set out than in the draft. The order had been altered and the initial contents page (v) was particularly unhelpful in tracing the information sought; data was often difficult to find.

6.33 Partly due to the methodology employed and partly due to the layout, it was more difficult (if not impossible) to disentangle the sections relevant to the assessment of the risk from the sections relevant to a consideration of risk management issues, in particular that of acceptable risk; in her opinion this was a serious flaw. In a risk analysis care should always be taken to distinguish between assessed risk and acceptable risk.

6.34 She further observed that the order of presentation was confusing. The major part of the information on the diseases themselves (Section 2) now came after the assessment in which that information was used (Section 1), as did an outline of "risk analysis" methodology (Appendix 1.7.7). The potential risk pathways considered were much less clearly laid out and less detailed than in the draft. In particular Sections 1.3.2 (Risk Analysis: Considerations) and 1.4 (Risk Analysis Considerations) were, in her opinion, poorly set out (and in addition the headings were confusing). This made the reaching of relevant assessment conclusions more difficult.

6.35 The responses from the consultation process, on which the changes in both risk assessment and risk acceptance were based, were documented in the final two sections (Sections 3 and 4), and were not easily related to the changes made in the final risk assessment as compared with the draft version. A clear separation of the responses by category (in particular whether concerning fact, or conclusion, or policy recommendations) and a system of cross-referencing these with their effect on the initial risk assessment data, risk estimate conclusions and risk management issues would enhance clarity and comparison of the risk analysis.

6.36 There was no obvious explanation as to why the finalised report should be less clear than the draft report. In her opinion it was far less transparent.

6.37 Dr. Wooldridge indicated that the next major difference was that the underlying basic methodology of the risk assessment had been altered. Both draft and final document were qualitative

assessments. In the final document there was a discussion of the impossibility, given information available, of undertaking any quantitative risk assessment (page 24) and specifically, on page 25, the final document stated that "This paper discusses potential routes of entry to the aquatic environment but does not calculate the likelihood that exposure will occur.". However, not only did the final document explicitly rule out the possibility of a quantitative assessment, but the qualitative assessment then proceeded implicitly on the basis that without quantification, the assessment could only be concerned with the possibility of agent entry, rather than making any attempt to qualitatively ascribe probabilities based on the information available.

6.38 This resulted in conclusions such as the following: "There will be an unknown chance - with some degree of uncertainty about the confidence that can be had in any estimation - that imported product will be infected." (page 50). But we can work this out before we undertake a risk assessment.

6.39 In Dr. Wooldridge's opinion, looking only at the *possibility* of particular consequences, rather than the *probability*, was neither an appropriate technical method nor adequate scientific outcome from a risk assessment. This was the most important difference between the draft and the final report.

6.40 Dr. Wooldridge further observed that there were differences in data used in the assessment. A number of specific additional risk factors were considered in the final document, and this was an appropriate result of the communication process. Those identified included, for example, biofilms on processing equipment (page 25), potential additional diseases (page 26) and a potentially incorrect assumption about the amount of salmon which would be cooked (page 30).

6.41 Some data was present in the initial risk assessment that did not appear to be present in the final assessment. Examples included the tables of data given in the section on risk factors in the draft document (e.g. page 17), although with the very different format, it was difficult to be completely certain that it had not been included elsewhere. She could find no explanation for the data having been left out.

6.42 In summary, Dr. Wooldridge stated that in her opinion the risk assessment methodology in the 1995 Draft Report was superior to the 1996 Final Report, and technically acceptable, whereas that in the 1996 Final Report was not. For the reasons given above, she did not consider that the 1996 Final Report met the explicit minimum methodological requirements of a risk assessment. She noted that she was not competent to comment upon the specific information regarding the fish diseases identified, nor the completeness of the hazard identification, nor on the technical information on the processes which the fish undergo. The accuracy and completeness of this information would of course affect the final conclusions from either assessment.

Question 2. The Panel notes that the government of New Zealand conducted a risk assessment with regard to the importation of Canadian Pacific salmon in 1994 (submitted by both parties). In what manner and to what extent do you consider the risk assessment undertaken by New Zealand to be technically/scientifically relevant to the dispute at hand? What is the relevance of the scientific evidence considered in the New Zealand risk assessment to the Australian Final Report?

6.43 **Dr. Burmaster** replied that the report completed by New Zealand in 1994 met the minimum requirements for quantification in a risk assessment of this nature. In terms of the relevance of the scientific evidence, he noted that based on conversations with a biologist familiar with New Zealand and Australia, he believed that there were many similarities between the conditions in the two countries. From his perspective as a probabilistic risk assessor (but not as a fisheries biologist), he thought that New Zealand's Report resolved many - and perhaps all - of the issues between Australia and Canada. If Australia did not agree that the New Zealand's Report resolved all the issues between Australia and Canada, he thought Australia needed to prepare a new risk assessment using probabilistic methods to quantify the risks associated with different policies.

6.44 **Dr. Rodgers** indicated that the 1994 New Zealand government risk assessment, referring to the risk of introducing exotic diseases of fish through the importation of ocean-caught Pacific salmon from Canada, contained some factual information which was relevant to the dispute at hand. As such it was useful background information. Data limitations at the time of the report led to a combination of both qualitative and quantitative risk assessments being carried out, although the latter was only concerned with one disease (furunculosis). The assessment analyzed the available data in a competent scientific way and used the opinion of experts, where necessary, to supplement published information and provide a substitute for gaps in the data base. Unfortunately, the lack of data in certain important areas meant that assumed outcomes were qualitative and therefore some were not relevant to the current dispute, since non-validated opinion can be open to different conclusions. In addition, the conditions applicable to New Zealand might not be of equal importance to another country and additional risk factors might need to be considered in another assessment. For instance, the environment, the fish species being farmed and the presence of susceptible host species would all have to be reassessed. Consequently, a similar risk assessment undertaken by Australia, using the same information in support of additional risk factors, might not arrive at the same conclusions.

6.45 Of equal, if not more relevance, Dr. Rodgers indicated, was the recently published (October 1997) report by the New Zealand government entitled "Import health risk analysis: salmonids for human consumption". This was effectively a more comprehensive update to the earlier 1994 Report, since it contained additional factual information on pathogen survival, inactivation and likely tissue levels. In addition, the quantitative risk assessment model had been modified and improved by using alternative distributions for the probabilities arising from expert opinion and the possible number of infected fish imported per tonne of product. It was also a more global report because it considered farmed Atlantic salmon from Norway, wild Pacific salmon from the Pacific North West of America and farmed rainbow trout from Denmark. As a result, two additional inputs were included, namely those of prevalence of infection of harvested fish and fish weight. Taking furunculosis as an example again, one of the conclusions had been that, whereas a qualitative risk assessment indicated that the risk of the introduction of *Aeromonas salmonicida* (the bacterial causal agent of furunculosis) through importations of the commodity (products) was low, quantification of the risk further demonstrated that such an event was unlikely to occur, particularly given the relatively low annual volumes which were likely to be imported.

6.46 **Dr. Wooldridge** replied that the New Zealand risk assessment addressed the question of import of the same commodity, ocean caught Pacific salmon from Canada, into New Zealand. As with Australia, it also took into account the effect of evisceration and head removal. It included a qualitative analysis, including an assessment plus management recommendations on the full range of hazards identified, and a quantitative assessment on one particular hazard, *Aeromonas salmonicida.*

6.47 In terms of the qualitative analysis and assessment, the potential pathway from hazard to unwanted outcome (the introduction of fish disease) was outlined on page 3. This included steps involved in release (i.e. import of infected material) and steps involved in exposure and transmission in New Zealand. The main assessment considered 23 diseases as hazards. These were all diseases included in the Australian risk assessment; the one considered in the Australian assessment but not included in the New Zealand assessment was Whirling Disease *(Myxobolus cerebralis),* but it was stated earlier in the document that Whirling Disease was already present in New Zealand (page 10).

6.48 Thus the same commodity was being assessed, and it was passing through the same processes in Canada before export. The export or release risks for each disease associated with the export of the same grade, quality and processing of salmon at the point of export would therefore be the same regardless of their intended destination. Up to this point therefore, this assessment was completely relevant both scientifically and technically to the dispute and the Australian Final Report. One would expect broadly the same data to be used, and the conclusions regarding the assessed risk of 'release' to be the same. Any discrepancy would be a cause for further investigation.

6.49 Differences in transit conditions, processing in the destination country, local exposure pathways, and susceptibility of local fish might be different, and data, assessment results and conclusions would not necessarily be the same for exposure and likely consequences. However, the basic methodology should be similar, and was therefore technically relevant. In actual fact, despite the possibility of differing exposures etc., the New Zealand qualitative assessment was for the most part similar in content, method and conclusions to that in the draft Australian assessment.

6.50 The New Zealand assessment also gave, for each disease, a very clear summary of the reasons for the conclusion reached, and this was a very useful feature of the assessment. From this it was possible to see which diseases were considered of negligible risk due to their release assessment results, and of the 23 considered, 15 were classified as of negligible risk on this assessment alone. Of the remaining 8, four were considered to be of negligible risk partly because they require specific intermediate hosts not considered present locally, and four partly because they were already present in New Zealand, although in all cases release assessment results also played a prominent part in reaching the conclusions. Nevertheless, the exposure patterns and local disease situation (that is, the data used) could, for these eight, be compared directly with Australia if required, as could that for Whirling disease.

6.51 Dr. Wooldridge also commented on the quantitative assessment as used in the New Zealand Report. In both countries assessments, furunculosis caused by *Aeromonas salmonicida*, was considered to be the most likely disease to be introduced. The New Zealand assessment reached the conclusion, based on the release assessment result, that "Wild, ocean-caught Pacific salmon from the west coast of North America are unlikely to introduce *A. salmonicida* when imported as headless, eviscerated fish" (page 35). It went on to say "However, because A. salmonicida is the one pathogen of salmon likely to be present in a high concentration in the muscles of diseased fish, it is the subject of a separate quantitative risk assessment" (page 36).

6.52 The method used in this quantitative assessment was based on Monte Carlo (stochastic) simulation, which allows real life uncertainty and variability to be used in the distributions incorporated into the model. Outputs, rather than being single point values, are also given as distributions, which can be illustrated graphically and analyzed statistically. They therefore give much more information than a single point deterministic model, and are in general the preferred method for such quantitative assessments.

6.53 The assessment evaluated the risk of four possible product presentations (page 56) but most importantly, the release assessment was explicitly separated from the exposure assessment (e.g. page 58). As with the qualitative assessment, this release assessment was both scientifically and technically applicable to Australia as well as New Zealand. Similarly, although specific import data (in particular estimated import tonnage per annum) and exposure routes and susceptibilities might be different, requiring an exposure model different in detail, the technical methods employed in this quantitative assessment were fully applicable to any other import destination including Australia.

6.54 Dr. Wooldridge noted that a quantitative assessment required also the availability of appropriate data, and the Australian Final Report argued that such data was not available. However, it was clear from the New Zealand assessment that sources of data for the release assessment part, for this disease at least, did exist and in her opinion no convincing argument was made as to why such data could not also have been utilised by Australia. She observed that there was generally much more data in existence for almost any quantitative risk assessment than at first sight seemed likely to be available. However the source and type of such data was not always immediately apparent until a model was under development, when specific data requirements could be fully considered.

6.55 In summary, Dr. Wooldridge considered that all of the technical methodology and a large proportion of the scientific data used in the New Zealand risk assessment was relevant to both the dispute and the Australian Final Report. She recalled that she was not competent to comment upon

the accuracy of the fish-based data, but specifically for that used in the release assessments and given the conditions specified, if it was correct for New Zealand, then it was also correct for Australia.

Question 3. Canada argues that for a risk assessment to be appropriate it is not enough to claim/prove the possibility of risk. According to Canada, one has to evaluate and give a certain probability of risk. What is your view on this point from a scientific/technical perspective? To what extent, from a scientific/technical point of view, does one have to quantify, or use expressions which qualify, a risk in a risk assessment for the risk assessment to be deemed satisfactory? To what extent can you establish the probability of occurrence of the risk involved when dealing with more than one disease agent?

6.56 **Dr. Burmaster** indicated that he agreed with Canada on this point. He thought that a quantitative risk assessment using probabilistic techniques was the most appropriate tool for resolving this dispute between the two countries. Although he could not specify sharp boundaries as to what extent it was necessary to quantify, or use expressions which quantify, a risk for a satisfactory risk assessment, he considered that the current dispute certainly fell within the region where a fully quantitative risk assessment was necessary. With regard to the establishment of the probability of occurrence of risk when dealing with more than one disease agent, he referred to his response to Question 4.

6.57 **Dr. Rodgers** replied that the difference between the possibility of risk and the probability of risk was largely based on the availability of reliable data. When there was insufficient data for a quantitative risk assessment it was necessary to undertake a qualitative analysis instead. Alternatively both types of analysis could be used to compliment each other. However, the more mathematical concept of quantitative risk assessment, which used probability distributions in a predictive way gave an indication of the probability of an event occurring. On the other hand the same probability could not be generated from a subjective qualitative analysis, since only the possible outcome of an event, or series of events, could be generated using this methodology. In other words, quantitative risk analysis attached numerical equivalents to qualitative estimates and assumptions. The quantitative approach was more accurate and ideally should be used (data permitting) to provide a more valid answer to a potentially complex chain of interactions. However, this would mean that all the variables associated with an importation would need to be known with some accuracy in order that the risks could be established mathematically.

6.58 The possibility and the probability of an event occurring both embodied elements of likelihood and risk. However, Dr. Rodgers was not aware of any pre-requisite to use the quantitative method, particularly in view of the lack of data in certain key areas of aquatic animal health. This applied equally when dealing with more than one disease agent, since, although many risk factors were common between different diseases, each disease might have unique factors to consider and each of these would have a variable quantity and quality of usable data.

6.59 **Dr. Wooldridge** indicated with regard to the question of probability versus possibility, that in her opinion, the requirement of a risk assessment was to evaluate the ***probability*** of risk. She identified this as one of the minimum requirements (see response to Question 1). Given the existence of a particular disease agent, one could *always* construct a *possible* infection transmission scenario, however improbable, and therefore demonstration of the possibility of successful transmission and disease was not adequate.

6.60 However, the probability did not have to be expressed quantitatively, and frequently it could not be. In qualitative assessment there was therefore the difficulty of what was meant by the terms used, for example high, medium or low risk, and subjectivity was a potential problem. If there were several hazards being evaluated, it was often possible to distinguish between them and thus class them as high or low within the group being considered. However, in import qualitative risk assessment and when dealing with a disease of serious consequences, one usually looked for something which could

be described or classified as a "negligible" risk with respect to the consequence of causing a disease outbreak. That is, given all the data available, the conclusion reached by most people with appropriate expert knowledge would be that the likelihood of the organism passing through every necessary stage in the pathway from potential hazard to unwanted outcome was highly unlikely. It was accepted that there was still a degree of subjectivity even in this classification, and that was why the assessment must be fully transparent.

6.61 Dr. Wooldridge further noted that regarding initial qualitative classification, whatever the initial (unknown) risk, it was often possible to quantify the amount by which that risk could be reduced if certain safeguards are put in place. Thus, given qualitative evidence that a "low" risk initially existed, it might be possible to deduce that a "negligible" risk existed after application of the safeguards and a quantitative assessment of the *difference*.

6.62 With more than one disease agent, if a quantitative assessment could be undertaken for each disease, then it was possible to quantify the total risk. However, individual quantitative assessments were time consuming and might not be possible. In any event, qualitative assessments were the type generally done initially.

6.63 Whichever method was used, if any one of the diseases being assessed individually was considered by itself to present a risk, at a level agreed by all concerned to be unacceptable to the importing country, then that commodity would not be imported. Given this, it was therefore necessary always to first assess each disease risk separately. A problem only arose when each disease taken individually was assessed as representing a very low level of risk, and when those assessments were qualitative.

6.64 In this situation, if each individual risk had been classed as "negligible" it might be argued with some justification that the overall risk was therefore negligible. However, given some way of further ordering the risks within this "negligible" category, it might still be possible to decide on that disease with the maximum risk. In the approach taken by New Zealand in this situation, the disease with the highest assessed qualitative risk was quantitatively assessed. Although not done by New Zealand, the maximum total risk could then quantitatively be assessed by assuming that each of the other diseases had the same level of risk. This would overestimate the maximum total risk. Variations on this method to more closely model the differences between the diseases might also be possible depending upon data available.

6.65 Dr. Wooldridge additionally noted that it may be (for example due to immunocompromisation) that one disease pre-disposed to another. The effect of this might be difficult to determine, as whilst this might increase the risk of infection with a given disease, it might also increase the total detection rate of disease at inspection. Where there were negligible disease levels for both, this might be assessed as of little relevance either way.

6.66 It was accepted that where a group of diseases were qualitatively classed as other than very low risk, with no additional data, estimating the total risk would be difficult. But the initial proviso above suggests the commodity would in that case be rejected in any event. Further, where a disease was not low risk, then it was often likely to be because it was more prevalent and therefore more was often known about it; if this was the case, there may well data available to quantify that risk.

6.67 Dr. Wooldridge summarized that, although it might not always be possible to fully estimate the total risk when dealing with multiple diseases, it was likely to be possible to come to usable conclusions about the probability of the overall level of risk.

Question 4. In the event a sanitary measure deals with several diseases, in terms of risk assessment technique, does one need to assess the likelihood of entry and establishment of each disease agent separately, all in combination, or both? To what extent is it necessary to account for

different characteristics of the hosts and disease agents; of the use and disposal characteristics of the products? Should the risk assessment also include an assessment of the likelihood of entry, establishment and spread of the disease agent from imports of products of other species known to carry the same disease(s)? From a scientific/technical point of view, is it valid to undertake a risk assessment either on a disease-by-disease basis or on a product-by-product basis, or could either approach be adopted? What factors should be considered when making such a decision?

6.68 **Dr. Burmaster** presented the following notation in his response:

N_{sa}	=	number of fish species of concern in Australia
N_{sc}	=	number of fish species of concern from Canada
N_{d}	=	number of fish diseases of concern
N_{p}	=	number of pathways of exposure
N_{e}	=	number of events to complete one pathway
N_{w}	=	number of different weather conditions of concern
N_{o}	=	number of other factors to include
N_{tot}	=	total number of variables/distributions to assess

Australia might say that it could not undertake a risk assessment for which it must develop probability distributions for N_{tot} variables:

$$N_{tot} = N_{sa} \cdot N_{sc} \cdot N_{d} \cdot N_{p} \cdot N_{e} \cdot N_{w} \cdot N_{o}$$

Dr. Burmaster disagreed with such a position. In his opinion, New Zealand had shown how to reduce the "dimensionality" of the problem to a manageable size by analyzing only certain combinations of N_{sa}, N_{sc}, N_{d}, N_{p}, N_{e}, N_{w}, and N_{o} that were selected as the "most important" or "dominant" combinations.

6.69 He also believed that New Zealand had demonstrated how to reduce the dimensionality of the problem of different characteristics of the hosts and disease agent, or of the use and disposal characteristics of the products, to a manageable size. Dr. Burmaster indicated that the risk assessment should possibly also include an assessment of the likelihood of entry, establishment and spread of the disease agent from imports of products of other species know to carry the same disease(s). As a hypothetical example, fish disease D could arrive in Australia via the importation of frozen, eviscerated, and beheaded salmon from Canada with probability P_c. The same fish disease could arrive in Australia via the importation of live, ornamental goldfish from Malaysia with probability P_m. If a risk assessment were to show that $P_c < P_m$, it would not make sense for Australia to ban the importation of the salmon from Canada and not ban the importation of the goldfish from Malaysia.

6.70 When preparing the scope for a quantitative risk assessment, Dr. Burmaster considered that it was essential for the risk assessor to consider both a disease-by-disease basis and a product-by-product basis. He further observed that New Zealand had shown how to reduce the dimensionality of the problem to a manageable size by focusing on certain key combinations of fish species, pathways, events, etc. Along the way, the risk assessor(s) should use expert judgment to rank the importance of different combinations of species, diseases, pathways, etc. as a way to determine which combinations to quantify first. This was always an iterative process. As the risk assessment developed, new insights would develop that would allow the risk assessors to understand and place suitable emphasis on the most important combinations of species, diseases, pathways, etc.

6.71 With regard to the risk assessment technique, **Dr. Wooldridge** replied that, as detailed in the previous question, one needed first to assess the likelihood of the unwanted outcome (here the

establishment of disease) separately for each disease. The outcome of this would determine the next step in the assessment, as detailed previously.

6.72 Hazard identification would automatically involve the initial host characteristics. As indicated in her answer to question 1, it was necessary to outline the steps in the pathway from hazard identification to unwanted outcome. This would include such things as inspection, processing etc. If different disease agents had different probabilities of being detected, inactivated, surviving in waste water, surviving whilst clinging to wrapping paper etc., then these characteristics must be taken into account. For some of these aspects (for example disease detection) the specific host being considered might also be relevant. For some of these characteristics (for example use of wrapping paper), use and disposal characteristics of the product might be relevant. Whenever relevant, such factors must be considered. In addition the susceptibility and disease status of the potential hosts in the importing country were relevant.

6.73 With regard to imports of other products of other species known to carry the same disease, information on the existence of such products was important in two respects. First, a comparison with other products might provide data necessary to assess the probability of exposure, transmission and consequences of a given disease post-entry within a country or region. Secondly, the information on the existence of such products was an important part of the overall risk analysis (as opposed to the risk assessment) and should be sought as part of that analysis. If such products were known to exist, it was relevant to the setting of acceptable levels of risk and therefore to the risk management part of the whole risk analysis.

6.74 Dr. Wooldridge considered that whether a complete risk assessment of any other particular product was required depended on the precise situation; in certain circumstances it might be enough to demonstrate that a particular product containing a given disease agent, and subject to similar use and disposal pathways, had been imported regularly for many years with no detected disease consequences.

6.75 The approach to a risk assessment depended upon the initial risk for which an assessment was required. If the question asked was "What is the risk of an exotic disease being introduced with product X?", then the hazard identification required that all exotic diseases potentially present in product X were identified, and the risk for each assessed. If the initial question asked was "What is the risk of introducing exotic disease Y into country Z?" then the hazard was disease Y and the potential pathways for import which would need to be considered included the initial identification of all products which could potentially contain disease agent Y and were (or might be) imported into country Z. Thus the crucial factor in the initial approach was the question asked (i.e. the risk to be assessed). Either approach was perfectly valid dependent upon the risk to be assessed. The exact question asked depended on the underlying reasons for the risk assessment being undertaken and was likely to be a risk management decision, although input from the risk assessor was frequently sought.

Question 5. Australia contends that one cannot compare the risk posed by other aquatic animals or products hosting any or all of the same disease agents with those posed by uncooked salmon in the absence of a risk assessment for those other aquatic animals or products. What is your view?

6.76 **Dr. Burmaster** referred to his answers to Question 4, above.

6.77 **Dr. Wooldridge** recalled her answer to question 4, indicating that there were circumstances where it was valid to compare the risk posed by other aquatic animals or products hosting any or all of the same disease agents with those posed by uncooked salmon, even in the absence of a risk assessment for those other aquatic animals or products. In any risk assessment, the more information available the less uncertainty in the final result. A full risk assessment for these other products might well markedly reduce uncertainty in the risk assessment under consideration; less than a full risk assessment was likely to reduce uncertainty by a lesser amount. Nevertheless such information as

was available might be adequate to reduce uncertainty to negligible levels for a given situation under consideration; much depended upon the level of similarity. Such information should not be ignored.

Question 6. Canada contends that for any given disease agent, the consequences of the disease becoming established in an importing country would be the same regardless of the original imported source. In your view, is this statement technically/scientifically correct?

6.78 **Dr. Burmaster** responded that the statement was correct; he could not think of a counter-example to this principle.

6.79 **Dr. Rodgers** replied that this statement was probably generally correct, although there were degrees of severity for some disease agents and the consequences of disease establishment could vary depending on the nature of the pathogen and the genetic basis of the indigenous species. The consequences might be limited depending on the efficiency of the responsible monitoring service and subsequent early detection. The presence or absence of a susceptible host species and unfavourable local conditions might also limit the spread, since the death of only a few fish could go unnoticed. The costs of control or eradication would vary too for the same reasons. The nature of the original import would have a bearing on the possible consequences because the risks for dead (processed) product would be different compared to that from live fish imports. The economic consequences might also be different, since there would be a potential negative effect on the local industry following the introduction of highly competitive cheaper fish product from a guaranteed aquaculture source. On the other hand, a finite resource, such as wild ocean-caught fish, might have less impact because it might not be able to compete as aggressively in terms of cost or quality. This of course might occur the other way round depending on the overheads attached to bringing each commodity to the market.

6.80 It was also relevant to consider that factors other than the presence of a pathogen were important in the consequences of disease entry, because some diseases were more serious in certain areas than in others (e.g. infectious haematopoietic necrosis (IHN), *V. ordalii* and *Piscirickettsia salmonis*). On the other hand, certain diseases only occurred in a limited area, such as infectious salmon anaemia (ISA) in Norway, *Oncorhynchus masou* virus in Japan, epizootic haematopoietic necrosis (EHN) virus in Australia and *Ceratomyxa shasta* on the Pacific northwest coast. It might be that these diseases could not establish themselves in other regions because the necessary combination of environmental factors, susceptible species and husbandry practices did not exist elsewhere. The opposite might also be true in that they could become very successful at establishing themselves in a new environment and be extremely virulent. The reason for their current "containment" might rely partly on efficient monitoring and subsequent movement controls and partly on the fact that development of aquaculture with the exact conditions necessary for their establishment had not yet occurred in other areas or countries.

6.81 **Dr. Wooldridge** replied that once a given disease was established country-wide in an importing country, the consequences from that point on would be the same whatever the original imported source or manner of establishment. However, any regional variation in disease establishment might conceivably affect the consequences, in particular the short to medium term consequences, and regional variation in disease establishment might be source-related. Long-term consequences would converge if the disease then became established country-wide.

6.82 This could be illustrated by assuming that Product A, containing agent K was imported into region W of country Z, but the product had no further widespread distribution in that country. Region W contained no susceptible animals of economic importance, although it did contain susceptible animals of no economic importance. One possible consequence was that disease K became established locally in Region W of importing country Z. In this scenario there were short-term biological consequences but no short-term economic consequences. Given these circumstances it might also be an undetected consequence.

6.83 To continue the example, one could assume that Product B, a different source but also containing disease agent K, was imported only into Region X of country Z, a region where there were susceptible animals of economic importance. Local establishment of disease K would then most probably result in both short-term biological and economic consequences. That is, given a different product source with a different import distribution, some of the short-term consequences of disease establishment would be different because the manner of initial establishment was different. Whether, given time, the disease would then spread from either region to become established country-wide would depend upon many country specific factors including, for example, animal migration patterns, agent virulence, climate, geographical barriers, human working patterns and so on. Therefore, when using information derived from the importation of other products or products from other sources in a current risk assessment, information on the ubiquity and history of that comparison import was of particular relevance.

The distribution and transmission of fish diseases

Question 7. Which disease agents (or strains of disease agent) have been identified as present in Canadian (i) adult, wild, ocean-caught Pacific salmon; (ii) adult wild freshwater-caught Pacific salmon; (iii) adult Pacific Salmon cultured in seawater on the Pacific coast; (iv) adult Atlantic salmon cultured in seawater on the Pacific coast; (v) adult Atlantic salmon cultured in seawater on the Atlantic coast? Please comment on the responses provided by Australia and Canada in this regard and in particular, the discrepancies in the answers provided by parties (7 October submissions "Responses to Questions", Question 2). In your view, what degree of scientific confidence is there of detecting the occurrence of diseases or disease agents given existing methods of monitoring and surveillance?

6.84 **Dr. Rodgers** responded that some diseases reported to occur in the above categories include:

(i) adult wild ocean-caught Pacific salmon: bacterial kidney disease (BKD), *Kudoa thyrsites*, *Parvicapsula* sp., plasmacytoid leukaemia (marine anaemia);

(ii) adult wild freshwater-caught Pacific salmon: BKD, *Ceratomyxa shasta* , enteric redmouth disease (ERM), flexibacteriosis, furunculosis, infectious haematopoietic necrosis (IHN), *Loma salmonae*, plasmacytoid leukaemia (marine anaemia), proliferative kidney disease (PKD);

(iii) adult Pacific salmon cultured in seawater on the Pacific coast: BKD, *Parvicapsula* sp., piscirikettsiosis;

(iv) adult Atlantic salmon cultured in seawater on the Pacific coast: IHN, pancreas disease (PD), piscirikettsiosis, viral haemorrhagic septicaemia (VHS):

(v) adult Atlantic salmon cultured in seawater on the Atlantic coast: BKD, ERM, furunculosis, infectious salmon anaemia (ISA), *Vibrio salmonicida*.

Dr. Rodgers noted that he had not been able to undertake a complete literature survey for each disease in each of the above categories due to the time available to respond to the questions. Neither had it been possible, for the same reason, to solicit additional information, in the form of personal communication, directly from other sources. Consequently, the above list of diseases was not exhaustive and it had not always been possible to identify which maturity state any particular disease had been isolated from (i.e. juvenile or adult). In addition, the identification of a particular disease agent did not imply that it occurred regularly, since only an occasional occurrence may have been reported in the literature. Other diseases, such as some parasitic (e.g. protozoal, etc.) or bacterial (e.g. vibriosis) conditions, occurred on a more global scale and would be expected to be ubiquitous.

6.85 There were discrepancies in the responses from both countries in regard to the question concerning the presence of certain disease agents in Canadian salmon. The answer from Canada was more detailed in the sense that it further subdivided the categories of salmon into the above five groups. As a result, this was more accurate, useful information and consequently had probably led to the majority of differences between the two responses. For instance, the presence of furunculosis in wild-caught Pacific salmon was acknowledged by both countries but Canada qualified the answer by stating that it did not, however, occur in ocean caught fish, only in freshwater caught fish and cultured stocks. The same was true for enteric redmouth disease, which Canada contended did not occur in ocean caught Pacific salmon, nor in farmed salmon (Atlantic and Pacific species) on the Pacific coast.

6.86 In other responses Australia indicated unknown or uncertain presence, due to lack of definitive scientific work or difficulty in detection, by the use of a question mark (i.e. Yes? or No?). In all these cases, Canada supplied a definitive "yes" or "no". The main discrepancies related to conflicting responses concern the presence of vibriosis (*V. anguillarum* and *V. ordalii*) in wild-caught Pacific salmon, Pacific salmon anaemia virus (EIBS) in Pacific salmon, viral haemorrhagic septicaemia (VHS) in farmed Atlantic salmon, proliferative kidney disease (PKD) in wild-caught Pacific salmon and infectious salmon anaemia (ISA) in farmed Atlantic salmon on the east coast. Canada specifically stated that EIBS and PKD were not known to occur in any of the five categories of salmon. Although there were a few reports in the scientific literature of these two diseases occurring in Pacific salmon in Canada, it was most probable that they referred to juvenile fish rather than adults and consequently the statement that they did not occur in adult fish would be true. As regards vibriosis in wild-caught Pacific salmon, the condition was likely to be widespread in the marine environment but in this particular case it was not clear which specific references had been used to prove or disprove this point. The occurrence of VHS in Canadian Atlantic salmon, which was not mentioned in the Australian response, represented 1995 published information which presumably the Australian case was not aware of at the time. The presumptive diagnosis of ISA in Canadian farmed Atlantic salmon was verbally reported in an international conference of fish pathologists in September 1997, but the current status of ISA was not listed by Canada in its responses to questions. However, this was perhaps not surprising since it was an addition to the Australian Final Report (in place of *Kudoa thyrsites*) and appeared for the first time in the responses to panel questions. Therefore, it was most likely that Canada was unaware that it had to comment on the current status of this disease.

6.87 Dr. Rodgers observed that there was much reliance in both submissions on personal communications with respected fish pathologists and these should be accepted at face value, since it was not possible to corroborate all this information within the current time frame. However, such information was usually based on more recent data and was usually unpublished, although it could contain an element of subjective opinion and assumption. The Canadian information was broken down into more relevant groups, since they had greater access to data from research projects, veterinary reports and monitoring and surveillance programmes, which were not always readily available to the general scientific community. Consequently, this should represent the most accurate up-to-date picture for the diseases of concern, since information in the published scientific literature could be quickly out of date and many historical published reports were not followed up by subsequent more recent studies.

6.88 The degree of scientific confidence in disease detection with existing methods of monitoring relied on the lowest limits of detection for each specific test or series of identification methods. Currently, there were some difficulties with the isolation of some fish viruses (e.g. PD, ISA, etc.) or bacterial strains (e.g. the lengthy incubation time for *Renibacterium salmoninarum* , the causal agent of BKD). In addition, there was a cut-off sensitivity point for most diagnostic methods which leads to the carrier state being very difficult to detect, except with the most sensitive of tests (e.g. PCR). However, even these tests had limits of sensitivity, which were albeit very low, and they did not always rely on culture as a prerequisite for identification. Nevertheless, these deficiencies in sensitivity for existing methods were generally accepted in terms of both their supportive science

(pending improvements) and the legislative policies that stipulated their use in regular surveillance programmes.

6.89 Regardless of the reason for carrying out a disease examination there was a need for some form of standardized sampling methodology which would allow a reasonably accurate assessment of the health status of a particular stock to be made. While local conditions in respect of the cultured or wild species and the presence of specific diseases might vary considerably, the principles of such a sampling methodology tended to remain constant. For a correct disease diagnosis it was often necessary to demonstrate the presence of the pathogen by culture, followed by some form of confirmatory serological test. However, there were certain measures that could be employed to increase the chances of detecting the presence of a pathogen. For clinical outbreaks it was usually prudent to sample moribund fish exhibiting clinical signs but at the same time selecting certain target tissues. Testing fish with the minimum or absence of symptoms (e.g. the "asymptomatic carrier" state) would normally be biased towards any fish with possible clinical signs, selecting the correct age of fish (e.g. at least one-month old fry in the case of infectious pancreatic necrosis (IPN) or screening five-month old fish for whirling disease) and sampling during periods when the disease was most likely to be detected (e.g. February-April in Europe for BKD). Examination of fish with no suspicion of disease for screening purposes would also consider these factors but in addition would sample a sufficient number of fish for effective sampling. This number was usually based on the work of Ossiander and Wedemeyer (1973), as stipulated in the OIE Diagnostic Manual for Aquatic Animal Diseases. This study indicates the minimum sample size for each lot of fish that provides a 95 per cent confidence of including infected specimens in the fish sampled, assuming a minimum prevalence of infection equal to or greater than 2 per cent, 5 per cent or 10 per cent. For instance, 150 out of 100,000+ fish need to be sampled at the 2 per cent level. This is reduced to 30 out of 100,000+ fish at the 10 per cent level. Testing for statutory purposes was generally conducted at the 95 per cent level of confidence with an assumed incidence of disease of 2 per cent. Occasionally, there might be justification for increasing the level of confidence from 95 per cent to 99 per cent (i.e. 225 fish at the 2 per cent level) for a particular examination. However, any subsequent increase in sample size gives a negligible increase in the statistical probability of finding an infected specimen.

6.90 Despite attempts by various international organisations, such as EIFAC, FAO and OIE, to discuss the possibility of producing a uniform system of monitoring, none really existed on a world-wide scale. Individual countries (e.g. Australia, Canada and the United States) or whole trading blocks, such as the European Union, had developed their own baseline rules relating to importations and these were well formed for those countries which had a heavy involvement in aquaculture or had an important sport fishery. In this context the receiving country or trading block tended to set the conditions of importation.

6.91 Dr. Rodgers noted that one other aspect to consider was that regularly tested stocks were normally considered as a lesser risk than occasionally, or untested stocks or products, since regular monitoring provided a background database of information over time. For instance, it would be considered that ova from wild salmonids would present a greater disease risk than ova from farmed stocks since the latter could be tested regularly throughout their lifetime. Estimates of prevalence data were usually based on surveillance information obtained from fish health authorities in potential exporting countries but such data were generally limited to those countries that had statutory monitoring in place. This type of data, however, was actually designed to overestimate the prevalence of infection in commercially harvested fish, since the monitoring programme targeted fish from which an infectious agent was most likely to be isolated, such as spawning fish, fry or fingerlings and fish exhibiting signs of infectious disease, as mentioned above. Unfortunately, this was rarely the case for wild populations of fish because regular monitoring programmes did not normally exist, unless diagnosis was related to the occurrence of large, noticeable mortalities. However, sampling returning anadromous salmonids in their freshwater phase was occasionally the exception. Post-harvesting testing for disease in fish destined for human consumption was very rarely undertaken.

Question 8. What aquatic animals, other than salmonids, are known to be carriers of any, several or all of the disease agents subject to this dispute? Please comment on the responses provided by Australia and Canada in this regard (7 October submissions "Responses to Questions", Question 3). Would the epidemiological factors relevant to disease transmission be the same in all cases?

6.92 **Dr. Rodgers** replied that it had not been possible to undertake a comprehensive literature search to determine which aquatic animals, other than salmonids, were known to be carriers of any, several or all of the disease agents subject to this dispute. However, an examination of the lists provided by both Australia and Canada indicated that they were comprehensive and authoritative. The list from Australia tended to be more general in content and used phrases such as salmonids, cyprinids or a wide range of salmonids, whereas the list from Canada was more detailed since it listed the relevant species separately. However, the Canadian list was incomplete because it did not deal with all the diseases, although the original question concerned "... any, several or all of the diseases ..." and there did not seem to have been a specific requirement to detail all species for all the diseases. Nevertheless, since the Canadian list did not include *Piscirickettsia salmonis*, *Renibacterium salmoninarum* (BKD), *Vibrio ordalii*, herpesvirus salmonis type 1, Pacific salmon anaemia virus, salmon leukaemia virus, salmon pancreas disease virus (PD), *Enterocytozoon salmonis*, *Loma salmonae*, *Ceratomyxa shasta*, *Henneguya salminicola*, *Myxobolus cerebralis*, *Parvicapsula* spp., proliferative kidney disease (PKD), rosette agent and infectious salmon anaemia (ISA), the Australian list was more useful in this respect. Neither list included *Kudoa thyrsites*, which to all intents and purposes was widely distributed and had a broad host range.

6.93 Disease transmission combined many biological, behavioural and environmental factors that were interrelated. The epizootiological factors relevant to disease transmission would not necessarily be the same for each disease, since they were complex and numerous, although the general aspects were common. Fish diseases manifested themselves as a result of a variety of circumstances, such as genetic background, nutrition, stress, injury or cohabitation. The relationship between disease epizootics among fish and fish stocking densities was important, since overcrowding of fish was often followed by infections of opportunist bacteria, fungi or parasites. Non-infectious disease that occurred as a result of fish culture mis-management could also be prevalent in these circumstances. Some fish pathogens were a constant and natural part of the environment, usually without causing disease problems and mortality (e.g. certain parasites). There was a unique relationship between fish, their pathogens and their environment which meant that a balance normally existed between the three factors, with the fishÿs immune system playing an active role in maintaining this balance. However, if there was an alteration in one or more of the environmental characteristics then there might be a shift in the balance to the benefit or detriment of either the fish or the pathogen. Another relevant disease-causing factor was the introduction of a potential pathogen into an already stable environment. The introduction of different types, strains or novel pathogens could upset the natural balance of a fish population. Indigenous fish developed a degree of immunity to relevant pathogens in their environment but they may never have encountered new strains.

6.94 The reasons for a disease outbreak were varied, representing complex interactions between the host and the disease-causing situation. In the cases of host-pathogen interactions, the onset of disease represented a decrease in the resistance of the host such as during reproductive stages or due to environmental stress, poor husbandry conditions, in conjunction with an increase in numbers and/or virulence of the pathogen. However, it was not clear what was the maximum number of cells which constituted a genuine infection, since there was a big difference in the number of cells required to establish clinical disease in aquatic animals. This might range from 1 (e.g. crayfish plague) to 100 (e.g. furunculosis) or more (e.g. BKD).

6.95 Dr. Rodgers stated that it was generally accepted that four major groups of disease might be identified in terms of epizootiology. These included sporadic diseases, which occurred sporadically in comparatively few numbers of a population; epizootics, which were large-scale outbreaks of communicable animal disease occurring temporarily within limited geographical areas; panzootics,

which occurred over large areas; and enzootics, which persisted or re-occurred as low level outbreaks in certain areas.

6.96 It had been suggested that dense populations of fish would maintain a given level of diseased individuals, regardless of whether the populations were shoals in the sea or aquacultured stocks. However, there was a generally accepted lack of information about the occurrence of disease in wild fish. Most studies related to the potential effects of pollution on free-living marine fish and the incidence of disease in returning anadromous salmonids. Much less information was available on disease transmission between wild and aquacultured fish and *vice versa*.

Question 9. The 1996 Final Report (as well as its earlier drafts) only deals with wild ocean-caught adult Pacific salmon. In your scientific/technical opinion, do any imports of aquatic animals or aquatic animal products, other than salmonids, into Australia entail the same (or even higher) risks with respect to the introduction of the identified diseases as those that would arise from the import of uncooked salmon from Canada (either on a disease-by-disease basis or in an overall manner)? Please explain the basis for your opinion.

6.97 **Dr. Rodgers** replied that the importation of several other groups would pose a potential risk of disease introduction that would probably be at least as high, if not higher, than that posed by the importation of uncooked salmon from Canada. These groups would include any live ornamental fish, bait fish and trash fish for feeding aquacultured species. It was not possible to predict though, without an import risk analysis study, which of these represented the highest risk. However, importation of live fish for stocking of open waters containing indigenous fish, and the feeding of trash fish or bait fish directly to aquacultured species as a feed supplement or substitute would probably be the most important in terms of risk. Escapees from a closed system into an open waterway could also be a problem. The arrival of furunculosis into Australia via imported goldfish or into Norway via salmon smolts and the first reported outbreaks of VHS in turbot from Scotland and Ireland helped to support the hypotheses of live fish importation and feeding respectively.

6.98 A recent risk analysis report (October 1997), by the Western Australian Fishing Industry Council on the practice of importing frozen fish as bait, considered the possible introduction of viruses that could have an impact on the rock lobster industry. The resulting analysis was not able to distinguish between a very low risk of introduction and no risk at all. The report stated that the analysis could not conclude that there was no risk of introducing an exotic disease only that the risk of introducing an exotic disease that was capable of producing a large scale fish kill was either very low or did not exist at all. In conjunction with this conclusion the report identified a series of risk reduction measures that could be implemented for frozen bait.

Question 10. Canada contends that for a given disease agent, the likelihood of disease establishment is higher for imports of whole, uneviscerated bait fish and for live fish known to host that disease agent than it is from imports of uncooked salmon for human consumption. In your view, are these contentions corroborated by scientific/technical evidence? If not, what factors would be needed to substantiate those views?

6.99 **Dr. Burmaster** responded that this seemed highly likely to him, but he had no independent information to support or refute such an opinion.

6.100 **Dr. Rodgers** replied that it was probably true to say that for a given disease agent, the likelihood of disease establishment was higher for imports of whole, non-eviscerated bait fish and for live fish than it was from imports of uncooked salmon for human consumption. However, the actual level of risk would be important and the opinion expressed in Question 9 was also relevant here. It was also a fact that there were complex processes that lead to disease establishment (see his response to Question 8). In addition, the final destination of a particular consignment would have an impact on potential disease establishment. For instance, a licensed, carefully controlled import of a live fish

species destined to be confined for research purposes would entail a very much lower risk than open water stocking. The same considerations would apply to processing establishments, since uncontrolled waste discharges could be a factor in possible disease transmission (e.g. ISA in Norway). It was also worth noting that comprehensive controls that prohibited the importation of certain species and products or failed to differentiate adequately between an ornamental species and a wild fish with the same taxonomic name might promote an illegal, difficult to control, underground trade. This had probably been a factor, for instance, in the introduction and spread of spring viraemia of carp in the United Kingdom in recent years, although the elevated value of certain cyprinid species for sport fishing might also be important in such cases.

Question 11. In their 7 October "Responses to Questions", Question 3, both Canada and Australia identify, for diseases subject to the dispute, non-salmonids which may also be carriers of these diseases. However, Australia seems to contend that a separate risk analysis may be necessary for these non-salmonids. In your view, can the risks represented by these non-salmonids be compared to those which arise from salmonids? If one presumes that the risks posed by salmonids are unacceptable, are there any scientific or technical reasons for not making the same presumption with respect to risks of the same diseases from non-salmonids? What factors should be taken into account in comparing the risks of entry, establishment or spread of a disease for one or several disease agents know to be carried by salmonids as well as non-salmonids? Can the data and findings contained in the Australian Final Report dealing with wild ocean-caught adult Pacific salmon be validly used in a risk assessment for the four other categories of salmon from Canada (see Question 7)?

6.101 **Dr. Burmaster** recalled his answers to Question 4. He believed that the risks represented by non-salmonids could be compared to those which arose from salmonids. With regard to making the same presumption of the acceptability of the risks posed by salmonids and non-salmonids for the same disease, he indicated that it all depended on the particular evidence. As discussed in his answer to Question 17, below, a risk assessor could answer this question by developing and combining probability distributions for the variables flowing from the seven conceptual steps identified by New Zealand. To identify what factors should be taken into account in comparing the risks of entry, establishment or spread of a disease for one or several disease agents known to be carried by salmonids as well as non-salmonids, a risk assessor must develop and combine probability distributions for the two (or more) scenarios. Dr. Burmaster did not believe that the data and findings contained in the Australian Final Report dealing with wild ocean-caught adult Pacific salmon could be validly used in a risk assessment for the four other categories of salmon from Canada because the 1996 Final Report did not meet the minimum standards for a risk assessment. New Zealand's final risk assessment did meet the minimum standards for a risk assessment and, as such, might contain an answer acceptable to the parties in this dispute. If the parties could not agree on the findings in New Zealand's Final Report, he did not think that the current dispute could be resolved without a new quantitative risk assessment using probabilistic methods.

6.102 **Dr. Rodgers** indicated that the basic underlying risk assessment would be the same but a good risk assessment model would be modular and therefore flexible enough to take account of any additional or different risks posed by non-salmonids. Although the risks might be compared, any additional risks, or those considered for salmonids that would be inappropriate for non-salmonids, would mean that a separate risk assessment would be necessary for each category of import. In addition, some of the diseases of concern are salmonid diseases and as such it would be inappropriate to transfer the data to a risk assessment of non-salmonids. However, non-salmonids could be carriers of some of the diseases of concern and therefore act as agents of dissemination. Essentially, although some data could be used to assess the risk factors, the outcome of an assessment might be different. This would apply to both qualitative and quantitative risk analysis. He noted that the points he made in response to Question 1 concerning the minimum requirements of a risk assessment were also valid here.

6.103 The same would be true for the four other categories of salmon from Canada, although these were closer in taxonomic concept and other considerations. Some of the data and findings contained in the Australian Final Report dealing with wild ocean-caught adult Pacific salmon could be validly used in a risk assessment for the four other categories of salmon. However, there were additional factors to consider for aquacultured species and wild freshwater-caught species, as opposed to wild ocean-caught fish. These would include the presence of known vectors (and alternative host species), the access of anadromous fish to water supplies, protected water sources, purchase of ova/fry/other fish/fish products, sharing equipment with other farms (vaccination, grading machines, etc.), sharing staff with other farms, density of farms locally, density of infected farms locally (introduction/reintroduction of fish), distance to sea, number of salmonid rivers locally, age of farm/hatchery, annual production, type of feed (cold processing, supplementation with trash/wild fish), the prevalence of residual infection in the area and the type of management practices undertaken.

6.104 **Dr. Wooldridge** observed that she had answered the majority of points in this question within her answers to other questions. Much of it concerned risk assessment technique. The risks from salmonids and non-salmonids could be compared by comparing available data pre-entry data plus potential exposure pathways. The decision on whether risk were acceptable or not depended on many factors but if the risks were assessed as being (or are otherwise believed to be) at a similar level then she believed they must be either equally acceptable or equally unacceptable regardless of the source. The comparison should take into account all available information. Any data used in one risk assessment which was valid in another assessment could be used in that assessment also. This would in such circumstances most probably include data from post-entry exposure onwards, and possibly pre-entry processing and inspection.

Question 12. Is evisceration an effective means of reducing the risk to a negligible level of each of the identified diseases? (See summary table provided by Australia in its 7 October "Responses to Questions", Question 13.) Would the effects of evisceration in terms of reducing the risk of disease transmission be similar in all circumstances? Which of the disease agents can be found in flesh (muscle), remnant kidney tissue, bone, skin, gills, head, or blood? Do you know of specific cases where diseases have been transmitted from one area to another by imported eviscerated fish? From imported eviscerated salmonids? Please identify and describe these cases.

6.105 **Dr. Burmaster** doubted that evisceration alone reduced the risk to a "negligible" one, but New Zealand's Report showed that evisceration in combination with other factors reduced the risks to acceptable levels.

6.106 **Dr. Rodgers** responded that evisceration was probably an effective means of reducing the risk to an acceptable level in certain of the identified diseases. The level of reduction would largely depend on the tissue location of the disease causing agent and the effectiveness of the evisceration process. Many of the disease agents of concern had the potential to remain at some level after evisceration, particularly those that might be concentrated in the head, brain, gills, musculature, heart, kidney remains and skin or external surfaces. Different pathogens could target different organs, although since viruses were intracellular they were particularly difficult to remove. Certain of the bacterial disease agents could also remain, especially those that caused lesions in the musculature (e.g. *Aeromonas salmonicida*) or were harboured in the kidney (e.g. *Renibacterium salmoninarum*). Evisceration would not remove all the parasites either, particularly those that appeared in the blood, on external surfaces or as cysts (e.g. *Loma salmonae*, *Henneguya salminicola* and *Kudoa thyrsites*). In addition, infected host individuals might serve as “carriers” or “reservoirs” of a disease agent without being demonstrably affected themselves and they therefore acted simply as vehicles of agent transmission. At such low levels they were very difficult to detect and therefore to know which particular tissues are affected.

6.107 Dr. Rodgers added that he did not know of any specific cases where fish diseases had been transmitted from one area to another by imported eviscerated salmonids or other eviscerated fish.

6.108 **Dr. Winton** stated that the FDC was unanimous in its belief that evisceration was an effective method to greatly reduce the risk of transmission of the notifiable fish diseases regardless of their source (hatchery or wild). Certainly for very stable pathogens (e.g. those with spore stages), there might be some residual infectivity in the flesh or heads of highly infected animals (typically this would be more likely to happen in fish harvested from hatcheries where a disease outbreak with attendant mortality was occurring), but the level of infectivity in the eviscerated animal could usually be expected to be considerably less than that present in viscera. The FDC considered that the risk of transmission of fish diseases by movement of eviscerated fish products was probably lower than the risk from certain other activities (movement of aquarium fish, ballast water in ships, etc.) and thus did not justify trade restrictions. Recently, the US government changed its regulations to exempt eviscerated fish from requirements for certification under US Title 50 based upon this same concept. Several other countries (e.g. the European Union and New Zealand) had also adopted this approach and reduced or eliminated disease control requirements for aquatic animals destined for human consumption.

6.109 Dr. Winton indicated that he knew of no case (salmonids or otherwise) where eviscerated fish had been shown to result in the importation and establishment of an infectious disease in fish; however, Australia was correct in that it might be difficult to find such cases if they occurred in wild fish. Nevertheless, where expansions of the geographic range of a fish disease had been documented, they were most often associated with increased surveillance efforts or the application of more sensitive diagnostic methods. There were also several documented cases where a fish disease had been introduced into an area previously known to be free of the disease through importation of live fish or eggs for rearing in hatcheries (infectious hematopoietic necrosis virus was a good example) and even a few diseases that were introduced by importation of uneviscerated fish for use as food for fish reared in net-pens (viral hemorrhagic septicemia virus in turbot in the United Kingdom).

6.110 Conversely, there were also examples where fish that potentially contained high levels of an infectious agent had not resulted in transmission of disease if eviscerated. For example, approximately 80 per cent of all rainbow trout produced in the United States came from the Hagerman Valley of Idaho where fish in virtually 100 per cent of the farms had been exposed to, or were infected with, infectious hematopoietic necrosis virus (IHNV). While there were perhaps more than a dozen documented cases of IHNV being spread by movement of infected fish or contaminated eggs, there was not a single case where transmission of IHNV was associated with fresh eviscerated fish for human consumption in spite of the fact that large numbers of these were sold in supermarkets throughout the United States within 24-48 hours of slaughter. Similarly, *Piscirickettsia salmonis* was present in many farmed salmon in Chile and infectious salmon anaemia was present in several salmon farms in Norway. No case of transmission of either agent to fish in any other part of the world had been documented in spite of the fact that thousands of metric tons of such products were shipped fresh throughout the world each year in the form of iced, eviscerated product.

6.111 While there were few actual studies on efficiency of transmission of a fish disease by various types of products, an unpublished study was conducted in Dr. Winton's laboratory in collaboration with the Clear Springs Trout Company in Idaho where nearly all fish were infected with IHNV at some level during various stages of rearing. Fresh fish were removed directly from the processing area and sampled for virus. They found no evidence of virus in the flesh of processed fish by either cell culture or by the polymerase chain reaction assay. Some of his colleagues had also conducted tests looking for IPN virus in Atlantic salmon imported fresh into the United States. These studies remained unpublished as no virus was found. In a few limited surveys of ocean-caught salmon, both the incidence and intensity of infection of a given disease was typically lower than found among fish reared at hatcheries where the disease was enzootic.

Question 13. With respect to the diseases at issue, what is the difference in effectiveness, with regard to reducing the risk of disease transmission, of evisceration as compared to heat treatment of the product? as opposed to full cooking of the flesh of the product?

6.112 **Dr. Burmaster** observed that no method was risk free. Cooking reduced the risk as a function of time, temperature, and pressure. Long ago, food technologists prepared and published tables showing the logarithmic efficiencies of different heat treatments (such as blanching, parboiling, or canning). He was unaware of any "hard" data to compare the effectiveness of evisceration to the effectiveness of cooking or canning. New Zealand's risk assessment concluded that a regulatory program that included evisceration as one step reduced risks to *de minimis* values.

6.113 **Dr. Rodgers** responded that he could not provide a complete answer to this question because comparative data for evisceration, heat treatment and full cooking were scarce. However, a published study (Whipple and Rohovec, 1994) on the effect of heat and low pH on selected viral and bacterial fish pathogens had been undertaken. The study concluded that *A. salmonicida*, *Mycobacterium cheloni* and the IHN virus were sensitive to a heat treatment of 65ºC for 15 minutes and 82ºC for 5 minutes. They were also sensitive to the fish silage process which used a pH of 4. In addition, although more heat resistant, the IPN virus and *R. salmoninarum* would also be killed when incorporated into fish silage and heated to 82ºC for 5 minutes after a 15 minute period at 65ºC. The study was carried out in order to test the efficacy of procedures used for processing fish viscera to be incorporated into fish diets. Full cooking should, of course, completely eliminate such pathogens providing the process was properly carried out. The only possible exception would possibly be a spore-forming organism, such as *Myxobolus cerebralis*, the causal agent of whirling disease, although there was some suggestion from the literature that this would not survive at a temperature of 100ºC for 10 minutes. Most of the other studies related to inactivation by heat were largely concerned with incubation and cultivation temperatures in artificial media, not to reduction of pathogen levels in tissue.

Question 14. Which of the disease(s) or disease agents of concern, if carried by live fish, can be detected by organoleptic examination? Which of the disease(s) of concern, if carried by uncooked salmon, can be detected by organoleptic examination?

6.114 **Dr. Rodgers** replied that in many cases the success of determining the presence of a particular disease agent and subsequent diagnosis relied on an interpretation of all the available information, including historical data, visual examination and tissue sampling. Unfortunately, no single sign was indicative of a specific individual disease condition. Similarly, not all reported clinical signs were present in every case of the disease.

6.115 Disease conditions were diverse and might elicit very varied response patterns in fish. The pathology and outcome of individual infections were the result of several factors including the physiological and immunological status of the host, species, age, stage of sexual development and nutritional status. Other properties included the water temperature, salinity, pH, pathogen numbers and their location within the host. Under certain circumstances fish might act as symptomatic carriers and pass the infective agent to susceptible animals. Unfortunately, the symptoms and gross pathology of many fish diseases were similar, and it could be difficult for even experienced fish pathologists to distinguish between the different pathological conditions, notably when two or more diseases might be present. Common visual signs of disease among salmonids included dark skin colour, excess mucus production (skin or gills), exophthalmia, distended abdomen, skin ulcers and petechial haemorrhages at the base of fins, skin, gills or muscle. These might be encountered to varying degrees in several disease conditions. In addition, spoilage organisms such as *Alteromonas* spp. and *Pseudomonas* spp. (and others) produced distinctive odours following contamination during storage and filleting operations. For these reasons, diagnosis should not be made solely on the basis of disease signs.

6.116 By way of example, Dr. Rodgers observed that the following disease signs could be indicative of several possible causal agents:

(a) *Exophthalmia* (many viral diseases such as IPN and IHN; bacterial diseases such as BKD, ERM; parasitic diseases such as PKD; nutritional deficiency such as lack of certain vitamins);

(b) *Dark skin colour* (viral diseases such as VHS; bacterial diseases such as ERM, furunculosis; nutritional deficiency such as lack of certain vitamins; stress due to poor water quality);

(c) *Excess mucus production* (skin or gills: parasitic infections in general; environmental irritant);

(d) *Distended abdomen* (virus diseases in general; several bacterial conditions; fungal infection; kidney malfunction; intestinal cestodes; nutritional imbalance);

(e) *Skin ulcers* (many different disease conditions);

(f) *Petechial haemorrhages* (skin or muscle: viral diseases such as VHS; bacterial diseases in general; protozoan or crustacean parasites).

It was possible to isolate specific fish pathogens from apparently healthy fish without evidence of any clinical disease. There were also many facultative fish pathogenic bacteria and viruses whose pathogenicity depended directly on environmental quality and which in cases of decreasing quality could lead to similar septicaemias to those caused by specific fish pathogenic agents. Therefore the identification of the pathogen was important, with disease diagnosis being a step-wise procedure divided into a consideration of archival information, general examination, collection of samples and subsequent analysis for pathogen identification. Organoleptic tests might be a part of the general examination but could not be relied on solely for disease identification, although a visual examination for grading purposes would identify unsightly looking fish (e.g. superficial damage, ulcers and possibly extensive haemorrhaging). Such fish might not then enter the supply chain as a quality product.

Question 15. Are you aware of any evidence of major disease spread with a significant impact on salmon production (wild or cultured, including recreational fisheries)? In regard to new introductions, to what extent is it feasible to identify the means/pathway of the introduction of the disease?

6.117 **Dr. Rodgers** replied that there had been several occurrences of disease spread with a significant impact on salmon production. The most notable documented incidences concerned the introduction of furunculosis in Atlantic salmon smolts and *Gyrodactylus salaris* on smolts into Norway, from Scotland and Sweden, respectively.

6.118 A recent graphic example of possible disease spread in non-salmonids concerned the large mortalities experienced in wild pilchards along the coast of South Australia and New Zealand. Frozen pilchards imported from California, Chile, Peru and Japan were fed to sea cage tuna in Australia, resulting in an epizootic among pilchards that eventually spread along 6,000 km of coastline. A herpesvirus was thought to be the cause of the mortalities, although this had not been proved definitively. The involvement of imported baitfish had also been suggested as a cause of disease introduction of enteric redmouth in France from minnows. The isolated cases of VHS in turbot recorded in Scotland and Ireland, linked to the feeding of marine fish as a feed supplement, should also be noted. Although these incidences referred to non-salmonids they served to indicate the potential for disease spread in certain circumstances. The importation of ova had also been blamed

for the spread or introduction of diseases such as furunculosis, IHN, BKD and IPN into countries as diverse as Sweden, Japan, China, Chile, Germany and Taiwan.

6.119 Scientific "detective work" was often the only solution available to identify the means or pathway of introduction for a disease. However, the main problem was normally that the manifestation of a new disease condition occurred after the initial causal event. This meant that there was no source material to work with and an educated assumption, based on corroborative evidence or circumstantial detail, was often necessary. Nevertheless, such conclusions were decided only after collecting all the necessary data and eliminating unlikely scenarios. This type of investigation would normally be carried out by experienced teams and would be very time consuming. The proportions and causes of the problem would have to be determined in order to discover whether there were any external influences that could be assigned to any particular introduction. The identification of the pathway of an introduction might be a complex diagnostic problem that would involve collecting information on environmental conditions, clinical signs, aetiological factors, possible transmission routes, identification of any potential pathogen, authorised movement records and the possible existence of illegal imports.

6.120 **Dr. Wooldridge** noted that risk assessments were originally developed precisely for the assessment of potential risks which had not yet occurred and for which the potential pathways from hazard to outcome had not been observed; for example, the risk of radiation release from new designs of nuclear power station and, on the biological side, the risks of new pathogenic bacteria returning to earth from space travel. In such cases identification of potential pathways from hazard to outcome was thus an integral part of the assessment. Therefore, with regard to new disease introductions, it was perfectly feasible, and an integral part of the risk assessment, to identify potential pathways for the introduction of disease. And in the assessment being undertaken here, this part was likely to have access to more relevant available information than in the "exotic" examples just quoted.

Question 16. Australia (in its 7 October response to Question 10) has stated that there are no reports on introduction of unwanted exotic diseases of fish through imports of product for human consumption. Australia has suggested, inter alia, that this can be explained because of the difficulty of recognizing -or establishing - any such occurrence, because many or all of the diseases of concern occur endemically and because of lack of research. What is your view on these points? To what extent, if any, are examples of disease transmission in terrestrial animals relevant to this case?

6.121 **Dr. Burmaster** agreed that there were no reports of introductions via imports of fish products for human consumption. While it was usually not possible to "prove the negative" from the "condition of no reports", the "condition of no reports" did allow one to put statistical bounds on the probability of the unwanted event. In other words, the "condition of no reports" did contain information that a risk assessor could use to put bounds on the probability. He thus disagreed with Australia's implicit argument that a "condition of no reports" supplied no evidence to a risk assessment.

Question 17. What chain of events must be met for uncooked salmon products to cause the entry, establishment and spread of the identified diseases into Australia?

6.122 **Dr. Burmaster** broadly agreed with the seven conceptual steps identified in the Summary (page 1) and again in the Introduction (page 3) of New Zealand's 1994 risk assessment report:

- the disease must be present in the waters of origin;

- the disease must be present in the particular fish caught (or the flesh mush have become contaminated during processing);

- the pathogen must be present in the imported tissues;

- the diseased fish must pass inspection and grading procedures;

- the pathogen in the flesh must survive storage and processing and be present in an infectious dose;

- the pathogen must be able to establish infection by the oral route or by the host being bathed in it;

- scraps of the flesh product must find their way into a susceptible fish host in New Zealand or an infectious dose of pathogen must find its way into contact with a susceptible fish host by some other means.

6.123 **Dr. Rodgers** observed that for uncooked salmon products to cause the entry, establishment and spread of the identified diseases into Australia the following criteria would have to be met:

- infection occurring in source stock;
- the presence of significant numbers of pathogens;
- no detection of disease on routine sampling of source stock;
- survival of the pathogen in processed fish (e.g. after evisceration and/or heat treatment);
- survival of the pathogen in transit (presumably chilled or frozen);
- processing plant with drain to water source (in the destination country);
- susceptible host fish at destination;
- interaction with susceptible host fish;
- pathogen to overcome host defences, possibly in a stressed host;
- subsequent pathogen reproduction (possible necessity for intermediate vector);
- favourable environmental conditions;
- local and national dissemination of disease.

Essentially, the disease agent must be present in the particular fish caught for processing, although contamination during processing was also a possible but unlikely factor, and the pathogen must be present in the imported tissues or products. In addition, the diseased fish/flesh must pass grading, inspection and testing procedures. After harvesting, the pathogen in the flesh must survive the death of the host, subsequent storage and processing, then still be present in an infectious dose. Finally, sufficient infected flesh must find its way into the local environment or a susceptible fish host and the pathogen must be able to establish an infection by the oral route or by contact.

6.124 **Dr. Wooldridge** noted that this question defined three potential outcomes; the entry of the identified diseases into Australia; their subsequent establishment; and their spread. The question (and therefore the answer given here) addressed only *possibility*, not *probability*.

Entry into Australia

6.125 For each of the diseases identified as a hazard, in order for it to enter Australia in uncooked salmon products, either the disease agent must originate from the fish harvest or it must be introduced as a contaminant at some point in the preparation and processing. If contamination occurred at any point before processing which would render the probable total amount of agent non-viable, then it need not be considered separately at the next stage.

6.126 Therefore, for entry to Australia, either:

(a) the fish must contain the disease agent at the point of harvest; **and**
(b) the disease agent must then remain present within the tissues selected for the imported product, at the point of import. If only part of the fish were selected for

import (e.g. headless, eviscerated) then the agent must be present in that part selected. If any examination of the fish were undertaken, either visual or otherwise, any agent present must escape detection (detection assumed to lead to rejection).

or

(c) the fish must become contaminated during the processing so far.

Then:

(d) the agent must remain viable within the tissues selected for the imported product, at the point of import. Therefore any processing (e.g., freezing, thawing, chemical application) must fail to render the agent non-viable.

or

(e) the product must become contaminated with the disease agent after any final processing before import.

Dr. Wooldridge noted that assessment of the probability of this occurring comprised a release assessment, of which the elucidation of the chain of necessary events was an essential component.

Establishment

6.127 For each of the diseases identified as a hazard, in order for it to become *established* in Australia from the import of uncooked salmon products the agent must first *enter* Australia in imported uncooked salmon products. That is, it must be present and viable at the point of import of the product. However this was not in itself enough to enable establishment.

6.128 Given entry, then the chain of events necessary for establishment of the disease in Australia required:

(a) the presence of susceptible animals (including fish); and

(b) the existence of possible exposure pathways from the product at the point of entry to agent contact with a susceptible species. There might be many potential exposure pathways; and

(c) for at least one of the potential pathways the disease agent must remain present and viable all the way through that potential exposure pathway. Therefore for at least one pathway all the following conditions must be met:

(i) any processing in the pathway (e.g., freezing, thawing, chemical application, cooking) must fail to render the agent non-viable; and

(ii) any regulatory activity in the pathway designed to reduce the potential for exposure (e.g. disposal method, siting of processing plant) must fail to render the agent non-viable; and

(iii) any natural occurrence in the pathway which by its nature would tend to reduce the potential for exposure (e.g. dilution, exposure to sunlight, lack of necessary intermediate host) must fail to render the agent non-viable; and

(d) At the point of exposure, conditions must be appropriate to enable successful transmission of agent in an infectious form into the susceptible species. This would be agent- and host-dependent; and

(e) At the point of exposure there must not only be viable agent present, but it must be in a sufficient quantity to result in infection. This would be agent- and host- dependent.

Spread

6.129 For each of the diseases identified as a hazard, in order for it to spread within local fauna, it first had to become established locally. However, this was not, in itself, enough to enable spread. Spread might mean spread to other species than those initially infected or other geographical areas or both.

6.130 Given local establishment, the chain of events necessary for the spread of disease required:

(a) that the initial establishment of disease did not only occur within a dead-end-host species (i.e. that transmission was possible from those initially infected at exposure).

For spread across species, requirements were:

(b) other susceptible species in Australia; and

(c) the existence of possible exposure pathways from the initially infected species to others. These exposure pathways were subject to the same kinds of considerations as in the previous section, though they would be different in detail; and

(d) at the point of exposure, conditions must be appropriate to enable successful transmission of agent from the initially infected to another susceptible species. This would be agent- and species-dependent; and

(e) at the point of exposure viable agent must be in a sufficient quantity to result in infection of the host second species. This would be agent- and species- dependent. A particularly susceptible initially infected species might allow for agent multiplication thus allowing infection of a second, less susceptible species.

For geographical spread, requirements were:

(f) the presence of susceptible animals to be more than just locally present; and

(g) the presence of exposure pathways from locally infected animals to those in other areas, with all the usual considerations plus, for waterway spread, the lack of natural geographical barriers; and

(h) the ability of the agent to survive in the environment encountered in other geographical conditions (e.g. climate, presence of intermediate hosts, etc.).

Question 18. In the period between May 1995 and December 1996, were there any advances in scientific knowledge that would justify a change in the conclusions from the 1995 Draft Report to the 1996 Final Report?

6.131 **Dr. Burmaster** replied that he did not think so.

Question 19. Canada contends (First Submission of Canada, para. 175, Oral Argument of Canada, 9 September 1997, para. 92) that in the 1996 Final Report, Australia omitted significant information for

the estimation of risk that was in its 1995 Draft Report, including data on which to base estimates of volumes of fish, prevalence of disease agents, quantities of waste and concentrations of waste. What is your view on this point?

6.132 **Dr. Rodgers** responded that in parts the 1996 Final Report was less detailed than the 1995 Draft Report and to a certain extent the specific section on qualitative risk analysis appeared to have been largely replaced by a straightforward textual summary. There also seemed to be more detail in the 1995 Draft Report in areas such as disease agent viability and infectious dose, although conversely it lacked some information contained in the 1996 Final Report (e.g. import country presence of infection data). In addition, the 1995 Draft Report presented some data in the form of a simple literature review for sections such as histopathology and diagnosis. On balance the best features of both draft reports should possibly have been combined to create a final analysis dealing with the aspects of a qualitative risk analysis, leading to an estimation of the possibility of each risk factor occurring. The 1996 Final Report put most emphasis on the unknown, or poorly understood, factors and the unique position of Australia, rather than accepting a low risk in conjunction with risk management (reduction) factors. Accurate data on prevalence of infection, fish weight and waste statistics, leading to an estimation of the disease risk per tonne of imported product, used particularly in combination with actual historical data that showed no disease introduction for similar importations elsewhere, was mainly valuable for a quantitative risk assessment. The more subjective approach of a qualitative risk assessment did not necessarily make full use of such detail. Nevertheless, the availability of such information, whether detailed or not, should warrant its inclusion in either scenario.

6.133 **Dr. Wooldridge** replied that it was precisely to facilitate the comparison of the information used that in her opinion the layout of the risk assessment should have been similar in both the draft and final document, and any change of data specifically indicated with the reason for the change. The change in format and order made comparison much more difficult and time consuming. Nevertheless, it was possible to identify data given in the 1995 Draft Report (for example the tables on pages 17, 24, 27, 29 giving data on fish, municipal waste water, etc.) which she was unable to find in the final assessment, and which was potentially relevant to the conclusions from the qualitative assessment and of potential use in a quantitative assessment.

OIE procedures and recommendations

Question 20. How are members of the FDC selected? Is membership of the FDC limited? How many, and which, OIE members are represented on the FDC? Is a quorum needed for FDC recommendations? How are members views taken into account?

6.134 **Dr. Winton** indicated that Members of the OIE Fish Diseases Commission were elected by formal vote of the delegates of OIE Member Countries at the annual General Session. They served 3-year terms and could be reelected. Candidates were nominated solely on the basis of their scientific expertise and were expected to be completely free from the influence of either national or commercial interests. There were currently 5 (formerly 3) elected members, listed below. Each was an internationally recognized authority in diseases of aquatic animals and all of them worked at national laboratories where they were either a senior researcher or program director. In addition, the FDC typically invited from 1-3 other participants. For example at the last FDC meeting in October 1997, Dr. R. Subasinghe, Director of the International Fish Health Programs for the FAO in Rome attended by formal agreement between FAO and OIE, and Dr. F. Berthe, research scientist from the national shellfish laboratory in Tremblade, France (IFREMER), attended by invitation of the FDC in order to provide added expertise in shellfish pathology. There were no formal procedures for voting or for establishment of a quorum. In the years he had been a member, all elected members attended every meeting. Decisions were reached by consensus of the members after examination of scientific evidence. The list of Members of the OIE Fish Diseases Commission at the 29 September-1 October 1997 meeting was the following:

Prof. T. Hästein (President)
Superintending Veterinary Officer in Fish Diseases
Central Veterinary Laboratory
Norway

Dr. C. Michel (Vice President)
Laboratoire de Virologie et d'Immunologie moléculaires
Centre de Recherches de Jouy-en-Josas
France

Prof. B.J. Hill (Secretary General)
Centre for Environment, Fisheries and Aquaculture Science (CEFAS)
United Kingdom

Dr. J.R. Winton
Research Team Leader
Western Fisheries Research Center
United States

Dr. K. Nakajima
Director of Pathogen Division
Fish Pathology Department
National Research Institute of Agriculture - Fisheries Agency
Japan

Question 21. Australia states that detailed minutes are not kept of meetings of the FDC where the categorization of measures to be applied for a particular disease are discussed. Does the FDC produce summary reports of these meetings? Are the FDC recommendations on disease guidelines based on scientific evaluations or assessments? What is the scientific content of FDC reports/records? What processes are under way in regard to the categorization or classification of fish diseases?

6.135 **Dr. Winton** replied that while detailed minutes regarding each decision were not kept, summary minutes of each meeting were prepared and distributed to the delegates from each OIE Member Country by mail. A synopsis of the activities of the FDC was also presented orally by the President of the FDC to delegates at the OIE General Session for approval. Due to a lack of any formal method for evaluation of disease risk, disease assessments were based on knowledge of the peer-reviewed literature or experience of the members of the FDC (which was quite extensive due to the large network of colleagues and the frequent contacts needed to prepare the OIE FDC annual report on the epidemiological situation for aquatic animal diseases worldwide). The scientific content of the FDC epidemiological report was high because information was gleaned from the peer-reviewed literature or from direct reports provided by fish disease experts and reference laboratories around the world who submitted information on the aquatic animal disease situation in their area. The annual epidemiological report and report of the meeting of the Fish Diseases Commission were occasionally cited.

6.136 There was no formal process for categorization of fish diseases and, in fact, there were no formal mechanisms for categorization of other animal diseases and only limited examples existed for human diseases. Development of such methods was a task for one of the Specialist Commissions of the OIE which produced an early draft that apparently failed to gain approval from the delegates of Member Countries. If approved for other animals, the FDC would attempt to adapt it to diseases of aquatic animals, but to date, efforts to construct a method that worked well in all cases had remained elusive. Recently, Australia provided a draft of a proposed mechanism for categorization of fish diseases. It was discussed at the most recent meeting of the FDC. While it seemed to perform

reasonably well for some of the notifiable diseases, other diseases of aquatic animals either lacked sufficient information or differed too greatly in their worldwide distribution, host range, or severity to allow a single method to be applied globally.

Question 22. Which of the 24 disease agents listed in the 1996 Final Report have been considered by the OIE and what were the conclusions for each? Which of the 24 diseases were considered but had no recommendation? (For a list of the 24 diseases of concern, see Australia's response to Question 1 of 7 October.) Is this documented in FDC/OIE records? When no recommendation is made, does it mean that after consideration the disease was found not to be of serious epidemiological or economic concern?

6.137 **Dr. Winton** stated that virtually all the 24 listed diseases and several others had, at one time or another, been considered by the FDC. In general, those diseases having worldwide distribution, limited impact, or which were readily controllable by drugs, vaccines or management strategies had received less emphasis. Typically, the FDC placed the greatest emphasis on uncontrollable diseases of proven etiology having a limited geographic distribution and for which robust diagnostic methods were available. This information was gleaned from the scientific literature and personal knowledge of the FDC members. Detailed records of the factors involved in each decision were not available. A lack of listing as notifiable did not mean the FDC considered the disease to be of low priority. It might be, for example, that a new and very severe disease lacked standard diagnostic methods and could not be listed as no adequate inspection methods existed.

Question 23. To what extent does the FDC factor take into consideration whether a disease is widespread in concluding whether diseases should be reported or whether guidelines should be established? Does the FDC consider the impact on trade when categorizing diseases or in developing guidelines.

6.138 **Dr. Winton** responded that distribution of diseases was very important in determining categorization as indicated above. The impact on trade was not, per se, a separate factor, but was included in the concept of the level of damage that could be expected if the disease were introduced. If a disease was uncontrollable, whether in wild fish or commercial fish, the FDC tended to rate it as having more effect.

Question 24. Does an OIE recommendation stating that dead fish be eviscerated before transit mean that OIE considers that the eviscerated product is sufficiently "safe" in terms of the specific fish disease under consideration? Do the OIE recommendations for the "Other Significant Diseases" of concern in this dispute, which only deal with uneviscerated fish, imply that the OIE considered eviscerated fish sufficiently "safe" in terms of the specific fish disease under consideration? Are such recommendations based on scientific principles? Please clarify what you mean by the term "safe" in your response.

6.139 **Dr. Burmaster** recommend that the WTO and the parties avoid the word "safe" because most people understand the word to imply a condition of "zero risk". He believed that conditions of "zero risk" never occurred in the world. Every plan or proposal, including the "do nothing" alternative, had (i) non-zero probabilities of adverse consequences (broadly called the "risks" of the plan or proposal) and, simultaneously, (ii) non-zero probabilities of favourable consequences (broadly called the "benefits" of the plan or proposal). Each possible plan or proposal had both risks and benefits. No single plan or proposal had just risks; no single plan or proposal had just benefits.

6.140 In some situations, there were only two possible plans or proposals, which could be called "Plan Yes" and "Plan No". Each of these choices had risks and benefits. In other situations, there might be more than two competing plans or proposals, perhaps called Plan A, Plan B, ... , and the "Do Nothing" Plan. Each of these choices had risks and benefits. The risks and benefits of the competing,

alternative plans or proposals might be measured in a variety of units, including economic or monetary units.

6.141 In a first step sometimes called "risk assessment", scientists, engineers, statisticians, and other professionals estimated the risks and benefits associated with each of the competing, alternative plans or proposals.

6.142 In a second step sometimes called "risk communication", the risk assessors conveyed their findings, complete with descriptions of the variabilities and the uncertainties in their findings, to the risk managers.

6.143 Then, in a third step sometimes called "risk management", government officials (including, possibly, judges and juries) and/or other groups of citizens chose the option from among the competing, alternative plans and proposals that had the most attractive combination of risks and benefits. Since all of the options had both risks and benefits, none could be called "safe".

6.144 **Dr. Winton** replied that the FDC had considered this point carefully and was unanimous in the opinion that evisceration of fin fish (e.g. salmonids in this case) provided a very high level of safety against transmission of disease and that none of the notifiable or other significant diseases were likely to be transported with such products. Thus, the FDC had judged that eviscerated products fell outside the concern of the FDC. In fact, a paragraph in the first edition of the Aquatic Animal Code (Article 1.5.5.2, paragraph 3) was specifically deleted in the current edition to clarify this point because the former language provided an option for countries to require inspections of any fish products (even eviscerated fish) that were, in the opinion of the importing country capable of introducing a disease of concern. Members of the FDC had reviewed the scientific evidence and were not aware of a known expansion of range for a fish pathogen due to the movement of eviscerated fish; conversely, there were many cases of disease transmission associated with shipment of infected live fish, live eggs, or even uneviscerated fish used to feed other aquatic animals that were documented in the scientific literature.

Question 25. To what extent do the OIE recommendations take into account the differing health situations or potential vulnerabilities of importing member governments?

6.145 **Dr. Winton** observed that the differing health conditions in various member countries (both exporting and importing) were a concern; however, it was impractical to have different recommendations for each country. This was why the FDC had tried to set minimum standards that could be applied worldwide, but encouraged countries to engage in bilateral negotiations where there were differences of opinion regarding quality of fish health services, presence of other pathogens of concern, etc. This flexibility, however, extended only to live fish, live gametes, and uneviscerated fish. As stated above, the FDC currently regarded eviscerated fish to represent a minimal risk that did not warrant restriction of trade.

Question 26. Could application of OIE guidelines by an importing country be considered to provide some sense of "safety" with regard to the particular fish disease addressed in the guideline (please clarify what you mean by the term "safe" in your response)? What is the "level of risk" implicit in OIE recommendations? Is this a quantifiable risk level (i.e., one in a million chance that ...) or can it be described in other terms (i.e., "negligible", "unmeasurable", "highly unlikely", etc.)? Is this (implicit) level of risk the same for all OIE recommendations regarding fish diseases?

6.146 **Dr. Burmaster** stated that he did not know the OIE's or FDC's policies and procedures with regard to this question, but terms such as "negligible", "unmeasurable", "highly unlikely", etc. often caused great confusion in risk assessment, risk communication, and risk management. These words had no common meaning; different people using the same word could and did have entirely different meanings in mind when using such terms.

6.147 For example, he noted that Professor M. Granger Morgan recently reported his findings from an expert elicitation of senior scientists serving on the Science Advisory Board (SAB) of the US Environmental Protection Agency (Morgan, 1997; see also: Morgan & Henrion, 1990; and Cooke, 1991). In this paper, Morgan worked with 14 members of one of the US EPA's SAB panels - mostly full professors of science or engineering at major universities - to quantify each individual's definition of three phrases: "likely", "something between likely and not likely", and "not likely". Morgan found that:

- some of the 14 SAB members use the word "likely" to mean the probability range from 80 per cent to 100 per cent, while other SAB members use the same word to mean the probability range from 0.1 per cent to 100 per cent chance of occurring; and

- some of the 14 SAB members use the words "not likely" to mean the probability range from 0 per cent to 10 per cent, while other SAB members use the same phrase to mean the probability range from 0 per cent to 0.001 per cent chance of occurring; and

- all of the 14 SAB members identified a probability range to describe "something between likely and not likely". For one of the SAB members, this intermediate condition had a wide range, 0.0003 < probability < 0.8, showing that the terms "likely" and "not likely" are <u>not</u> logical complements of each other as one might expect.

Professor Morgan concluded, and Dr. Burmaster agreed, that these words had such large differences in meanings - even among senior scientists - that the words created more misunderstanding than they did enlightenment. When a lay person heard these words spoken by a full professor from a major university, what conclusion should he or she draw?

6.148 **Dr. Winton** believed the OIE guidelines, if properly applied by competent personnel, represented a very significant level of safety against importation of the listed diseases. He knew of no procedures that would offer improvements in safety sufficient to justify the added expense or effort. He was not aware of any examples of importation of disease in groups of live fish or eggs nor in uneviscerated fish when imported in accordance with these or similar (US, Canadian, EU) procedures, while there were many cases where fish diseases had been imported through movement of both live and uneviscerated fish in the absence of these methods.

Question 27. What are the criteria used by OIE to decide whether or not a particular disease/disease agent should be included in the Code? Are OIE member governments permitted or expected to request consideration by the OIE of fish diseases which they have identified as being of concern?

6.149 **Dr. Winton** responded that the criteria are stated in the Aquatic Animal Health Code. These were: proven etiology, limited geographic distribution, untreatable, and of severe impact. Member countries were encouraged and expected to review the Code and Manual and to propose the addition or deletion of aquatic animal diseases or to suggest modifications in wording, diagnostic methods, etc. based upon scientific evidence. In fact, several countries (including both Canada and Australia) had been rather diligent in doing so on a regular basis. The FDC had both added and deleted diseases based upon scientifically-constructed arguments from several member countries. In some cases, the FDC had received conflicting opinions from countries (some wanting to add diseases and others wishing to delete the same diseases). In these cases, the scientific evidence and opinions of the members of the FDC were used.

Question 28. Are OIE guidelines primarily directed at eliminating or reducing disease transmission? Do they also address the spread or management of diseases? Are some diseases considered sufficiently capable of being managed so as not to warrant controls on transmission in all circumstances?

6.150 **Dr. Winton** indicated that ultimately, the OIE guidelines sought to prevent international shipment of disease agents. Because there could be no absolute guarantee that transmission would not occur unless no trade were allowed, the guidelines were, in fact, designed to reduce the risk to sufficiently low levels that international trade could proceed in a safe manner. It was up to the member countries to control or restrict the distribution of diseases within their country and to maintain information about this status for the OIE. Several diseases of aquatic animals could be adequately managed and were thus not included on the OIE list. These diseases could be subjects for bilateral negotiations if they could be shown to be of legitimate concern to the importing country and trade were anticipated in live or uneviscerated fish.

Question 29. Have, from a technical/scientific point of view, the risk assessment techniques and guidelines contained in Section 1.4 of the OIE Code been taken into account in Australia's 1996 Final Report? Do these OIE techniques and guidelines impose a separate risk assessment for each individual disease of concern to the country imposing the sanitary measure and for each sanitary measure that country decides to consider? Alternatively, do these OIE techniques and guidelines impose the necessity to assess within a risk assessment, the likelihood of establishment and consequences of each disease as well as the effects of each sanitary measure on the likelihood and consequences of disease establishment? When a country finally chooses one of these options, do the OIE techniques and guidelines on risk assessment require that country to justify or explain why that particular option has been preferred, i.e. does that country need to establish a causal link between the option chosen and the reduction of risks allegedly identified in its risk assessment? Do the OIE techniques and guidelines require a country to quantify (i.e. to state the probability of), or use expressions which qualify, the risk which allegedly justifies its sanitary measure?

6.151 **Dr. Wooldridge** replied that Section 1.4 of the OIE Code was at present undergoing a re-writing process in order to update, expand upon, and clarify the guidelines in the code. The basic premise was that the guidelines for import risk analysis and assessment should reflect the best methodology available.

6.152 The version currently in use stated in the Introduction that: "Import risk analysis is preferable to a zero-risk approach because it provides a more objective decision" and the section entitled "Guidelines for Risk Assessment" focused on the probability of disease agent entry and exposure rather than just the relevant possibilities. In addition it advised that "Because of the multiplicity of disease agents it may be necessary to carry out multiple risk estimates for any commodity considered for importation", and "If information on the probability of the presence or survival of a particular agent following application of a risk reduction option is not available, documented experience could be an alternative source of information". All of these basic guidelines were still valid. The OIE Code did require an evaluation of probability (either qualitatively or quantitatively) rather than merely possibility of a given outcome or consequence even if, given current knowledge levels, the confidence limits on that probability are wide.

6.153 The failure to consider the probability of the various outcomes in the 1996 Final Report rather than just their possibility meant that, in her opinion, the guidelines given in Section 1.4 of the OIE Code had not been properly taken into account.

6.154 Whether one considered that a separate risk assessment was undertaken for each disease, or whether within a single risk assessment each disease was considered separately was, in Dr. Wooldridge's view, merely a case of semantics; the OIE guidelines did not *impose* either of the suggested alternatives. The fact was that, in considering any particular product for import, and in

undertaking a risk assessment for that product, each potential disease hazard identified had to be separately assessed. The potential consequences might be different for each disease. The effect of any particular sanitary measure would affect the pathway from hazard to outcome for each disease, and might affect it differently for different diseases. Thus the initial assessments, and any re-assessments considering the application of any risk reduction measures would need to consider each disease separately. Performance of the necessary number of individual assessment procedures for any particular product was part of the full risk analysis process and depended upon the commodity.

6.155 Dr. Wooldridge stated that, in her opinion, once a particular set of sanitary measures had been chosen by a particular country, transparency in the rationale for that choice was required to demonstrate that there was a reasonable basis in the case in question for expecting that the risk reduction measure would have the desired effect.

6.156 **Dr. Winton** noted that the risk assessment guidelines of Australia or New Zealand had been read with interest by members of the FDC, but had not been formally taken into account. He believed the FDC would support the concept of individual risk assessment for each listed disease because important epidemiological features (presence of susceptible hosts, temperatures, etc.) would vary with each country. That was why the notifiable disease list was relatively short. Those diseases considered notifiable were ones that almost everyone could agree upon would be very harmful to the importing country if it were presently free of them. Other aquatic animal diseases could be added by bilateral agreement if the importing country could make a good case based upon its unique situation. The FDC did not anticipate this would be done for eviscerated or processed fish products destined for human consumption unless a human pathogen was involved.

Question 30. Australia seems to contend that a separate risk analysis may be necessary for each aquatic animal or animal product. What are the reasons behind the OIE's adoption of recommendations on a disease-by-disease basis (not on a product-by-product basis)?

6.157 **Dr. Winton** replied that the notifiable diseases in the OIE Code probably did not need a case-by-case analysis as this list represented the most significant diseases of aquatic animals and virtually all cases of movement of infected live aquatic animals or uneviscerated fish were judged to present risk. In the case of other diseases of concern, bilateral agreements between countries regarding live fish, live eggs, or uneviscerated fish should take into account the volume of trade, anticipated use of the product, presence of different strains of the pathogen, etc. that might require a product-by-product or case-by-case analysis.

VII. INTERIM REVIEW [192]

7.1 On 7 April 1997, Canada and Australia requested the Panel to review, in accordance with Article 15.2 of the DSU, precise aspects of the interim report that had been issued to the parties on 26 March 1997. Australia also requested the Panel to hold a further meeting with the parties. We met with the parties on 21 April 1998.

7.2 Following comments by Canada and Australia on the descriptive part of our report, we modified paragraphs 2.8, 2.27, 2.28, 4.4, 4.22, 4.26, 4.51, 4.56-4.64, 4.66, 4.71 and 4.175. We considered that several of the additions sought by Australia were already addressed, particularly in paragraphs 4.29, 4.30 and 4.35.

[192] 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.

7.3 Australia requested a "whole of report review" of the interim report. In so doing, it referred to Article 11 of the DSU setting out the function of a panel and requiring that it "should make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements". Australia argued that a large part of the legal reasoning of the interim report was not based on an objective assessment of the matter before the Panel and submitted that the interim report contained a number of factual inaccuracies and assertions not supported by evidence before the Panel. At the interim review meeting, Canada objected to Australia's request for "a whole of report review". Canada referred to Article 15.2 of the DSU which provides an opportunity for parties to request the panel to "review precise aspects of the interim report". According to Canada, it is not open to the Panel to consider anything other than comments dealing with "precise aspects" of the interim report. We agree with Canada and have therefore only reviewed our interim report in light of the comments made by the parties which relate to "precise aspects" of the interim report.

7.4 Australia submitted a series of comments on the definition of the measure at issue and the product coverage of the dispute as set out in the interim report. Australia argued that the 1988 Conditions - which, according to Australia, are only guidelines and not comprehensive - only apply to products imported in heat-treated form and have no application to fresh, chilled and frozen product; that substantial quantities of commercially canned salmon are imported into Australia and that these imports are not covered by the 1988 Conditions; that the Panel re-interpreted its terms of reference and was inconsistent in its definition of the measure at issue; and that heat-treated and fresh, chilled or frozen salmon are not the same products. We adopted some of Australia's arguments and clarified our rejection of others. We accordingly redefined and specified both the Australian measures and the salmon products at issue and ensured a consistent approach to the measure and products in dispute. These modifications are reflected in paragraphs 8.7-8.21, 8.24, 8.29, 8.95-8.101, 8.167-8.169, 8.173-8.179 and 8.182 and in the deletion of paragraph 8.23 in the interim report.

7.5 Australia provided factual clarifications as to the status of several reports and studies we referred to in our report. In response, we made modifications to paragraphs 8.130, 8.132 and 8.136. We recall, in particular, that for purposes of our examination, the scientific and technical content of these reports and studies is relevant, not their administrative status (i.e., whether they are official government reports or not).

7.6 Following Australia's more detailed objections to take into account evidence submitted by Canada after the 7 October 1997 deadline we imposed, we modified paragraph 8. and added paragraph 8.5.

7.7 Canada requested us to review our finding in paragraph 8. that steelhead/rainbow trout falls outside our terms of reference because, Canada submitted, the measure subject to the terms of reference applies to all salmonids, not only to salmon. Canada further indicated that some debate exists as to whether steelhead/rainbow trout is a salmon or only a salmonid and that practice in North America considers it to be a salmon. We recall that in paragraph 8. we stated that "steelhead/rainbow trout ... is - according to the experts advising the Panel on this issue - not a "salmon" species but only part of the wider "salmonid" family". We also stated that "the Panel request, which defines our terms of reference, only refers to "salmon", not to the wider category of "salmonid" " and thus found that "steelhead/rainbow trout falls outside our terms of reference". In our view Canada did not bring forward evidence which overrides the general validity of the scientific opinions we received from the experts advising the Panel. Nor do we consider that the measure at issue in this dispute - which is, according to the Panel request, only before us in so far as it applies to a specific category of "salmon" - should be broadened in product coverage to all "salmonids" because the measure referred to in the Panel request in principle applies to all salmonids. In the Panel request Canada not only limited the scope of this dispute to a specific measure, but also to specific products (a category of "salmon"). We

therefore did not incorporate Canada's suggested change to paragraph 8.20. In response to a comment by Australia that the genus Oncorhynchus is but one genus in the family Salmonidae, we rephrased paragraph 8.20.

7.8 Australia claimed that paragraph 8.22 is an inaccurate rendition of the situation. Australia submits that it should have been given the opportunity to rebut the "fundamental changes" introduced by Canada through a formal written submission, not through a written comment limited to certain matters. We confirm that paragraph 8.22 is an accurate reflection of what happened and what Australia agreed upon. Whether the additional opportunity we granted to the parties to submit arguments resulted in a formal written submission or a written comment is in our view irrelevant.

7.9 Both Canada and Australia provided comments on paragraphs 8.34 to 8.37 of our findings relating to the question of which definition of "sanitary measure" (as provided in paragraphs 1(a) and (b) of Annex A to the SPS Agreement) applies to the measure at issue in this dispute. We redrafted these paragraphs to accommodate most of the parties' concerns. However, with respect to Canada's argument that the definition in paragraph 1(b) of Annex A does *not* apply to this dispute, we recall that we stated that "both definitions of a "sanitary measure" invoked by Australia might be applicable to the measure in dispute", without deciding whether they are. We only found that (1) the definition in paragraph 1(a) covers the measure at issue and (2) even in the event the definition in paragraph 1(b) would also cover to the measure at issue, "the objectives for which that measure is being applied are more appropriately covered by the definition in paragraph 1(a)". The four elements referred to in paragraphs 8.35 and 8.36 indicate the validity of the last statement. They are not, as submitted by Canada, "reasons ... as to why paragraph 1(b) does *not* apply in this case". On that basis, we maintain our finding that "in the specific circumstances of this case we need to examine this measure as a [sanitary] measure ... in the sense of paragraph 1(a)".

7.10 With respect to paragraph 8.46, Australia stated that the OIE Code does not set adequate international guidelines since it is under substantial revision, not representative of global conditions, not grounded on a scientific basis and the result of nontransparent decision-making. Canada responded that the OIE Code *is* a "finalised document" adopted in 1995 and that the fact that it has been revised in 1997 does not make the guidelines it contains any less legitimate, but to the contrary ensures that these guidelines reflect advances in scientific knowledge. According to Canada, it is disingenious for Australia as an active participant in the OIE to suggest that the OIE process ignores southern hemisphere concerns or lacks transparency. To the extent we refer to the OIE Code in our report, we recall that the SPS Agreement (paragraph 3(b) of Annex A) explicitly directs us to the OIE and the standards, guidelines and recommendations it develops. Article 5.1 also refers us to "risk assessment techniques developed by the relevant international organizations". The fact that the OIE Code is subject to revision or the way it has been adopted in our view does not change its validity for our purposes.

7.11 On several occasions Australia referred to Article 5.3, which it invoked for the first time at the interim review stage. It submitted that the Panel "ignored the right of WTO Members to take into account the factors referred to in Article 5.3". When addressing this provision in paragraph 8.50 we noted the following: "Canada does not challenge the measure at issue under Article 5.3 (elaborating on the "relevant economic factors" to be taken into account in a risk assessment) nor do we see any reason to further examine this provision". Indeed, Article 5.3 is a provision imposing an *obligation* on Australia to take into account certain economic factors in assessing risk. It is, therefore, a provision - we would expect - to be invoked by Canada. However, by not addressing this provision we do by no means ignore the *right* of Australia to take into account these factors. The definition of risk assessment we applied, for example, refers to "economic consequences" and we have addressed such consequences consistently in, e.g., paragraphs 8.72 and following and 8.121 and following.

7.12 With respect to paragraph 8.60, Canada submitted that the Panel should not have limited its findings under Articles 5.5 and 5.6 of the SPS Agreement to adult, wild, ocean-caught Pacific salmon.

Canada argued that we thus make a distinction "not among *claims* but among *categories of products* covered by the same claims". For Canada, the Appellate Body Report on *United States - Measures Affecting Imports of Woven Wool Shirts and Blouses* - to which we refer in support of the principle of judicial economy - only allows Panels to dispense with addressing only particular *claims*. We changed paragraphs 8.60, 8.102 and 8.104 to clarify some of the concerns raised by Canada but maintained our position in applying the principle of judicial economy with respect to the salmon products at issue other than those from adult, wild, ocean-caught Pacific salmon for our examination under Articles 5.5 and 5.6. We recall that we found an inconsistency with Article 5.1 of the SPS Agreement with respect to all salmon products at issue (including those other than from adult, wild, ocean-caught Pacific salmon). In principle we might thus have stopped our examination there. However, we considered it appropriate to also address in the alternative (i.e., in case we were to have found that the measure at issue is consistent with Article 5.1) Articles 5.5 and 5.6 but limited our examination under these provisions to the salmon products at issue specifically addressed by the Australian risk assessment, i.e., those from adult, wild, ocean-caught Pacific salmon. Whether one considers this limitation to imply a distinction between claims or a distinction between categories of products covered by one and the same claim does not in our view preclude us from adhering to the prudential dictates of judicial economy as we did in this dispute.

7.13 Australia referred to, *inter alia*, paragraphs 8.68 and following and argued that they do not address differences between additives, contaminants or toxins on the one hand (for which only the definition in paragraph 1(b) of Annex A to the SPS Agreement applies) and naturally occurring diseases on the other hand (for which several definitions in paragraph 1 of Annex A might apply). We consider that this issue is sufficiently covered in paragraphs 8.34 and following and paragraphs 8.68 and following.

7.14 With respect to paragraph 8.96, Australia submitted - for the first time during our proceedings - that the heat treatment requirements it currently imposes are based on a risk assessment, reflecting the scientific knowledge of the 1980s, in accordance with assessments and practices that predate the entry into force of the SPS Agreement. However, Australia never provided us any such risk assessment. We therefore decided not to change that part of our report.

7.15 With respect to paragraph 8.107, Canada - for the first time in this dispute - invoked paragraph 3(c) of Annex B to the SPS Agreement (referred to in Article 7 of that Agreement) in support of its claim under Article 5.5 that there rests an obligation on Australia to identify or quantify its appropriate level of protection. We note that claims under Article 7 - which is not mentioned in the Panel request setting out our terms of reference - fall outside our mandate. Moreover, even in so far as paragraph 3(c) of Annex B is part of the context in which the wording of Article 5.5 should be read, we do not consider that it imposes a substantive obligation on Members to identify or quantify their appropriate level of protection. In our view, paragraph 3(c) of Annex B imposes a mainly procedural obligation to provide "answers to all reasonable questions from all interested Members" as well as "relevant documents" regarding "the determination of the appropriate level of sanitary protection". We therefore kept our position in paragraph 8.107 unchanged. We did rephrase part of that paragraph to avoid some further misunderstandings hinted at by Canada.

7.16 Canada further commented on paragraphs 8.127 and 8.128. We took this comment into account and accordingly made some changes in paragraphs 8.120, 8.127 and footnote 335 to clarify that Canada not only forwarded the four comparisons we further examined under Article 5.5 but also referred to others.

7.17 We incorporated changes suggested by Canada in paragraph 8.144 specifying that the arguments contained in that paragraph predate the circulation of the Appellate Body Report on *EC - Hormones*.

7.18 In the context of paragraph 8.154, Australia submitted that our legal reasoning and reference to the difference in conclusions reached by the 1995 Draft Report and the 1996 Final Report will discourage Members from issuing draft reports for domestic public comment and for comments from other Members. We recall, however, that in our view risk communication is an important aspect of a risk analysis. Nowhere should our report be interpreted as discouraging risk communication. All we refer to in this respect is (as stated in paragraph 8.154) that Australia did not explain why the risk communication exercise - conducted between the two reports - brought about the change in recommendations between the 1995 Draft Report and the 1996 Final Report. We accept, of course, that changes are made between draft reports sent out for public comment and final reports. However, one may reasonably expect that substantial changes in the recommendations contained in these reports can be explained and justified in terms of Members' commitments under the WTO agreements.

7.19 With respect to paragraph 8.185, Canada requested the Panel to also find a violation of Article XI of GATT 1994 since we "already made the findings necessary to support" such finding. Even if this were the case, in our view a finding that the measure at issue also violates Article XI of GATT 1994 would not contribute to the resolution of the matter at issue in this dispute nor, in terms of Article 11 of the DSU "assist the DSB in making the recommendations or in giving the rulings provided for in the covered agreements". Indeed, if we were to find that Article XI of GATT 1994 is violated, we would not be able to stop our examination there. The issue would then arise whether such violation could not be justified under Article XX of GATT 1994 which, in turn, would lead us to the SPS Agreement under which we already found inconsistencies. We therefore maintained our position of applying the principle of judicial economy in this respect.

7.20 The comments made by Canada on paragraphs 8.73, 8.74, 8.75, 8.80, 8.105 and 8.107 are explicitly addressed or have been incorporated in these paragraphs. Canada also provided some technical corrections - to which Australia did not object - which we took into account in finalizing our report. These dealt in particular with the technical distinction to be made between a "disease" and a "disease agent", a distinction to which, in this report, no substantial legal consequence is attached.

7.21 The comments made by Australia on paragraphs 8.30, 8.53, 8.54, 8.55, 8.57, 8.58, 8.67, 8.81, 8.83, 8.90, 8.98, 8.106, 8.118, 8.128, 8.129, 8.140, 8.145, 8.147, 8.148 and 8.163 are explicitly addressed or have been incorporated in these paragraphs. We also modified paragraphs 8.72, 8.93, 8.107, 8.121, 8.126, 8.137, 8.139, 8.149-8.156, 8.171 and 8.180; added paragraphs 8.40 and 8.135; and deleted paragraphs 8.98, 8.117 and 8.152 in the interim report, to accommodate or respond to some of Australia's concerns.

VIII. FINDINGS

A. CLAIMS OF THE PARTIES

8.1 Canada claims that certain Australian quarantine measures which, it alleges, effectively ban the importation of fresh, chilled and frozen salmon, are inconsistent with Article XI of GATT 1994 and Articles 2, 3 and 5 of the SPS Agreement. In the alternative, Canada claims that the Australian measures nullify or impair benefits accruing to it under the WTO Agreement within the meaning of Article XXIII:1(b) of GATT 1994. Australia rejects these claims and submits that its measures applying to fresh, chilled and frozen salmon are fully consistent with Australia's rights and obligations under both the SPS Agreement and GATT 1994.

B. ORGANIZATIONAL ISSUES

8.2 At our first substantive meeting we decided to seek advice from individual scientific experts in accordance with Article 13 of the DSU and Article 11.2 of the SPS Agreement. The procedures we adopted for our consultation with the experts advising the Panel are set out in paragraphs 6.1-6.6. We

first solicited advice from the experts advising the Panel on a series of scientific and technical questions. An overview of the experts' written answers to these questions can be found in paragraphs 6.7-6.157. The parties commented extensively on the experts' answers. We then held a meeting with the parties and the scientific experts advising the Panel to allow the experts to express their views orally and to enable both the Panel and the parties to ask additional questions. The *verbatim* transcript of this meeting is attached to our report as Annex 2 (and hereafter referred to as "transcript"). The meeting with experts advising the Panel took place the day before our second substantive meeting in order to allow the parties to incorporate - in their rebuttal statements - the comments and conclusions they might draw from the scientific evidence gathered by the Panel. On request by the parties, we delayed our second substantive meeting - and the meeting with experts advising the Panel - to 4 and 5 February 1998 to enable the parties to make their rebuttal statements in light of the Appellate Body Report on *European Communities - Measures Concerning Meat and Meat Products (Hormones)* (hereafter referred to as "*EC - Hormones*").

8.3 To allow the experts advising the Panel to take into account all material evidence before the Panel when answering our questions, we requested the parties - at the end of our first substantive meeting - to submit any additional evidence they might have together with their rebuttal submission which was due on 7 October 1997. However, we also made clear that the parties would still be given the opportunity to comment on the experts' answers, both in writing until 18 December 1997 and at the meeting with the experts advising the Panel.

8.4 At our second substantive meeting, Australia requested us to exclude Annex K submitted by Canada as part of its comments on the experts' written answers, hereafter referred to as the "Vose Report"[193], as well as Exhibit C-14 annexed by Canada to the oral statement it made at the second substantive meeting held after the meeting with experts advising the Panel.[194] Australia argues that for due process reasons documentary evidence needs to be provided at the earliest stage of the panel process and that both documents have been submitted after the 7 October 1997 deadline. Both the Vose Report and Exhibit C-14 were submitted after the 7 October 1997 deadline we imposed. Even though Canada transmitted the Vose Report before our meeting with the experts advising the Panel as an annex to its comments on the experts' written answers, it is unclear to us whether the Vose Report - given its complexity and length (it allegedly constitutes a complete alternative risk assessment commissioned by Canada) - can be qualified as a "comment" on the specific answers provided by the scientific experts advising the Panel which parties were allowed to make after the 7 October 1997 deadline. We recall, however, that - as is outlined in paragraph 8.22 - we granted Australia the one additional week it requested to respond, *inter alia*, to the Vose Report in a third written submission. Against this background and since, in our view, the Vose Report is in any event not crucial to our report, we shall not further consider it in our examination. With respect to Exhibit C-14, submitted by Canada at our second substantive meeting and thus *after* the meeting with the experts advising the Panel, we agree with Australia that the 7 October 1997 deadline applies and that it should, therefore, be rejected. The experts advising the Panel never received this document. The experts could thus not comment on it. We therefore exclude Exhibit C-14 from our examination.

8.5 Finally, at the interim review meeting Australia also pointed out that the risk assessment conducted by New Zealand in 1997 which Canada attached to its comments on the experts' written responses, hereafter "1997 New Zealand Risk Analysis".[195] should be excluded since it was submitted after the 7 October 1997 deadline. In one of our questions to the experts advising the Panel we inquired whether the risk assessment conducted by New Zealand in 1994 - and which had been submitted to us by Canada as an exhibit to its first submission - was scientifically relevant to this dispute. In response, one of the experts advising the Panel referred to and discussed the more recent

[193] David Vose, "Quantitative analysis of the risk of establishment of *Aeromonas salmonicida* and *Renibacterium salmoninarum* in Australia as a result of importing Canadian ocean-caught salmon".

[194] Lester and Sewell, "Checklist of Parasites from Heron Island, Great Barrier Reef".

[195] Stone, MacDiarmid and Pharo, "Import Health Risk Analysis: Salmonids for Human Consumption, New Zealand, Ministry of Agriculture Regulatory Authority", 1997.

1997 risk assessment carried out by New Zealand. In its comments to this answer, Canada submitted this risk assessment. On this ground, we consider that we can take into account the 1997 New Zealand Risk Analysis in our further examination.

C. GENERAL INTERPRETATIVE ISSUES

1. Scope of the Australian measures in dispute

8.6 Our terms of reference direct us to examine "in light of the relevant provisions of the covered agreements cited by Canada in document WT/DS18/2 [the request for establishment of this Panel], the matter referred to the DSB by Canada in that document".[196]

8.7 In the Panel request Canada specified the contested measures as follows:

> "The Australian Government's measures prohibiting the importation of fresh, chilled or frozen salmon ... include Quarantine Proclamation 86A, dated 19 February 1975, and any amendments or modifications to it. The measures adversely affect the importation of Canadian salmon".[197]

In its first submission to the Panel, Canada specifies that the Australian measures at issue are "Quarantine Proclamation 86A ("QP86A") and published requirements pursuant to QP86A that together require salmonid product to be heat treated for certain prescribed durations and temperatures, prior to importation into Australia".[198] Canada sums up the following Australian measures as published requirements pursuant to QP86A: (1) "Guidelines for the Importation of Smoked Salmon and Trout into Australia", issued in July 1983 by the Australian Department of Primary Industries and Energy ("1983 Guidelines"; these Guidelines are no longer in effect and we shall thus not further address them); (2) "Conditions for the Importation of Salmonid Meat and Roe into Australia", issued on 1 June 1988 by the same department and replacing earlier guidelines, including the 1983 Guidelines ("1988 Conditions"); (3) "Requirements for the importation of individual consignments of smoked salmon meat", issued by the Australian Quarantine and Inspection Service ("AQIS") on 24 January 1996 ("1996 Requirements"); and (4) the Decision of the Director of Quarantine, dated 13 December 1996, that a permit will not be issued for the importation into Australia of "uncooked, adult, wild, ocean-caught Pacific salmonid product from the Pacific rim of North America" ("1996 Decision").[199]

8.8 Australia submits that the measure at issue is the 1996 Decision. For Australia, QP86A is not at issue since it does not constitute an import prohibition but only provides the legal basis for conditions of entry of salmon. Australia submits that the fact that imports of appropriately heat-treated and canned salmon have been permitted, is evidence that QP86A does not constitute an import prohibition. If Australia is correct, the scope of this dispute would be limited to the specific category of salmon covered by the 1996 Decision. At the interim review stage, Australia further alleged that the 1988 Conditions only apply to products imported in heat-treated form and are not comprehensive since other products may enter Australia provided the decision-maker is satisfied that the risk is acceptable. Such other products which are allowed for importation are commercially canned salmon (according to Australia, not subject to formal guidelines) and material for scientific and research purposes.

8.9 Canada counters that it does not argue that QP86A is an import prohibition, but rather, that it has been *applied* as an import prohibition, by means of the published guidelines and conditions on

---

[196] WT/DS18/3, 3 June 1997.
[197] WT/DS18/2, 10 March 1997, p.1.
[198] Canada, First Submission, para. 4.
[199] The first three measures were referred to by Canada in its first submission, footnote 2, p.1. Later in the proceedings Canada also referred to the 1996 Decision.

heat treatment. For Canada, it is a fact that Canadian fresh, chilled and frozen salmon cannot enter Australia and that, therefore, the measures in question operate as an import prohibition. Furthermore, Canada notes that if the measure at issue would only be the 1996 decision by the Director of Quarantine, the scope of the measure would be limited to uncooked, adult, wild, ocean-caught Pacific salmon from Canada and the United States. However, according to Canada, the terms of reference of the Panel extend to *all* fresh, chilled and frozen salmon from Canada.

8.10 QP86A provides in relevant part:

> "NOW THEREFORE I, ..., the Governor-General of Australia, ..., hereby,
>
> ...
>
> (d) prohibit the importation into Australia of dead fish of the sub-order Salmonidae, or any parts (other than semen or ova) of fish of that sub-order, in any form unless
>
> (i) prior to importation into Australia the fish or parts of fish have been subject to such treatment as in the opinion of the Director of Quarantine is likely to prevent the introduction of any infectious or contagious disease, or disease or pest affecting persons, animals or plants; (underlining added) and
>
> (ii) the Director of Quarantine or a person authorized by him has, by instrument in writing, consented to the importation and the instrument is produced to a Collector ... or to a quarantine officer".[200]

8.11 The 1988 Conditions, which replaced earlier guidelines (including the 1983 Guidelines) which we do not need to address, provide as follows:

> "CONDITIONS FOR THE IMPORTATION OF SALMONID MEAT AND ROE INTO AUSTRALIA
>
> 1. All uncanned salmon and trout meat and salmon roe will require a quarantine permit to enter Australia.
>
> ...
>
> 3. On current information approved temperature time relationships are as follows:
>
> | | | |
> |---|---|---|
> | 35° for 7 hours |) | |
> | 40° for 5 1/2 hours |) | |
> | 50° for 3 hours |) | oven temperatures |
> | 60° for 1 hour |) | |
> | 70° for 0.25 hour |) | |
> | 120° for 0.2 hour |) | |
>
> ...
>
> 5. The Australian Quarantine and Inspection Service is willing to consider variations to the current requirements which could take into account the effects of the auxiliary processing such as "flash-baking", "par boiling", "gamma irradiation",

[200] Commonwealth of Australia Special Gazette No. S 33, 21 February 1975.

> "brining" or "freezing" where the effectiveness of this process in inactivating organisms can be demonstrated ...
>
> ...
>
> 12. These conditions valid at 1 June 1988, are subject to alteration at the discretion of the Director of Animal and Plant Quarantine (Australia) or if the fish disease status of any exporting country changes".[201] (underlining added)

8.12 The 1996 Requirements specify new requirements for the importation of individual consignments of smoked salmonid meat (under 5 kg in weight) accompanied by passengers. These consignments are:

> "exempt from the certification requirement of Condition Code 5055 in Volume 5 of the Quarantine Manual. However, treatment to the prescribed processing is still required".[202]

8.13 The 1996 Decision of the Director of Quarantine reads in relevant part:

> "The [Chief Veterinary Officer] recommends "that the status quo for quarantine policies for uncooked salmon products continue"
>
> - i.e., that the requests from Canada and US for access for uncooked, adult, wild, ocean caught Pacific salmonid product not be approved.
>
> ...
>
> On the basis of these considerations I have decided that, having regard to Australian Government policy on quarantine and after taking account of Australia's international obligations, importation of uncooked, adult, wild, ocean-caught Pacific salmonid product from the Pacific rim of North America should not be permitted on quarantine grounds".[203]

8.14 In addressing the argument raised by Australia - that QP86A is not an "import prohibition" and that the only "import prohibition" at issue is the 1996 Decision - we note that the argument relates primarily (and for the purpose of our present examination, exclusively) to the interpretation of our terms of reference (in particular, the terms "measures prohibiting the importation" in the Panel request). We, therefore, recall the Appellate Body's statement in its report on *Brazil - Measures Affecting Desiccated Coconut*:

> "A panel's terms of reference are important for two reasons. First, terms of reference fulfil an important due process objective - they give the parties and third parties sufficient information concerning the claims at issue in the dispute in order to allow them an opportunity to respond to the complainant's case. Second, they establish the jurisdiction of the panel by defining the precise claims at issue in the dispute".[204]

---

[201] Department of Primary Industries and Energy ("DPIE"), Document T88/90, 1 June 1988.
[202] AQIS, Quarantine Operational Notice 1996/022, 24 January 1996, p.2.
[203] AQIS, Policy Decision, 13 December 1996, Australian Exhibit 33 to its First Submission.
[204] Adopted 20 March 1997, WT/DS22/AB/R, p.22. See also Appellate Body Reports on *EC - Regime for the Importation, Sale and Distribution of Bananas*, adopted 25 September 1997, WT/DS27/AB/R, para. 142, and *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, adopted 16 January 1998, WT/DS50/AB/R, paras. 87-88.

We note, however, that in this dispute Australia does not argue that either QP86A or any of the guidelines, conditions or requirements mentioned by Canada fall outside our terms of reference due to lack of specificity of the Panel request, in the sense of Article 6.2 of the DSU.[205] In line with this, Australia does not submit that the request for consultations or the Panel request did not give it adequate notice that Canada would also contest measures implementing QP86A. Australia only argues that none of the measures challenged by Canada, other than the 1996 Decision, can be considered as an "import prohibition", i.e., the kind of measure mentioned in the Panel request.

8.15 Considering, first, whether QP86A falls within our terms of reference, we note that our terms of reference are defined in the Panel request and that in this case the Panel request explicitly identifies QP86A. We find, therefore, that QP86A, irrespective of how Canada characterizes it (*in casu*, Canada considers it to be a measure "prohibiting the importation of fresh, chilled or frozen salmon"), falls within our terms of reference. In this respect, we note, moreover, that in 1975 a Chief Quarantine Officers (Animals) Conference decided that under QP86A "all fresh or frozen salmonid flesh is prohibited".[206] The 1996 Final Report as well stated unambiguously that under QP86A "commercial quantities of fresh, frozen and chilled salmon product are not permitted entry into Australia".[207]

8.16 We next examine whether the published requirements pursuant to QP86A referred to by Canada (i.e., the 1988 Conditions, the 1996 Requirements and the 1996 Decision) fall within our terms of reference. We note that none of these requirements are explicitly mentioned in the Panel request. We recall, however, that the Panel request does refer to "measures prohibiting the importation of fresh, chilled or frozen salmon" and explicitly mentions QP86A as being one such measure.

8.17 The 1996 Decision is a decision taken by the Director of Quarantine on the basis of the authority delegated to him by QP86A. Following a recommendation of the Chief Veterinary Officer "that the status quo for quarantine policies for uncooked salmon products continue", it explicitly states that the "importation of uncooked, adult, wild, ocean-caught Pacific salmonid product from the Pacific rim of North America should not be permitted on quarantine grounds". It thus confirms the general prohibition in principle imposed by QP86A on the importation of all salmonid products (unless special authorization is granted) for a limited category of salmonid products. It confirms, more particularly, the decision taken by the Chief Quarantine Officers (Animals) Conference, referred to in paragraph 8., that "all fresh or frozen salmonid flesh is prohibited". We consider, therefore, that the 1996 Decision is a measure "prohibiting the importation of fresh, chilled or frozen salmon" as referred to in the Panel request and this even though it only prohibits importation of a specific category of "fresh, chilled or frozen salmon" (namely, "uncooked, adult, wild, ocean-caught Pacific salmonid product"). In our view, the 1996 Decision is, moreover, subsidiary and so closely related to QP86A that it can be said to be part of the application of QP86A.[208] On these grounds, we find that the 1996 Decision falls within our terms of reference.

8.18 In our view, the same reasoning applies to the 1988 Conditions. They impose - as the title of the 1988 Conditions reads - "conditions for the importation of salmonid meat and roe into Australia". They authorize - by decision of the Director of Quarantine who was granted the authority to do so in

[205] Article 6.2 of the DSU provides in relevant part: "The request for the establishment of a panel shall be made in writing. It shall indicate whether consultations were held, identify the specific measures at issue and provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly".

[206] Chief Quarantine Officers (Animals) Conferences 1975, (Canberra) 23-24 September, (Melbourne) 17 November, p.20.

[207] 1996 Final Report, p.4.

[208] Panel Report on Japan - Measures Affecting Consumer Photographic Film and Paper, adopted on 22 April 1998, WT/DS44/R, para. 10.6-10.11, especially at para. 10.10: "In our view, "measures" that are subsidiary or closely related to specified "measures" can be found to be "adequately identified" as that concept was applied in the Bananas III case".

QP86A - the importation of salmonid meat and roe into Australia subject to heat treatment in accordance with certain approved temperature-time relationships. In that sense, they are - as the 1996 Decision is - subsidiary and so closely related to QP86A that they can also be said to be part of the application of QP86A.[209] Contrary to what Australia alleges, nothing in the 1988 Conditions implies that the 1988 Conditions only apply to heat-treated product. Only the actual *requirement* for importation imposed in the 1988 Conditions (not the scope of application of these conditions) refers to heat treatment. According to Australia, only two other categories of salmonid product (for which no formal guidelines exist) may enter Australia: canned salmon[210] (which, however, according to Australia will *a fortiori* meet the heat treatment requirements contained in the 1988 Conditions) and frozen, uncooked salmon tissue to be used for scientific purposes or for taxidermy.[211] Therefore, to the extent that the 1988 Conditions require salmon product to be heat-treated before they can enter Australia and given the fact that, according to Australia, only some minuscule quantities of salmon product not so heat-treated can enter Australia (namely, frozen, uncooked salmon tissue used for scientific purposes or taxidermy), we consider that the 1988 Conditions, read in that context, in effect deny the importation of commercial quantities of salmon product not heat-treated as prescribed.[212] The 1988 Conditions can, in that sense, also be said to constitute a measure "prohibiting the importation of fresh, chilled or frozen salmon" as referred to in the Panel request.[213] For the above reasons, we consider that also the 1988 Conditions fall within our terms of reference. Finally, with respect to the 1996 Requirements - which deal with the importation of individual consignments of salmonid meat and confirm that the heat treatment requirements imposed in the 1988 Conditions apply for such imports - we consider that the same reasoning as that developed above for the 1988 Conditions applies. We thus consider that the 1996 Requirements fall within our terms of reference.

8.19 For the above reasons, we consider that, according to our terms of reference, the measure we need to examine in this dispute is QP86A as implemented or confirmed by the 1988 Conditions, the 1996 Requirements and the 1996 Decision and this in so far as it prohibits the importation into Australia of fresh, chilled or frozen salmon.

8.20 In its first submission, Canada specifies certain limits on the scope of the dispute. Australia does not object to this and we see no reason to do so either. First, Canada limits its challenge to the treatment of Canadian salmon. Second, Canada further specifies that only salmon products for human consumption are at issue. Third, Canada also clarifies the notion of "fresh, chilled or frozen" salmon, the only category of salmon mentioned in the Panel request (also referred to by Canada as "uncooked salmon") to mean salmon which has not been heat treated as required by Australia prior to importation. Fourth, Canada identifies the Canadian salmon for which it seeks access to the Australian market to consist of the following seven species:

(1) pink salmon;
(2) chum salmon;
(3) coho salmon;
(4) sockeye salmon;
(5) chinook or king salmon;
(6) steelhead/rainbow trout; and
(7) Atlantic salmon.

---

[209] Ibid.

[210] 1996 Final Report, p.4: "commercially canned salmon products in hermetically sealed containers not requiring refrigeration may be imported".

[211] Ibid., p.4: "small amounts [of fresh, frozen and chilled salmon product] have been permitted entry into approved premises for scientific purposes".

[212] 1996 Final Report, p.4: "commercial quantities of fresh, frozen and chilled salmon product are not permitted entry into Australia" and Chief Quarantine Officers (Animals) Conferences 1975, (Canberra) 23-24 September, (Melbourne) 17 November, p.20: "all fresh or frozen salmonid flesh is prohibited".

[213] At our interim review meeting, Australia stated that it was reviewing its heat treatment requirements but that in the interim the 1988 Conditions are applied.

The first five species are all Pacific salmon. The sixth species, steelhead/rainbow trout, differs from the other species referred to by Canada in that it is - according to the experts advising the Panel on this issue[214] - not a "salmon" species but only part of the wider "salmonid" family (including, *inter alia*, the genus *Oncorhynchus*). Since the Panel request, which defines our terms of reference, only refers to "salmon", not to the wider category of "salmonid", we find that steelhead/rainbow trout falls outside our terms of reference.

8.21 Considering our terms of reference as interpreted above and taking into account the further refinements provided in Canada's first submission, we shall, therefore, only examine Australian QP86A as implemented or confirmed by the 1988 Conditions, the 1996 Requirements and the 1996 Decision and this only in so far as it prohibits the importation of salmon products (i.e., dead salmon or any part thereof) (1) imported from Canada, (2) for human consumption, (3) which are "fresh, chilled or frozen" (i.e., which have *not* been heat-treated as required by Australia prior to importation) and (4) which originate from any of the species of salmon identified by Canada other than steelhead/rainbow trout. Hereafter we refer to this measure as "the measure in dispute" or "the measure at issue" and to the specific category of salmon products fulfilling all four above-mentioned conditions as "the salmon products in dispute" or "the salmon products at issue".[215]

2. The "fundamental changes" introduced by Canada in its oral statement at the second substantive meeting

8.22 At our second substantive meeting, Australia raised a procedural claim related to Canada's oral statement made at that meeting. According to Australia, Canada's oral statement introduced fundamental changes in the nature of its specific legal claims which are of such significance that Australia should be allowed to rebut them through a formal written rebuttal submission. On this ground, Australia requested the Panel to give it more time - suggesting one extra week - to submit a third written rebuttal submission. The "fundamental changes" referred to by Australia are outlined in paragraphs 4.8-4.17. We consider that some of these changes - most of them inspired by the expert advice gathered by the Panel at the experts meeting and by the Appellate Body's Report on *EC - Hormones* - are, indeed, substantial and for reasons of due process warrant an additional rebuttal period for Australia. We thus granted Australia's request to submit a third written submission within one week after our second substantive meeting. We gave the same opportunity to Canada and specified that both third submissions had to be limited to the "fundamental changes" introduced by Canada as they were identified in an oral statement made by Australia at the second substantive meeting. On 13 February 1998, we received such third submission from both parties.

8.23 In its third submission Australia argues that some of these "fundamental changes" are "new claims". However, Australia does not submit that they are "new claims" in the sense that they fall outside our terms of reference. The document which defines our terms of reference is Canada's request for this Panel. In relevant part Article 6.2 of the DSU requires that "[t]he request for the establishment of a panel shall ... identify the specific measures at issue and provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly". Moreover, as noted by the Appellate Body in *European Communities - Regime for the Importation, Sale and Distribution of Bananas:*

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

[214] Rodgers, Transcript, para. 23 and Winton, Transcript, para. 46.

[215] We note that we need not address in this dispute the importation of live salmon or salmon used as feedstuff or bait.

> Article 7 of the DSU, which set out the claims of the complaining parties relating to the matter referred to the DSB".[216]

8.24 Canada's request for this Panel sufficiently identifies the measures at issue [217] and specifies, *inter alia*, that these measures "are inconsistent with (i) the Agreement on the Application of Sanitary and Phytosanitary Measures, and in particular Article 2, 3 and 5 thereof". We next address whether the, according to Australia, "new claims" made by Canada at our second substantive meeting fall within our mandate. First, Australia argues that Canada extended its claim under Article 5.1 to include claims in respect of heat-treated salmon and salmon not covered by the 1996 Final Report. This "new claim" remains a claim under Article 5.1, which falls within our terms of reference. The product coverage of this dispute, set out in the Panel request and specified by Canada in its first submission, has been determined in paragraph 8.18. It does not only include salmon products covered by the 1996 Final Report. It does exclude heat-treated product. Second, Australia alleges that Canada introduced a new specific claim under Articles 5.1, 5.2 and 2.2, on the basis that there was no rational relationship between the measure and the scientific evidence. We consider this "new claim" to be a new argument (put forward in support of claims under Articles 2 and 5 which do fall within our terms of reference), inspired by the Appellate Body Report on *EC - Hormones*, not a new claim. Third, in respect of Article 5.5, Australia submits that Canada had not previously made a legal claim that the measure resulted in a disguised restriction on international trade. We consider this "new claim" (which refers to one of the requirements under Article 5.5 and has been raised by Canada in its first submission) to be a claim under Article 5.5, which does fall within our terms of reference. Fourth, in regard to Article 3.3, Australia argues that Canada had not previously requested the Panel to make a finding of violation in respect of Article 3.3. Claims under Article 3, including Article 3.3 to which Article 3.1 explicitly refers, fall within our terms of reference. Moreover, in its first submission, Canada already submitted that Australia does not fulfil the conditions in Article 3.3. Fifth, in regard to Article 5.6, Australia argues that Canada introduced a new legal claim in respect of heat-treated product. As we found in paragraph 8.18, heat-treated product falls outside the product coverage of this dispute. However, as set out in paragraph 8.18, the 1988 Conditions - which impose specific heat-treatment requirements before importation is allowed - do fall within our terms of reference.

8.25 We thus consider that all of the "new claims" introduced by Canada at our second substantive meeting fall within our terms of reference and can be taken into account in our examination of this dispute.

3. Canada's claim under Article XXIII:1(b) of GATT 1994

8.26 Australia argues that Canada's claim under Article XXIII:1(b) of GATT 1994, i.e., its claim of non-violation nullification and impairment, falls outside our terms of reference since it was not identified in Canada's Panel request. Canada disagrees and submits that this claim was raised in its requests for consultations under GATT and the WTO and in its request for the establishment of this Panel.

8.27 Article 6.2 of the DSU provides in relevant part:

> "The request for the establishment of a panel shall ... identify the specific measures at issue and provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly".

The Appellate Body Report on *European Communities - Regime for the Importation, Sale and Distribution of Bananas* noted the following:

---

[216] Op. cit., para. 145.
[217] Paras. 8.6 ff.

> "Article 6.2 of the DSU requires that the claims ... must all be specified sufficiently in the request for the establishment of a panel in order to allow the defending party and any third parties to know the legal basis of the complaint. If a *claim* is not specified in the request for the establishment of a panel, then a faulty request cannot be subsequently "cured" by a complaining party's argumentation in its first written submission to the panel or in any other submission or statement made later in the panel proceeding".[218]

In its Report on *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, the Appellate Body found:

> "In this case ... there is a failure to identify a specific provision of an agreement that is alleged to have been violated. This falls below the "minimum standards" [established by Article 6.2 of the DSU] that we were willing to accept in *European Communities - Bananas*".[219]

8.28 Since in this dispute, Article XXIII of GATT 1994 is not mentioned by Canada in its request for this Panel as a legal basis for its complaint (only as a legal ground to obtain the establishment of the Panel) and the Panel request does not refer at all to the more specific and quite different non-violation provision of Article XXIII:1(b) (the Panel request only refers to the idea of "nullification and impairment" in the context of measures "inconsistent" with WTO rules in the sense referred to in Article XXIII:1(a)), we find that Canada's claim under Article XXIII:1(b) falls outside our terms of reference.

4. Application of GATT 1994 and the SPS Agreement

8.29 Canada first claims that the measure in dispute violates GATT 1994. We note that this dispute relates to trade in goods (*in casu*, imports of certain fresh, chilled or frozen salmon products) and that on its face GATT 1994 applies.

8.30 Canada next invokes the SPS Agreement. Both parties agree that the SPS Agreement applies to the measure in dispute. Article 1.1 of the SPS Agreement provides that it applies to

> "all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement".

Neither of the parties to this dispute contests that the measure at issue affects international trade. We agree that it does so.

8.31 With respect to the question whether the measure in dispute is a "sanitary measure", paragraph 1 of Annex A to the SPS Agreement defines what is considered to be a "sanitary measure" for purposes of the SPS Agreement. Australia claims that the measure in dispute falls under the following two definitions of a "sanitary measure":

> "[a]ny measure applied:
>
> (a) to protect animal ... life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases ... or disease-causing organisms;

[218] Op. cit., para. 143, emphasis in original.
[219] Adopted 16 January 1998, WT/DS50/AB/R, para. 91.

(b) to protect ... animal life or health within the territory of the Member from risks arising from ... disease-causing organisms in foods ...".[220]

8.32 According to Australia, the measure at issue is applied to protect the life and health of animals in Australia, more particularly salmonids and other aquatic animals. The protection of human life or health is not at issue in this dispute. With respect to the definition of a "sanitary measure" in paragraph 1(a), Australia argues that the measure at issue is intended to protect Australian salmonids and other aquatic animals against 24 disease agents ("diseases ... or disease-causing organisms") of concern to it.[221] To justify that its measure also falls under the definition of a "sanitary measure" in paragraph 1(b), Australia notes that, if allowed into Australia, Canadian salmon would be used as *food* (for human consumption). According to Australia, this food could incidentally enter Australian waterways, (e.g., through waste disposal) where it might be consumed (as feedstuff) by salmon or other fish and thus adversely affect animal health with any of the 24 diseases of concern.

8.33 Canada argues that the measure in dispute only falls under the definition of a "sanitary measure" contained in paragraph 1(a) of Annex A. Canada refers to the first introductory paragraph of the "Salmon Import Risk Analysis, Final Report" of December 1996, put forward by Australia as the risk assessment on which its measure is based ("1996 Final Report"). That paragraph, entitled "Purpose of paper", states that the main issues discussed are, *inter alia*, "the likelihood of disease entry and establishment" and "the consequences that may arise from that disease entry and establishment".[222] Canada submits that there is no mention of assessing risks to salmon from disease-causing organisms in food and that one would not expect such an assessment when the product in question is intended for human consumption.

8.34 In the circumstances at hand, we consider that the definition of a "sanitary measure" in paragraph 1(a) encompasses the coverage sought by Australia under the definition in paragraph 1(b). The definition in paragraph 1(a) deals with risks arising from "the entry, establishment or spread of pests, diseases ... or disease-causing organisms" in general. In the context of disease-causing organisms, the definition in paragraph 1(b) is limited in the sense that it only addresses risks arising from "disease-causing organisms in foods, beverages or feedstuffs" (hereafter also referred to as food-borne risks). We are of the view that, even though both definitions of a "sanitary measure" invoked by Australia might be applicable to the measure in dispute, the objectives for which that measure is being applied are more appropriately covered by the definition in paragraph 1(a). These objectives have been clearly expressed by Australia on several occasions.

8.35 First, QP86A itself provides that the import of salmon products is prohibited unless they have been "subject to such treatment as in the opinion of the Director of Quarantine is likely to *prevent the introduction of any infectious or contagious disease, or diseases or pest affecting persons, animals or plants*".[223] Second, in the 1996 Decision as well, the risk against which protection is required is stated to be "the probability of establishment of ... diseases". None of the Australian measures submitted to the Panel are limited to, or even explicitly mention, food-borne risks. Third, also the 1996 Final Report, submitted by Australia as the risk assessment on which its measure is based, assesses the risks related to "disease entry and establishment" and "the consequences that may arise from that disease entry and establishment".[224] Even though the Report is based on the premise that the imported product is food intended for human consumption, it does not only address risk to fish life or health arising from this "food" infected with diseases in the event this "food" were to end up in Australian waterways and be eaten by individual fish. The scope of the 1996 Final Report is, indeed, much wider in that it assesses risk related to the *entry, establishment and further spread of these diseases* in Australia more generally.

[220] Paragraph 1(a) and (b) of Annex A.
[221] The 24 diseases of concern to Australia are summed up in Table 3 of the descriptive part.
[222] DPIE, Salmon Import Risk Analysis, Final Report, December 1996, p.3.
[223] QP86A, p.2, emphasis added, see para. 8.10.
[224] 1996 Final Report, p.3.

8.36 In this respect we also note that all Australian measures submitted to the Panel, as well as the 1996 Final Report, are explicitly presented by Australia as "quarantine" measures or documents, (e.g., *Quarantine* Proclamation 86A, the 1988 Conditions issued by the Director of *Quarantine*, the 1996 Final Report is subtitled "An assessment by the Australian Government of *quarantine* controls on ..."). Without defining the word "quarantine" as it is used in the SPS Agreement, we consider that the concept of "quarantine" more generally is commonly understood to relate to avoiding the spread of pests or diseases (in the sense of the definition of a "sanitary measure" in paragraph 1(a)). It is not limited to protecting the life or health of individual human beings or animals against food-borne risks (in the sense of the definition in paragraph 1(b)).[225]

8.37 On these grounds, we find that, even though both definitions of a "sanitary measure" invoked by Australia might be applicable to the measure in dispute, in the specific circumstances of this case we need to examine this measure as a measure applied "to protect animal ... life or health within [Australia] from risks arising from the entry, establishment or spread of pests, diseases ... or disease-causing organisms" in the sense of paragraph 1(a) of Annex A to the SPS Agreement. Given our earlier considerations in paragraph 8., we thus find that the SPS Agreement applies to the measure in dispute.

5. Relationship between the SPS Agreement and GATT 1994

8.38 We found that both GATT 1994 and the SPS Agreement apply to the measure in dispute. The question now arises which of these we should examine first.

8.39 Canada recognizes that the SPS Agreement provides for obligations additional to those contained in GATT 1994, but, nevertheless, first addresses its claim under Article XI of GATT 1994. Australia invokes Article 2.4 of the SPS Agreement, which presumes GATT consistency for measures found to be in conformity with the SPS Agreement[226], to first address the SPS Agreement. We note, moreover, that (1) the SPS Agreement specifically addresses the type of measure in dispute, and (2) we will in any case need to examine the SPS Agreement, whether or not we find a GATT violation (since GATT consistency is nowhere presumed to constitute consistency with the SPS Agreement). In order to conduct our consideration of this dispute in the most efficient manner, we shall, therefore, first address the claims made by Canada under the SPS Agreement before addressing those put forward under GATT 1994.[227]

D. THE SPS AGREEMENT

1. Burden of proof

8.40 Turning first to the question of burden of proof under the SPS Agreement, we note the following statement of the Appellate Body in its Report on *EC - Hormones*:

> "The initial burden lies on the complaining party, which must establish a *prima facie* case of inconsistency with a particular provision of the SPS *Agreement* on the part of

[225] The New Shorter Oxford English Dictionary defines "quarantine" as "[a] period of isolation, orig. of forty days, imposed on a person, animal, or thing that might otherwise *spread a contagious disease*" (Clarendon Press, Oxford, Vol. 2, p.2440, emphasis added). Webster's New Encyclopedic Dictionary (Könermann, Cologne, 1994, p.828) defines "quarantine" as "2: a restraint upon the activities or movements of persons or the transport of goods designed to *prevent the spread of disease or pests*" (emphasis added).

[226] SPS Article 2.4 provides as follows: "Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)".

[227] In this respect, we follow the approach taken in the Panel Reports on *EC - Hormones*, complaints by the United States and Canada, adopted 13 February 1998 (modified on appeal on other grounds), WT/DS26/R/USA and WT/DS48/R/CAN, para. 8.42, and para. 8.45, respectively.

> 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".[228]

In this dispute it is thus for Canada to establish a *prima facie* case of inconsistency of the Australian measure at issue with each of the provisions of the SPS Agreement Canada invokes. Once this is done, it is for Australia to counter or refute the claimed inconsistency. In other words, if Canada "adduces evidence sufficient to raise a presumption that what is claimed is true, the burden then shifts to [Australia], who will fail unless it adduces sufficient evidence to rebut the presumption".[229]

8.41 In this respect - and especially following comments made by Australia at the interim review stage that our legal reasoning and findings do not reflect an objective assessment of the matter before us, undertake a *de novo* risk assessment and are based on motives or intent - we stress that in examining this case we did not attempt (nor are we, in our view, allowed) to conduct our own risk assessment or to impose any scientific opinion on Australia. We only examined and evaluated the evidence - including the information we received from the experts advising the Panel - and arguments put before us in light of the relevant WTO provisions and, following the rules on burden of proof set out above, based our findings on this evidence and these arguments.

2. Sequence of claims to be addressed

8.42 Canada claims, in the following order, violations of Articles 3.1 and 3.3, Articles 5.1, 5.2, 5.5 and 5.6 and Articles 2.2 and 2.3 of the SPS Agreement. Australia addresses these claims in a different order, first presenting arguments under Article 2 of the SPS Agreement and further following a numerical order.

8.43 The question thus arises which of these provisions of the SPS Agreement we should address first in this particular dispute.

8.44 We note that Article 3, the first Article invoked by Canada, provides in relevant part:

> "1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.
>
> 2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.
>
> 3. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5. Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures

[228] Adopted 13 February 1998, WT/DS26/AB/R, para. 98. See also the Panel Reports on *EC - Hormones*, op. cit., respectively, at paras 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.

based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement".

According to Article 3.2, if the measure in dispute conforms to international guidelines, it shall be presumed to be consistent with both the SPS Agreement and GATT 1994. In that event, there would, at first sight, be no further need to address the SPS provisions at issue other than Article 3 (*in casu*, Articles 2 and 5). This could be a reason to first address Article 3.[230] However, in the particular circumstances of this case, several considerations lead us to not first examine Article 3.

8.45 First, Australia - in this case the WTO Member imposing the sanitary measure - does *not* claim that its measure conforms to international guidelines. Australia submits, *inter alia*, that there are no international guidelines for some of the diseases of concern and that the measure at issue validly aims at a higher level of protection than that reflected in the international guidelines referred to. Therefore, the reason to address Article 3 first, because it could lead to a presumption of consistency with all other SPS provisions, does not apply in this case.

8.46 Second, the dispute before us concerns the importation of *salmon* products, which according to Australia could carry up to *24 diseases*. Paragraph 3(b) of Annex A to the SPS Agreement indicates that the international standards, guidelines or recommendations referred to in Article 3 *for animal health* (the concern at issue in this dispute) are those developed under the auspices of the International Office of Epizooties ("OIE"). Both parties agree that the International Aquatic Animal Health Code adopted by the OIE in 1995 ("OIE Code") provides international guidelines on a disease-by-disease basis. However, they also agree that as of today no relevant OIE guideline exists which deals with salmon on a product specific basis. Moreover, both parties also agree that OIE guidelines do not exist for all of the 24 diseases of concern to Australia. Therefore, even if we were to examine first, if and how many relevant international guidelines exist and second address the question of whether Australia deviates from these guidelines, we would thereafter still need to examine either (1) in the event Australia does deviate from any such guidelines contrary to Article 3, whether the measure in dispute could not be based on Australia's concern for any of the other diseases for which no international guideline exists (*in casu*, under Articles 2 and 5); or (2) in the event Australia's measure is based on and/or conforms to any such guidelines, whether that part of the measure for which no guidelines exist, is consistent with the provisions of the SPS Agreement other than Article 3 (*in casu*, Articles 2 and 5). In this respect, we are of the view, however, that the fact that in this case no international guidelines exist for *all* 24 diseases of concern does not mean that an international guideline which applies to only *one* of these diseases cannot be relevant (or, according to the language of Article 3.1, does not "exist") for the measure at issue.

8.47 For the reasons mentioned above, even if we were to start our examination of this dispute under Article 3, we would in any event be referred to and thus still need to address Articles 2 and 5. To conduct our examination of this case in the most efficient manner, we shall, therefore, first address Articles 2 and 5.

8.48 Article 2, entitled "Basic Rights and Obligations", elaborates on the basic rights and obligations of WTO Members under the SPS Agreement. Article 5, under the heading "Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection", provides, *inter alia*, more detailed obligations with respect to risk assessment, establishes the objectives of minimizing negative trade effects and of achieving consistency in levels of protection and specifies that sanitary measures should not be more trade-restrictive than required. The Appellate Body Report on *EC - Hormones* on several occasions stressed the close relationship between Articles 2 and 5 (in particular between Articles 2.2 and 5.1 and Articles 2.3 and 5.5, all of which are at

[230] We note that the Panels in *EC - Hormones* started their examination under Article 3 (op. cit., US complaint, paras. 8.45 and 8.56 ff.; Canadian complaint, paras. 8.48 and 8.59 ff.).

issue in this dispute).[231] The Appellate Body repeatedly noted that the more general Article 2 imparts meaning to and is part of the context of the more specific Article 5 and that both Articles should constantly be read together.[232] However, even if we read Articles 2 and 5 together during our examination of this case, in practice we still have to decide which set of Canadian claims (those under Article 2 or those under Article 5) to address first. Since in this particular case, (1) Canada itself first presents its claims under Article 5, before addressing those under Article 2, and (2) the provisions invoked by Canada under Article 5 (i.e., Articles 5.1, 5.2, 5.5 and 5.6) all provide for more specific and detailed rights and obligations than the "Basic Rights and Obligations" set out in rather broad wording in the provisions invoked by Canada under Article 2 (i.e., Articles 2.2 and 2.3)[233], we consider it more appropriate in the circumstances of this dispute to first deal with Canada's claims under Article 5.[234]

3. Canada's claims under Articles 5.1 and 5.2: Sanitary measures are to be based on a risk assessment

8.49 Canada submits that the measure in dispute is inconsistent with Articles 5.1 and 5.2, which provide as follows:

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

Both parties agree that the OIE Code, in particular its Section 1.4 on "Import risk analysis"[235] which, *inter alia*, provides "Guidelines for Risk Assessment", contains "risk assessment techniques developed by the relevant international organizations" to be taken into account by Australia under Article 5.1.

8.50 Canada does not challenge the measure at issue under Article 5.3 (elaborating on the "relevant economic factors" to be taken into account in a risk assessment) nor do we see any reason to further examine this provision.

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[236], which provides as follows:

> "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on

[231] Op. cit., paras. 180, 212, 238 and 250.
[232] Ibid.
[233] In this respect we note, however, that not only Article 5, but also most other provisions of the SPS Agreement provide for more details on the basic rights and obligations set out in Article 2.
[234] In this respect we refer to the Appellate Body Report on *EC - Regime for the Importation, Sale and Distribution of Bananas*, adopted 25 September 1997, WT/DS27/AB/R, para. 204, which in a different context applied a similar reasoning: "Although Article X:3(a) of the GATT 1994 and Article 1.3 of the *Licensing Agreement* both apply, the Panel, in our view, should have applied the *Licensing Agreement* first, since this agreement deals specifically, and in detail, with the administration of import licensing procedures. If the Panel had done so, then there would have been no need for it to address the alleged inconsistency with Article X:3(a) of the GATT 1994".
[235] OIE Code, pp.29-37.
[236] Para. 8.48 and Appellate Body Report on *EC Hormones*, op. cit., para. 180.

> scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5". (underlining added)

As stated by the Appellate Body in *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".[237]

8.52 For these reasons, we consider, more particularly, that Articles 5.1 and 5.2 - in the words of the Appellate Body in *EC - Hormones* when dealing with the relationship between Articles 2.3 and 5.5 - "may be seen to be marking out and elaborating a particular route leading to the same destination set out in" Article 2.2. Indeed, in the event a sanitary measure is not based on a risk assessment as required in Articles 5.1 and 5.2, this measure can be presumed, more generally, not to be based on scientific principles or to be maintained without sufficient scientific evidence. We conclude, therefore, that if we find a violation of the more specific Article 5.1 or 5.2 such finding can be presumed to imply a violation of the more general provisions of Article 2.2. We do recognize, at the same time, that given the more general character of Article 2.2 not all violations of Article 2.2 are covered by Articles 5.1 and 5.2.

(a) The salmon products in dispute other than those from adult, wild, ocean-caught Pacific salmon[238]

8.53 Canada claims that Australia maintains the measure at issue with respect to the salmon products in dispute other than those from adult, wild, ocean-caught Pacific salmon, without any form of risk assessment. Australia acknowledges that the salmon products at issue in this dispute are not limited to adult, wild, ocean-caught Pacific salmon. Australia argues that it had initially set in train a risk assessment of all salmonid product of Canadian or US origin, but that it acceded to the request from Canada and the United States in late 1994 that priority be accorded to a risk assessment on adult wild, ocean-caught Pacific salmon, which would reduce the complexity of the process in regard to a product of higher commercial significance for Canada and the United States. Australia submits that since, thereafter, Canada never requested to extend the product coverage of Australia's risk assessment to all Canadian salmon, Australia cannot be reasonably expected to have a formal risk assessment for all salmon products at issue. In this respect, Australia refers to Article 5.1 which requires a risk assessment "as appropriate to the circumstances".

8.54 We recall that the scope of the measure in dispute covers salmon products (1) imported from Canada, (2) for human consumption, (3) which are fresh, chilled or frozen and (4) which originate from any of six species of salmon identified by Canada (pink salmon, chum salmon, coho salmon, sockeye salmon, chinook or king salmon, all five being Pacific salmon; and Atlantic salmon).[239] Within this broad category of salmon products at issue five subdivisions can be made: (1) adult, wild, ocean-caught Pacific salmon; (2) adult, wild, freshwater-caught Pacific salmon; (3) adult Pacific salmon cultured in seawater on the Pacific coast; (4) adult Atlantic salmon cultured in seawater on the Pacific coast; and (5) adult Atlantic salmon cultured in seawater on the Atlantic coast.[240] Of the salmon products at issue, Australia only claims to have a risk assessment for the first of these five categories, namely those from adult, wild, ocean-caught Pacific salmon. This category represents the

---

[237] Op. cit., para. 180.

[238] The salmon products addressed in this section are the salmon products in dispute from (1) adult, wild, freshwater-caught Pacific salmon; (2) adult Pacific salmon cultured in seawater on the Pacific coast; (3) adult Atlantic salmon cultured in seawater on the Pacific coast; and (4) adult Atlantic salmon cultured in seawater on the Atlantic coast.

[239] Para. 8.21.

[240] In its answer to original Panel Question 2, Canada stated that it only harvests adult salmon for export and that it does not harvest wild *Atlantic* salmon for export.

majority of Canadian exports of uncooked salmon.[241] With respect to this category of salmon products Australia submits that the measure in dispute is based on the "Salmon Import Risk Analysis, Final Report" published by the Department of Primary Industries and Energy in December 1996 (hereafter referred to as the "1996 Final Report"). With respect to the other four categories of salmon products in dispute, Australia concedes that it has not conducted or relied upon a risk assessment in the sense of Article 5. In its Rebuttal Submission Australia states the following:

> "The risk has been assessed in relation to diseases or disease agents in adult, wild, ocean caught uncooked salmon of Canadian and US origin. The Final Report of December 1996 is an assessment of the risk. There is no other risk assessment. No formal assessment has been undertaken on all uncooked salmon of Canadian origin. It was the intention to undertake such a risk assessment, but the product coverage was subsequently limited to the Pacific salmon at the request of Canada and the USA".[242] (underlining added)

The 1996 Final Report itself explains its limited scope as follows:

> "Canada and the United States have requested access for salmon products without reference to the species. However Australia, after consulting with the United States and Canada, has so far addressed the import of wild, ocean-caught Pacific salmon only. This allows more focused debate on the disease issues associated with Pacific salmon. Other classes of product, including aquaculture product and product derived from other species and/or locations, are expected to be characterised by different disease factors".[243] (underlining added)

To this Australia adds in its first submission that "to the extent that a disease agent is common to the wild Pacific and other Canadian salmon products, the conclusions [reached in the 1996 Final Report] are equally valid for all fresh, chilled and frozen salmon of Canadian origin".[244]

8.55 Canada counters that it only suggested to Australia to proceed *first* with an assessment of adult, wild, ocean-caught Pacific salmon, on the understanding that an assessment of other salmon products would soon follow. Canada further submits that given that Australia has prohibited the importation of all uncooked salmon, and not only adult, wild, ocean-caught Pacific salmon, it is obliged by the SPS Agreement to assess risk with respect to all uncooked salmon; Australia is not entitled to limit its assessment to adult, wild, ocean-caught Pacific salmon.

8.56 In addressing this issue, we note that Article 5.1 does not qualify - either in terms of application in time or product coverage - the substantive obligation imposed on all WTO Members to base their sanitary measures on a risk assessment. As far as the application in time of the SPS Agreement is concerned, we refer to the Appellate Body Report on *EC - Hormones*, which confirmed that the SPS Agreement applies to sanitary measures enacted *before*, but maintained *after*, the entry into force of the SPS Agreement.[245] In particular Article 2.2 - in light of which Article 5.1 has to be read - confirms this reading. It provides that sanitary measures have to be "*based* on scientific principles" and "not *maintained* without sufficient scientific evidence". (emphasis added)

---

[241] According to figures submitted by Canada (not contested by Australia), adult, wild, ocean-caught Pacific salmon represents seven-year average (1990-1996) of 58 % of all Canadian uncooked salmon for export (see Table 1 in the descriptive part).

[242] Australia, Rebuttal Submission, para. 84. See also Australia's answer to Panel Question 2, Australia answers, p.4: "Australia has not done a risk analysis on farmed Pacific salmon or on commercially produced Atlantic salmon (which, in Canada, all originates from farms)".

[243] 1996 Final Report, p.25.

[244] Australia, First Submission, para. 137.

[245] Op. cit., paras. 126-130.

8.57 As to the product coverage of Article 5.1, the reference contained in Article 5.1 to base sanitary measures on an assessment "as appropriate to the circumstances" cannot, in our view, annul or supersede the substantive obligation resting on Australia to base the sanitary measure in dispute (irrespective of the products that measure may cover) on a risk assessment. We consider that the reference "as appropriate to the circumstances" relates, rather, to the way in which such risk assessment has to be carried out.[246] Only Article 5.7 allows for an exception to the obligation to base sanitary measures on a risk assessment, namely "in cases where relevant scientific evidence is insufficient". In such event "a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information". Article 5.7 adds, however, that "[i]n such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time". In this dispute Australia has not invoked Article 5.7. Nor do we consider that this provision applies to the measure in dispute, given the fact that it was imposed more than 20 years ago and can thus hardly be seen as a measure "provisionally" adopted. Articles 5.2 and 5.3, in turn, only qualify the way in which a risk assessment has to be carried out, not the substantive obligation to base a sanitary measure on a risk assessment.

8.58 Furthermore, we do not consider that Canada's request or agreement to initially limit the scope of Australia's risk assessment to adult, wild, ocean-caught Pacific salmon overrides Australia's substantive obligation to base the sanitary measure in dispute on a risk assessment for all salmon products covered by that measure. We recall, in this respect, that to the extent Canada brought a complaint under QP86A the scope of this dispute is wider than adult, wild, ocean-caught Pacific salmon. As to the second argument forwarded by Australia on this issue[247], we do not consider - nor has Australia claimed - that the 1996 Final Report (which is explicitly limited to adult, wild, ocean-caught Pacific salmon) constitutes a risk assessment, in the sense of Article 5.1, for the other categories of salmon products covered by the measure in dispute. We do, however, agree with Australia that some of the evidence, assessments and conclusions contained in the 1996 Final Report might be relevant for the risk assessment to be carried out (or relied upon) for the other categories of salmon products and that, therefore, a completely new risk assessment for these other categories of salmon products might not be necessary. In support of this, we note the opinion of the following scientific experts advising the Panel[248]:

> Burmaster (Transcript, para. 14):
>
> "... here we have, in this situation, multiple fish diseases, potentially multiple fish diseases and potentially multiple target species of fish. The question has arisen if there are ten diseases of fish - ten different diseases - and five different fish species, to make up a hypothetical argument, do we have to multiply those and do fifty, ten times five, different risk assessments? I think, as a practical matter one need not have to do fifty different risk assessments. I think that there are ways to sort through that, it may be that you would have to do one or two or smaller number of risk assessments not a full number of fifty".
>
> Rodgers (Answer to Panel Question 11, Rodgers answers, page 15[249]:
>
> "Some of the data and findings contained in the Australian Final Report dealing with wild ocean-caught adult Pacific salmon could be validly used in a risk assessment for the four other categories of salmon [adult wild freshwater-caught Pacific salmon, adult Pacific salmon cultured in seawater on the Pacific coast, adult Atlantic salmon

[246] See further in para. 8.70.
[247] Para. 8.54 *in fine*.
[248] We only refer to three of the four experts advising the Panel since only these three have expressed an opinion on this issue.
[249] See also Rodgers, Transcript, para. 28.

> cultured in seawater on the Pacific coast and adult Atlantic salmon cultured in seawater on the Atlantic coast]. However, there are additional factors to consider for aquacultured species and wild freshwater-caught species, as opposed to wild ocean-caught fish. These would include the presence of known vectors (and alternative host species), the access of anadromous fish to water supplies, protected water sources ...".
>
> Wooldridge (Answer to Panel Question 4, Wooldridge answers, page 10):
>
> "With regard to imports of other products of other species known to carry the same diseases, information on the existence of such products is important in two respects. First, a comparison with other products may provide data necessary to assess the probability of exposure, transmission and consequences of a given disease post-entry within a country or region. Secondly, the information on the existence of such products is an important part of the overall risk analysis (as opposed to the risk assessment) and should be sought as part of that analysis ...
>
> Whether a complete risk assessment of any other particular product is required depends on the precise situation; in certain circumstances it may be enough to demonstrate that a particular product containing a given disease agent, and subject to similar use and disposal pathways, has been imported regularly for many years with no detected disease consequences".

8.59 Recalling the relatively wide range of salmon products covered by the sanitary measure in dispute and noting the relatively limited scope of salmon products dealt with in the 1996 Final Report - the only risk assessment submitted by Australia - we consider, therefore, that Canada has raised a presumption (i.e., made a *prima facie* case) that the measure in dispute in so far as it relates to salmon products at issue other than those covered by the 1996 Final Report (i.e., other than adult, wild, ocean-caught Pacific salmon) is not based on a risk assessment in accordance with Article 5.1 and that Australia, in turn, has not provided evidence to rebut that presumption. To that extent we thus find that Australia, by maintaining the measure at issue, acts inconsistently with Article 5.1. Given our earlier finding -that a violation of the more specific Article 5.1 can be presumed to imply a violation of the more general provisions of Article 2.2[250] - we find that Australia, to that extent, also acts inconsistently with Article 2.2.

8.60 Given the fact that (1) most of the studies and reports before us, and in particular the 1996 Final Report (Australia's only formal risk assessment) specifically address and discuss adult, wild, ocean-caught Pacific salmon (even though the data they contain may relate to or be relevant for other salmon) and (2) Canada itself also focused on adult, wild, ocean-caught Pacific salmon during our proceedings, we, in turn, concentrated our attention and questions (to both the parties and the experts advising the Panel) on adult, wild, ocean-caught Pacific salmon. For these reasons, the evidence and arguments before us which are relevant to Articles 5.5 and 5.6 are centred on adult, wild, ocean-caught Pacific salmon. We do not therefore consider it appropriate or necessary "in order to resolve the matter in issue in the dispute"[251] to further address the salmon products in dispute other than those from adult, wild, ocean-caught Pacific salmon. Any subsequent findings we thus make are limited to those salmon products at issue from adult, wild, ocean-caught Pacific salmon. Hereafter, we refer to this more limited category of salmon products at issue as "the salmon products further examined".

---

[250] Para. 8.52.

[251] Appellate Body Report on *US - Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, adopted 23 May 1997, WT/DS33/AB/R, pp.17-20, addressing the issue of judicial economy, at p.19 ("A panel need only address those claims which must be addressed in order to resolve the matter at issue in the dispute").

(b) Salmon products in dispute from adult, wild, ocean-caught Pacific salmon (i.e., the "salmon products further examined")

(i) Arguments of the parties

8.61 Canada argues that the 1996 Final Report - invoked by Australia as the risk assessment on which its measure as it applies to the salmon products further examined is based - is not a "proper" risk assessment in the sense of Articles 5.1. For Canada, a "proper" risk assessment has to: (1) evaluate the likelihood (i.e., determine the *probability*) of the establishment of the diseases of concern on the basis of an examination of the different possible scenarios and the different sub-events required for such establishment to take place (not simply posit, as - according to Canada - Australia did, the *possibility* of disease establishment, however remote); (2) make such evaluation for each disease of concern (not just assess, as - according to Canada - Australia did, the totality of risk linked to 24 different diseases); and (3) make such evaluation for each SPS measure which might be applied (i.e., for all five quarantine policy options mentioned in the 1996 Final Report). For Canada these three requirements can be deduced from the first part of the definition of "risk assessment" provided in paragraph 4 of Annex A to the SPS Agreement:

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

In support of its claim that these three requirements exist, Canada further refers to the definitions of risk and risk assessment, as well as the "Guidelines for Risk Assessment", provided in the OIE Code which, according to Canada, have to be taken into account as "risk assessment techniques" in accordance with Article 5.1.

8.62 According to Canada the second part of the definition of "risk assessment" in paragraph 4 does not apply in this case. Canada submits that the two parts of the definition are mutually exclusive. In support of this Canada puts forward the same arguments as those it developed under paragraph 1 of Annex A which provides the definitions of a "sanitary measure".[252]

8.63 Canada also argues that the SPS measure at issue - which is in Canada's view heat treatment - is not "based on" a risk assessment in the sense required by the Appellate Body in *EC - Hormones*. For Canada, there is no rational relationship between the heat-treatment conditions set out in Australia's measure and the available scientific evidence contained in the 1996 Final Report. Canada further submits that Australia, therefore, also violates Article 5.2 in that it does not "take into account available scientific evidence" in assessing risk.

8.64 Australia points out that the definition of "risk assessment" as set out in paragraph 4 of Annex A contains two parts joined by the word "or". For Australia, this clearly indicates that there is no requirement for a risk assessment to meet all the terms in paragraph 4. According to Australia, compliance with either of the two parts of the definition is sufficient and Canada does not contest that the 1996 Final Report complies with the second part.

8.65 Australia argues that Canada's assertion that a risk assessment needs to make probabilistic estimates has been rejected by the Appellate Body in *EC - Hormones* where the requirement for a risk

[252] Para. 8.33.

assessment "to establish a minimum magnitude of risk"[253] was rejected. For Australia, a risk assessment in accordance with Article 5 need not be a quantitative risk assessment, but may also be - especially where scientific data is not complete - qualitative and need not separately evaluate risk of occurrence for each disease and for each measure which might be applied. Australia submits that Canada reads requirements in the definition of "risk assessment" provided in the SPS Agreement for which there is no textual basis. For Australia, the important words in the definition of risk assessment are "evaluation of likelihood". According to Australia, there is no limitation as to the form that this evaluation should take except that it should consider the possible management measures and the consequences. Australia concludes that the 1996 Final Report achieves this and makes an evaluation that the risk is unacceptable. Australia submits that there are many different methodologies for risk assessment and that views of risk assessment techniques vary between experts, over time and on a case by case basis, as explicitly recognized by the requirement in Article 5.1 that a risk assessment should be "as appropriate to the circumstances".

8.66 With respect to the OIE risk assessment techniques relied upon by Canada, Australia argues that they have been fully "taken into account" in the 1996 Final Report as required in Article 5.1. Australia also refers to Article 1.4.1.3 of the OIE Code on "Methodology":

> "Risk analysis must be able to deal with the complexities of real life situations and no single method is applicable in all cases. For this reason, countries wanting to conduct import risk analyses may find it necessary to design their own process for carrying out the exercise. Several countries have already developed processes".[254]

8.67 With respect to Canada's claim that the measure at issue is not "based on" the 1996 Final Report, Australia submits that Article 5.1 requires that the results of a risk assessment must sufficiently warrant or reasonably support the SPS measure at stake, but that this does not require the risk assessment to embody only the view of the majority of the scientific community. Australia argues that heat-treated product was not addressed in the 1996 Final Report because Canada's request for access was limited to fresh, chilled and frozen product.

(ii) The applicable definition of "risk assessment"

8.68 We first address the problem of which of the two definitions of "risk assessment", provided in paragraph 4 of Annex A to the SPS Agreement, apply to this dispute. We recall our finding that in this case we need to examine the measure in dispute as a sanitary measure applied "to protect animal ... life or health within [Australia] from risks arising from the entry, establishment or spread of pests, diseases ... or disease-causing organisms" in the sense of paragraph 1(a) of Annex A (rather than a "sanitary measure" in the sense of paragraph 1(b) of that Annex). We consider, moreover, that there is a close link between the defnition of a "sanitary measure" in paragraph 1(a) and the first definition of "risk assessment" in paragraph 4, as well as between the definition of a "sanitary measure" in paragraph 1(b) and the second definition of "risk assessment" in paragraph 4. The first set of definitions deals with risks arising from the entry, establishment or spread of pests or diseases. The second addresses risks arising from specific substances in food, beverages or feedstuffs. We note that this link has been confirmed in the panel and Appellate Body Reports on *EC - Hormones* where the measure at issue was found to be a sanitary measure in the sense of paragraph 1(b) and the risk assessment had to be in accordance with the second definition in paragraph 4.[255]

8.69 In this case, we find, therefore, that since the measure in dispute is a "sanitary measure" in the sense of paragraph 1(a), it has to be based on a "risk assessment" in the sense of the first definition of paragraph 4, i.e., on an

---

[253] Appellate Body Report, op. cit., para. 186.
[254] OIE Code, Chapter 1.4.1, p. 30.
[255] Op. cit., para. 182, and Panel Reports, op. cit., paras. 8.21, and 8.98, (US complaint) and paras. 8.24, and 8.101, (complaint by Canada).

> "evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences ...".

(iii) Is the 1996 Final Report a risk assessment in accordance with Articles 5.1 and 5.2 ?

8.70 To answer the question whether the 1996 Final Report constitutes a risk assessment as required under the SPS Agreement, we need to examine and apply Articles 5.1 and 5.2[256] as well as the definition of risk assessment applicable in this case and this, in our view, in light of both Article 2.2 and the "risk assessment techniques developed by relevant international organizations" (*in casu*, those of the OIE) which WTO Members, in accordance with Article 5.1, have to "take into account".

8.71 Following Article 5.1, a risk assessment needs to be "appropriate to the circumstances". Answering a Panel question in this respect, Canada is of the view that the circumstances thus referred to are the source of the risk (e.g., an animal pathogen or a chemical contaminant) and the subject of the risk (i.e., whether it is to human, animal or plant life or health). For Australia, the phrase "as appropriate to the circumstances" confers a right and obligation on WTO Members to assess the risk, on a case by case basis, in terms of product, origin and destination, including, in particular, country specific situations. We agree that both interpretations may be covered by the term "as appropriate to the circumstances". In our view, also the OIE risk assessment techniques as well as the scientific opinions we gathered, may shed light on what is a risk assessment "appropriate to the circumstances".

8.72 Examining the definition of risk assessment applicable to the measure at issue, i.e., the "evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences", we consider, first of all, that the risk thus to be assessed includes (1) the risk of "entry, establishment or spread" of a disease and (2) the risk of the "associated potential biological and economic consequences". When we refer hereafter to the risk related to a disease, this risk thus includes the risk of entry, establishment or spread of that disease as well as the biological and economic consequences associated therewith. We further note that, in our view, three elements are contained in this definition of risk assessment:

> (1) the definition of risk assessment implies that the Member imposing the sanitary measure first has to *identify* the disease(s) whose "entry, establishment or spread" within its territory it wants to prevent as *well as* the "associated potential biological and economic consequences";
>
> (2) the definition then requires an "*evaluation of the likelihood*" of entry, establishment or spread of these diseases *and* of the associated potential biological and economic consequences"; and
>
> (3) the definition further requires that the evaluation of the likelihood of entry, establishment or spread of these diseases be conducted "*according to the sanitary ... measures which might be applied*".

We next examine whether the 1996 Final Report fulfils these three requirements.

[256] We recall that in this dispute Canada does not contest that the 1996 Final Report meets the requirements contained in Article 5.3 (see para. 8.50).

Identification of the disease(s) whose "entry, establishment or spread" Australia wants to prevent and of the "associated potential biological and economic consequences"

8.73 The 1996 Final Report identifies 24 diseases whose "entry, establishment or spread" Australia wants to prevent[257] as well as the "potential biological and economic consequences" associated to the entry, establishment or spread of these 24 diseases.[258] We thus find that the 1996 Final Report meets the first requirement of a risk assessment in accordance with Article 5.1. In reply to a Canadian comment made at the interim review stage, we note that our finding that Australia thus identified 24 diseases of concern to Australia does not mean that the measure at issue also actually addresses these diseases in the sense that this measure actually affects the likelihood of the entry, establishment or spread of these diseases into Australia. The latter element is addressed in the section of our report where we examine whether the measure at issue is "based on" a risk assessment.[259]

An "evaluation of the likelihood" of entry, establishment or spread of the disease(s) of concern and of the associated biological and economic consequences

8.74 We agree with Canada that, given the definition of risk assessment applicable in this case (the "evaluation of the likelihood of entry, establishment or spread of a ... *disease*", in the singular form), a risk assessment for the measure at issue in this dispute at least has to *identify* risk on a disease specific basis, i.e., it has to identify the risk for any given disease of concern separately, not simply address the overall risk related to the combination of all diseases of concern. (The issue of how the risk thus identified should be *evaluated* is addressed in paragraphs 8.76 and following.) The experts advising the Panel on this issue confirmed this.[260] In the *EC - Hormones* case as well, both the panels and the Appellate Body required some degree of specificity for a risk assessment - or a study or report allegedly part thereof - to be in accordance with the requirements imposed in Article 5.1.[261] We recognize, however, that some of the elements of an assessment of risk related to one disease might be used as part of the assessment for another disease and that, in that sense, disease-by-disease assessments may overlap.[262] We also acknowledge that as soon as there is a disease specific assessment for one disease of concern on which the sanitary measure as a whole can be based, there might be no more need to assess risk related to the other diseases of concern.

---

[257] 1996 Final Report, pp.18-19. Australia slightly changed this list in its submissions before the Panel (see Table 3 in the descriptive part).

[258] 1996 Final Report, Section 3 (Impact of salmonid disease introduction into Australia).

[259] Paras. 8.93 ff.

[260] Rodgers, Transcript, para. 28: "If you are concerned about several diseases, effectively the risks are identified by drawing up a list of the potential diseases of concern that would be associated with the importation of a particular fish product, followed by an examination of the consequences of their entry and establishment. Now, although many risk factors are common between different diseases, each disease may have unique factors to consider and each of these will have a variable quality and quantitative of available data that will need to be dealt with separately, *which does make it necessary to assess risks on a disease-by-disease basis*" (emphasis added); Winton, Answer to Panel Question 29, Winton answers, p.4: "I believe the FDC ["Fish Diseases Commission" of the OIE] would support the concept of individual risk assessment for each listed disease because important epidemiological features (presence of susceptible hosts, temperatures etc.) will vary with each country"; Wooldridge, Answer to Panel Question 29, Wooldridge answers, p.14: "... in considering any particular product for import, and in undertaking a risk assessment for that product, each potential disease hazard identified has to be separately assessed"; see also Wooldridge, Answer to Panel Questions 3 and 4, Wooldridge answers, p.9 and Wooldridge, Transcript, para. 242. Burmaster did not express his view on this specific issue.

[261] This, not in the sense of requiring a disease specific assessment, but by requiring a separate assessment for each of the six hormones at issue, when used for growth promotion purposes and requiring the evaluation of risks arising specifically from hormones in meat or meat products (Appellate Body Report, op. cit., paras. 199-200, also confirmed in para. 141 and Panel Reports, op. cit., paras. 8.129 and 8.257 (US complaint), and paras. 8.132 and 8.260 (complaint by Canada).

[262] Para. 8.58.

8.75 We note, however, that, according to the experts advising the Panel on this issue [263], the 1996 Final Report does *identify* the risk of disease "entry, establishment or spread" on a disease specific basis. Section 1.4 of the Report examines "Risk analysis factors" on a disease-by-disease basis and provides specific "Disease agent conclusions".[264] Section 2 provides a detailed "Technical Review of Data for 24 Salmonid Diseases", doing so disease-by-disease.[265] We, therefore, reject Canada's claim to the extent it implies that the 1996 Final Report does not identify risk on a disease-by-disease basis. In response to a Canadian comment made at the interim review stage, we note that our finding that Australia thus *identified* risk on a disease specific basis, does not mean that Australia also *evaluated* or *assessed* this risk as required in the definition of risk assessment. The requirement of an "evaluation of the likelihood" of risk is addressed in the following paragraphs of our report.

8.76 Canada also puts forward the requirement - allegedly contained in Article 5.1 - to determine the *probability* of the adverse effects occurring, as opposed to only addressing *possibility*. In its answer to Panel Question 19, Canada agreed, however, that this requirement can be fulfilled by either a quantitative or qualitative risk assessment. For Canada, probability could be expressed qualitatively by saying, for example, that the probability of a risk event is "extremely low" or is "negligible".

8.77 We recall, first, that the definition of risk assessment applicable in this dispute requires the "evaluation of the *likelihood* of entry, establishment or spread of a pest or disease ... and of the associated potential biological and economic consequences". We further note the following statement by the Appellate Body in *EC - Hormones* with respect to the meaning of "potential" or "possibility" as opposed to "probability":

> "The ordinary meaning of "potential" relates to "possibility" and is different from the ordinary meaning of "probability". "Probability" implies a higher degree or a threshold of potentiality or possibility".[266] (underlining added)

A footnote to this sentence reads as follows:

> "The dictionary meaning of "potential" is "that which is possible as opposed to actual; a possibility"; L. Brown (ed.), *The New Shorter Oxford English Dictionary on Historical Principles*, Vol. 2, page 2310 (Clarendon Press, 1993). In contrast, "probability" refers to "degrees of likelihood; the appearance of truth, or likelihood of being realized", and "a thing judged likely to be true, to exist, or to happen"; Id., page 2362". (underlining added)

The Appellate Body, referring to the ordinary meaning of "probability", thus related "likelihood" (the word used in the definition of risk assessment applicable in this case) to "probability". The dictionary meaning of "likelihood" refers, indeed, to "a thing that is likely, a probability".[267]

8.78 We further note that the requirement to evaluate "likelihood" or "probability" is also reflected in the OIE definition of risk and risk assessment, as well as in the OIE "Guidelines on Risk Assessment":

---

[263] Rodgers' Answer to Panel Question 1, Rodgers answers, p.3, when assessing both the 1995 Draft Report and the 1996 Final Report: "The other basic factors required for a risk assessment, namely country factors, commodity factors, exposure factors and reduction factors, are considered on a diseases by disease basis from a textual technical/scientific point of view. The potential adverse consequences of disease introduction are also outlined in the same way" (see also Rodgers, Transcript, para. 26) and Wooldridge, Transcript, para. 59: "Section 2 of the 1996 Final Report describes, with references, the diseases it considers relevant on a disease-by-disease basis, with a summary of the information given". Burmaster and Winton did not express their view on this specific issue.

[264] 1996 Final Report, pp.37-56.

[265] Ibid., pp.132-270.

[266] Op. cit., para. 184.

[267] L. Brown (ed.), *The New Shorter Oxford English Dictionary on Historical Principles*, Vol. 2, p.1588, Clarendon Press, 1993.

"Risk - means the probability of an adverse event of aquatic animal health, public health or economic importance, such as a disease outbreak, and the magnitude of that event.

Risk assessment - means the processes of identifying and estimating the risks associated with the importation of a commodity and evaluating the consequences of taking those risks".[268] (underlining added)

"Guidelines for Risk Assessment
Article 1.4.2.1
Estimation of the probability of an adverse event

In the risk assessment of an importation, the risk associated with one or more disease agents may have to be considered. The importing country should elaborate the scenarios that could be involved in the introduction of a disease agent in an imported commodity and its subsequent exposure and transmission to aquatic animals and humans.

In constructing a scenario by which a disease agent might be introduced into the importing country, some or all of the following factors (and other factors) need to be considered:

(1) the probability of the disease agent being present in aquatic animal populations in the water of origin;
(2) the probability of the disease agent being present in the particular aquatic organism;
(3) he risk of flesh becoming contaminated during processing;
(4) the probability of the disease agent being present in the particular tissues imported;
(5) the probability of infected or contaminated aquatic animals, gametes, embryos or product passing diagnostic screening, inspection or grading procedures;
(6) the probability of the disease agent surviving at an infectious dose during processing, transport or storage of the aquatic animals, gametes, embryos or products under consideration;
(7) the probability of the disease agent coming into contact with susceptible hosts in the importing country at a suitable dose and by a suitable route to cause infection;
(8) the risk of disease spreading from the index case and establishing in host populations in the importing country;
(9) risk mitigation by optimising detection of pathogens and minimising their likelihood of survival (see Risk reduction factors).

Each scenario would comprise a set of factors that should be identified for the estimation of the likelihood of some risk. In these guidelines, the factors are loosely grouped into four categories, namely country factors, commodity factors, exposure factors and risk reduction factors. Depending on the commodity and disease agent, any number of these factors may be used to estimate the probability of an adverse event for the importing country. Point estimates or probability distributions are

[268] OIE Code, Section 1.1, Definitions, p.13.

employed to represent the values associated with each factor ...".[269] (underlining added)

8.79 In this respect we also note the following opinions from experts advising the Panel:

Burmaster (Answer to Panel Question 1, Burmaster answers, page 1):

"With some exceptions in some situations (of which this dispute is not one), I think that a risk assessment must use quantitative methods to estimate the probability and the magnitude of desired and adverse consequences".[270] (underlining added)

Rodgers (Written version of Rodgers' statement at the meeting with experts, page 3):

"This concept [determination of probability based on the information available] is though embodied in the OIE guidelines, which indicate that the risk factors should be used to estimate the probability of an adverse event occurring with point estimates or probability distributions then employed to represent the values associated with each factor. Effectively, risk assessment should estimate, either quantitatively or qualitatively, the probability of an adverse effect occurring"[271]. (underlining added)

Winton (Transcript, para. 47):

"... the idea at least that you can begin to assess probability estimates, I think is important and I think that all of us will be looking towards that approach in the future". (underlining added)

Wooldridge (Answer to Panel Question 3, Wooldridge answers, page 8, emphasis in original):

"In my opinion, the requirement of a risk assessment is to evaluate the *probability* of risk. This is one of my minimum requirements ... Given the existence of a particular disease agent, one can *always* construct a *possible* infection transmission scenario, however improbable, and therefore demonstration of the possibility of successful transmission and disease is not adequate.

However, the probability does not have to be expressed quantitatively, and frequently it cannot be. In qualitative assessment there is therefore the difficulty of what is meant by the terms used, for example high, medium or low risk, and subjectivity is a potential problem".[272]

The experts advising the Panel thus agree that an evaluation and expression of probability or likelihood, either quantitative or qualitative, is crucial to a risk assessment.

8.80 For the above reasons, we find that for the measure at issue in this dispute, a risk assessment - in accordance with Article 5.1 and paragraph 4 of Annex A and taking into account the risk assessment techniques developed by the OIE - not only has to state that there is a *possibility* of the diseases of concern being introduced into Australia when imports of the salmon products further examined would be allowed, but also needs to provide some evaluation or estimation of the likelihood or probability, expressed either qualitatively or quantitatively, of these diseases thus being introduced and of the associated biological and economic consequences then occurring. In our view, the SPS

[269] OIE Code, Chapter 1.4.2, pp. 33-34
[270] See also Burmaster, Transcript, para. 13.
[271] See also Rodgers, Transcript, para. 13.
[272] See also Wooldridge's answer to Panel Question 1, Wooldridge answers, p.3 and p.6 and Wooldridge, Transcript, paras. 51, 52 and 55 and (with respect to associated consequences) paras. 127-128.

Agreement does not require that such evaluation needs to be done quantitatively. Moreover, we consider that this requirement on *how* a risk assessment should *evaluate* risk does not at all imply that a risk assessment in accordance with Article 5.1 needs to demonstrate a certain magnitude or threshold *level* or *degree* of risk (expressed either quantitatively or qualitatively).[273]

8.81 In this respect, we consider that a risk assessment, on which to base an import prohibition in accordance with Article 5.1, cannot be premised on the concept of "zero risk". Otherwise, all import prohibitions would be based on a risk assessment since there is a risk (i.e., a *possibility* of an adverse event occurring), however remote, associated with most (if not all) imports.[274] In this respect, we refer to the Appellate Body's Report on *EC - Hormones*:

> "In one part of its Reports, the Panel opposes a requirement of an "identifiable risk" to the uncertainty that theoretically always remains since science can never provide absolute certainty that a given substance will not ever have adverse health effects.[275] We agree with the Panel that this theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed".[276]

8.82 We next examine whether the requirement set out above is met in the 1996 Final Report. We note that the 1996 Final Report uses the words probability, possibility and likelihood on different occasions and evaluates elements of probability for some of the diseases of concern.[277] For example,

> in the Executive Summary:
>
> "Clearly there is a possibility that up to 20 disease agents exotic to Australia may be present in Pacific salmon products. It is acknowledged that the probability of establishment of disease would be low ...".[278] (underlining added)
>
> with respect to *Aeromonas salmonicida*:
>
> "Infection with *A. salmonicida* may be unusual in adult, wild, marine Pacific salmon and, if it exists, the concentration of bacteria present in fish may be low and the likelihood of transmission of infection to Australian fish would be consequently low.

---

[273] Appellate Body Report on *EC - Hormones*, op. cit., para. 186: "In another part of its Reports, however, the Panel appeared to be using the term "scientifically identified risk" to prescribe implicitly that a certain magnitude or threshold level of risk be demonstrated in a risk assessment if an SPS measure based thereon is to be regarded as consistent with Article 5.1. To the extent that the Panel purported to require a risk assessment to establish a minimum magnitude of risk, we must note that imposition of such a quantitative requirement finds no basis in the *SPS Agreement*" (footnote omitted).

[274] Australia, First Submission, para. 19: "Australia does not have a no risk policy with respect to imports of salmon products - imports of heat-treated salmon are permitted. Stopping the import of a particular product does not mean that there is a no risk policy, only that the risk is too high and that the product cannot be treated to reduce the risk to an acceptable level". See also Australia, Rebuttals, para. 16; Australian Quarantine - Looking to the Future: a Government policy statement, circulated by Senator the Hon. Peter Cook, Minister for Resources, December 1988, p.12 ("The Government accepts the strongly expressed view of the Quarantine Review Committee that a policy of 'no risk' would be impossible to implement. Such a policy would mean for example a ban on most products"); the 1995 Draft Report, p.217 and Nairn, M.E., *et. al*., Australian Quarantine: a shared responsibility, DPIE, 1996, pp.21-22 and 83-84. See also Burmaster, Transcript, para. 177, Winton, Transcript, para. 43 and Wooldridge, Transcript, para. 52.

[275] The Appellate Body refers to the Panel Reports, op. cit., paras. 8.152-8.153 (US complaint) and paras. .155-8.156 (complaint by Canada).

[276] Op. cit., para. 186, underlining in original.

[277] At the meeting with experts advising the Panel Australia stated that "we contend we have conducted a probability risk assessment" and implied that assessing risk as low or small is a statement of probability (Transcript, para. 155).

[278] 1996 Final Report, p.XI.

> The more significant scenario may be one in which untreated waste products are continually discharged into water over time ...".[279] (underlining added)
>
> with respect to *Parvicapsula sp.*
>
> "Since *Parvicapsula* is a myxosporean parasite, it needs an alternate host to complete its life cycle. Parvicapsula disease has not spread from the Pacific rim of North America, despite the substantial trade in uncooked salmon product from the region. The possibility that the disease could become established in Australia cannot be completely discounted; however, the likelihood is considered to be very low".[280] (underlining added)
>
> disease agent conclusions:
>
> "Some general observations can be made about the likelihood of the disease agents under consideration being present in product imported into Australia. The risk reduction procedures raised for each disease agent would be expected to have an impact on the risk - both by removing tissues that potentially could contain the agent and by removing tissues that would have a higher propensity for being disposed of in Australia.
>
> However, the critical gaps in the information base for each of the disease agents makes it difficult to estimate with any confidence the likelihood that product entering Australia would be infected. There will be an unknown chance - with some degree of uncertainty about the confidence that can be had in any estimation - that imported product will be infected. Limitations on the source of product and its preparation will reduce that chance to low, but uncertain, levels".[281] (underlining added)
>
> "It is clear that all the questions arising in relation to the likelihood that animal products intended for human consumption may, in one form or another, ultimately be consumed by, or come into direct contact with susceptible animals, cannot be resolved. This risk factor is difficult to quantify; the chance, although present, is likely to be small. However, because of the potential consequences this chance cannot be ignored".[282] (underlining added)

8.83 Considering the evidence before us, we note that the 1996 Final Report addresses some elements of both probability and possibility. We shall, therefore, assume - without making a finding on this issue - that it meets the requirement set out above.[283] We do note, however, that the 1996 Final Report (as stated by several of the experts advising the Panel[284]) lends more weight to the unknown and uncertain elements of the assessment than the 1995 Draft Report (on which the 1996 Final Report is based). This, on occasions, results in general and vague statements of mere possibility of adverse

---

[279] Ibid., p.39.
[280] Ibid., p.48.
[281] Ibid., p.50.
[282] Ibid., p.56. See also on pp.66-68 (Conclusions), e.g., at p.66: "The *potential* for pathogenic exotic organisms to enter Australia via imports of salmon from Canada and the United States is a risk and for some of the disease agents under consideration it is *probable* that if commercial quantities of product were imported some of the exotic agents would be introduced with the product" (emphasis added).
[283] Para. 8.80.
[284] Wooldridge answers, p.6, quoted in para. 8. and Rodgers answers, p.1 ("As such, the 1995 report is a more useful document, in the sense of an internal risk assessment exercise, since it 'evaluates' the data to conclude that a negligible risk exists, while at the same time recognising that the overall risk of disease introduction cannot be quantified. The final report seems to lend more weight to the unknown elements of the assessment and as such is more cautious, which results in an outcome closer to the 'unacceptable' rather than the 'negligible but acceptable' end of the scale").

effects occurring; statements which constitute neither a quantitative nor a qualitative assessment of probability.[285] We consider that this methodology is surprising in this case where Australia has already carried out a risk assessment which (according to two of the three scientists advising the Panel on this issue[286] fully examined probability (i.e., the 1995 Draft Report).[287]

An evaluation of the likelihood of the entry, establishment or spread of the diseases of concern "according to the sanitary ... measures which might be applied"

8.84 In this respect, Canada submits the requirement - allegedly contained in Article 5.1 - to evaluate risks for each of the SPS measures or options which might be applied.

8.85 We recall, first, the definition of risk assessment applicable in this case, namely the "evaluation of the likelihood of entry, establishment or spread of a pest or disease ... *according to the sanitary or phytosanitary measures which might be applied"* (emphasis added). We also note that according to Article 5.2, "[i]n the assessment of risks, Members shall take into account ... relevant processes and production methods; relevant inspection, sampling and testing methods ... and quarantine or other treatment".

8.86 We further refer to the OIE "Guidelines on Risk Assessment", quoted above [288], which list a series of factors to be considered in a risk assessment. One important category of factors to be assessed covers the so-called risk reduction factors:

> *"Risk reduction factors*
>
> For many aquatic organisms there is a dearth of information relating to the prevalence of disease in the source population and available diagnostic tests may be of limited use. In such cases, the analysis must pay particular attention to factors that reduce risks. Risk reduction factors are parameters specific to measures that are applied to reduce the probability that a disease agent will be introduced into the importing country, exposed to and/or transmitted to an aquatic or human population.
>
> Options that exist to reduce risk associated with a particular importation include:
>
> - choice of the origin of the commodity
> - restricting the destination
> - pre- and post-shipment quarantine

[285] This led the experts advising the Panel on this issue to the conclusion that the 1996 Final Report does *not* appropriately assess probability as is required in their view. See Burmaster's answer to Panel Question 1, Burmaster answers, p.1; Rodgers, Transcript, para. 26 ("[The 1996 Final Report] assesses risks on a disease-by-disease basis but in a textural form and does not assign any probabilities that would be needed to reach a conclusion. In this respect, therefore, I think, it possibly does fall short of determining any probability based on the information available") and Wooldridge, Transcript, para. 55 ("... since [the 1996 Final Report] looks only at the possibility of the unwanted outcomes of infection and disease importation, rather than the probability, in my opinion, it does not in any event fulfil the essential requirements of a risk assessment").

[286] Rodgers answers, pp.2-3 and Transcript, para. 24; Wooldridge answers, p.6 and Transcript, para. 54. *Contra*: Burmaster answers, p.1, who goes further and considers that a risk assessment needs to be quantitative.

[287] In this respect, see Wooldridge, Transcript, para. 57, addressing a risk assessment carried out by New Zealand ("Anyway, where it is not the case that everybody has actually agreed on a decision that there are negligible risks, or where further demonstration of a low level of probability is required, as I say, a quantitative assessment is in my opinion the next obvious process to attempt. This is what New Zealand has done, and I cannot actually see any reason Australia did not attempt to undertake the same kind of assessment - selecting the disease which, qualitatively they assessed as the most risky in their Draft Report. In my opinion, as I have stated in my written evidence, the basic New Zealand method and much of the data is equally applicable"). The New Zealand risk assessments (one dates from 1994, another from 1997) seem to imply that an assessment with more quantitative elements than the 1996 Final Report may be technically and scientifically feasible.

[288] Para. 8.78.

- diagnostic testing
- vaccination
- processing, maturation and storage for a specified time and temperature
- treatments, e.g., heat treatment for a specified time and temperature, use of antibiotics and chemotherapeutics, disinfection procedures, manipulation of salinity or pH, etc.
- limiting the size and the frequency of importation.

When a series of risk-reducing measures is applied to an importation, it may be possible to demonstrate that the extent to which risk is reduced is sufficiently great that an accurate estimate of the initial unrestricted risk is unnecessary.

Specific risk reduction methods for particular diseases are described in each chapter of the Code. If information on the probability of the presence or survival of a particular disease agent following application of a risk reduction option is not available, documented experience is an acceptable source of information".[289] (underlining added)

8.87 In this respect we further note the following opinions from experts advising the Panel: [290]

Burmaster (Answer to Panel Question 24, Burmaster answers, page 9):

"In some situations, there are only two possible plans or proposals, perhaps called Plan Yes and Plan No. Each of these choices has risks and benefits. In other situations, there may be more than two competing plans or proposals, perhaps called Plan A, Plan B, .. and the 'Do Nothing' plan. Each of these choices has risks and benefits. The risks and benefits of the competing, alternative plans or proposals may be measured in a variety of units, including economic or monetary units.

In a first step sometimes called 'risk assessment', scientists, engineers, statisticians, and other professionals estimate the risks and benefits associated with each of the competing, alternative plans or proposals". (underlining added)

Rodgers (Answer to Panel Question 1, Rodgers answers, page 4), when dealing with the "risk factors" involved in a risk assessment:

"Risk reduction factors can be considered to include options available to reduce the probability of introducing a disease agent. These may include factors such as the origin of the product, selective destination establishments and specified product processing or treatments".

Rodgers (Transcript, para. 36[291]):

"What I would say though is that additional fears about the acceptability of such a low level of risk should be allayed by considering a series of risk reduction factors, that is quite acceptable. But those risk reduction factors should be accepted by both parties. In this way, the application of such a series of measures may demonstrate that the extent to which risk is reduced is sufficiently great that an accurate assessment of the initial unrestricted risk is unnecessary".

[289] OIE Code, Chapter 1.4.2, Article 1.4.2.2, pp. 36-37.
[290] We only refer to three of the four experts advising the Panel since only three of them have expressed an opinion on this issue.
[291] See also Rodgers, Transcript, para. 123.

Wooldridge (Transcript, para. 64):

> "Risk management options generally involve the putting in place of risk reduction measures, otherwise called safeguards. ... In an import risk analysis, if the assessed baseline risk, or the risk with current regulatory or 'usual' safeguards in place was considered acceptable to the importing country, there would be no requirement or need to assess any further scenario. Only if this baseline or initial risk is unacceptable would one need to go further. If, in such a case, there are additional safeguards identified which are considered practicable to employ, then in my opinion, it would be necessary for the importing country to assess the risks with the most stringent practicable combination of these in place, and demonstrate that the risks were still unacceptable, in order to refuse imports. Whether it is necessary to assess intermediate combinations of safeguards separately depends on the precise problem being addressed".

8.88 For the above reasons, we find that for the measure at issue in this dispute a risk assessment in accordance with Articles 5.1 and 5.2 and paragraph 4 of Annex A and taking into account the risk assessment techniques developed by the OIE - has to evaluate the likelihood of entry, establishment or spread of the diseases of concern according to and taking into account the sanitary measures or options - considered to reduce the alleged risk - which might be applied.

8.89 We next examine whether the 1996 Final Report meets this requirement. We note that the 1996 Final Report examines risk reduction factors on a *disease-by-disease* basis. It does so under heading seven ("Risk Reduction Factors") for each of the 24 diseases examined in Section 2. For *Aeromonas salmonicida*, for example, under the heading "Risk Reduction Factors" the following elements are addressed: restricting zone of origin, species of origin, life cycle stage; pre and post shipping quarantine; product testing with tests having high sensitivity; processing, maturation and storage for specified time and temperature; treatments, (e.g., heating, disinfection); restricting the destination; vaccination; and certification.[292] A similar examination is undertaken for all other 23 diseases of concern. For most of these risk reduction factors, the 1996 Final Report provides some evaluation of the extent to which these factors could reduce risk. A summarized version of this disease-by-disease examination, repeating some of the risk reduction factors addressed in Section 2, is outlined in Section 1 under the heading "Risk Analysis Factors".[293]

8.90 With respect to the quarantine options considered to reduce the *total* risk associated to all diseases of concern, the 1996 Final Report is less explicit. In Section 1, the 1996 Final Report sums up a series of "Risk Management Measures" which would "contribute to a lessening of *likelihood* that imported product would contain pathogenic organisms" as well as "reduce the *likelihood* that this product would cause disease if accidentally or deliberately fed to Australian fish" (emphasis added) and provides definitions for most of these measures.[294] In Section 1.5.4, the 1996 Final Report *identifies* five potential quarantine policy options - put forward to reduce the total disease risk related to the imports it examined - which incorporate and develop some of the risk reduction factors addressed earlier.[295] However, we note that the 1996 Final Report does not substantively *evaluate* the relative risks associated with these different options.[296] Even though the definition of risk assessment requires an "evaluation ... according to the sanitary ... measures which might be applied", the 1996 Final Report identifies such measures but does not, in any substantial way, evaluate or assess their relative effectiveness in reducing the overall disease risk.

[292] 1996 Final Report, pp.139-140.
[293] Ibid., pp.37-49.
[294] Ibid., pp.56-58.
[295] Quoted in para. 8.97.
[296] Paras. 8.174 ff.

8.91 Considering the evidence before us, we recall that the 1996 Final Report addresses and to some extent evaluates a series of risk reduction factors, in particular, on a disease-by-disease basis. We shall, therefore, assume - without making a finding on this issue - that the 1996 Final Report - to the extent that we earlier assumed that it "evaluates the likelihood of the entry, establishment or spread" of the diseases of concern[297] - does make such evaluation according to and taking into account the sanitary measures or options - considered to reduce the alleged risk - which might be applied.

Summary

8.92 Referring to our findings in paragraphs 8.73, 8.75, 8.80 and 8.88 and to our assumptions in paragraphs 8.83 and 8.91, we recall that the 1996 Final Report identifies the diseases of concern as well as the associated biological and economic consequences. It does so on a disease-by-disease basis. To some extent it also addresses elements of probability of occurrence of the identified risk. It analyzes risk reduction factors on a disease-by-disease basis and identifies five quarantine options to reduce the total disease risk. For the purpose of our further examination we shall, therefore, assume - without making a finding on this issue - that the 1996 Final Report meets the requirements of a risk assessment set out in Articles 5.1 and 5.2.

(iv) Is the sanitary measure at issue "based on" a risk assessment as required in Article 5.1 ?

8.93 We assume that the 1996 Final Report meets the requirements of a risk assessment. However, Article 5.1 prescribes that "Members shall ensure that their sanitary ... measures are *based on* an assessment ... of the risks" (emphasis added). The next question arising under Article 5.1 is, therefore, whether the measure at issue, in so far as it applies to the salmon products further examined, is "based on" a risk assessment.

8.94 We note that the Appellate Body in *EC - Hormones* stated the following regarding the requirement in Article 5.1 that sanitary measures are to be "based on" a risk assessment:

> "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".[298] (underlining added)

Applying this test to the measure at issue in *EC - Hormones*, the Appellate Body concluded:

> "The absence of such a risk assessment, when considered in conjunction with the conclusion actually reached by most, if not all, of the scientific studies relating to the other aspects of risk noted earlier, leads us to the conclusion that no risk assessment that reasonably supports or warrants the import prohibition embodied in the EC Directives was furnished to the Panel".[299] (underlining added)

8.95 We recall that the measure at issue is Australia's QP86A as implemented or confirmed by the 1988 Conditions, the 1996 Requirements and the 1996 Decision and this in so far as it prohibits the importation of fresh, chilled or frozen salmon products (for present purposes we only address the salmon products further examined).[300] The measure at issue, as it stands today, in effect prohibits the

[297] Para. 8.83.
[298] Op. cit., para. 193.
[299] Ibid., para. 208.
[300] Para. 8.21.

importation into Australia of fresh, chilled and frozen salmon.[301] Except for minuscule quantities of frozen, uncooked salmon allowed for import for scientific purposes, it only allows the importation of salmon if it has been heat-treated as prescribed in the 1988 Conditions. It also allows imports of canned salmon but such imports *a fortiori* meet the 1988 Conditions. From a trade perspective (focusing on what product cannot enter the Australian market) the measure at issue in effect constitutes an import prohibition on, *inter alia*, fresh, chilled and frozen salmon. However, if we approach the measure at issue to determine its sanitary aspects (focusing on what is required for the product to be *allowed* for importation) - an approach we need to conduct in the context of the SPS Agreement - we find that it, in effect, imposes heat treatment as a sanitary solution to the risk posed by the importation of salmon. These two perspectives are two sides of a single coin: a consequence of Australia's sanitary requirement that salmon be heat-treated before it can be imported, is that imports of fresh, chilled and frozen salmon are prohibited.[302] As Canada puts it, to contend that the heat treatment requirements have nothing to do with importation of fresh, chilled or frozen salmon is like saying that a "no smoking" regulation has nothing to do with smoking or that a requirement to offer proof of legal drinking age when entering a bar has nothing to do with prohibiting consumption of alcohol by minors. Australia's decision (the 1996 Decision) to continue to prohibit fresh, chilled and frozen salmon did not alter the heat treatment requirements imposed in the 1988 Conditions nor the fact that only heat-treated product can enter Australia. In that sense the 1996 Decision confirms the 1988 Conditions.

8.96 Following this approach, we need to examine whether the measure at issue, to the extent it prohibits the importation of commercial quantities of fresh, chilled and frozen salmon and - in effect and from a sanitary perspective - imposes certain heat treatment requirements, is "based on" a risk assessment. The only risk assessment put forward by Australia in support of this measure is the 1996 Final Report. Australia argues that the heat treatment requirements currently in place (which are, according to Australia, in the interim, the 1988 Conditions and this until further risk assessments are carried out) are based on the scientific evidence which was available in the 1980s. However, Australia never came forward with any such evidence. We thus need to address whether the measure at issue is "based on" the 1996 Final Report.

8.97 We recall that the 1996 Final Report (Section 1.5.4) first identifies two quarantine options, namely (1) the removal of all quarantine restrictions and (2) banning the importation of all salmon products. However, it considered that "neither of these two options can reasonably be considered as appropriate, having regard to associated quarantine risk".[303] On that ground, these two options were not further discussed. The 1996 Final Report then identifies five potential quarantine policy options which it did further address:

> "The quarantine policy options, in no particular order of merit, are as follows:

---

[301] Para. 8.17.

[302] To further illustrate the relationship between what is prohibited and what is permitted, it may help to consider the original product and the various processes to which it may be submitted in order to allegedly ensure that the product will not pose an unacceptable risk of entry, establishment or spread of certain diseases. In all cases, the original product is, of course, the live salmon, but upon its capture and death, the initial product is fresh salmon. This fresh salmon may be "processed" by, for example, requiring its evisceration or the removal of the head and gills, etc. To facilitate its storage and transportation, the fish may be chilled or frozen. However, in Australia imports of salmon in its fresh, chilled or frozen form are not permitted (except for minuscule quantities for scientific or taxidermy purposes). This occurs on the grounds that the disease risks linked to such salmon are unacceptably high. To be permitted, the same initial product, fresh salmon, must be subject to further processing, i.e., to heat treatment according to the 1988 Conditions, or to commercial canning. Canada is not seeking access for heat-treated or canned salmon. What Canada is challenging before this Panel is Australia's justification for the measures that prohibit access for fresh, chilled or frozen salmon - or, in other words, which permit access for salmon only if it has been heat-treated in accordance with the 1988 Conditions or commercially canned.

[303] 1996 Final Report, p.62.

1. Permit the importation of product effectively heat treated for pathogens of concern
   - product might be heat treated prior to export, or
   - heat treated on arrival prior to general distribution
2. Implement the recommendations of the BRS report "Aquatic Animal Quarantine in Australia: Report of the Scientific Working Party on Aquatic Animal Quarantine" in part or in full.
3. Permit the importation of retail-ready fillets, for distribution in raw form under specified conditions.
4. Implement the recommendations of AQIS's draft IRA, that is, permit the importation of headless, gilled, eviscerated product under specified conditions.
5. Permit importation of product that complies with current international standards for trade in salmon product for human consumption, that is, OIE recommends that product be eviscerated and that no other risk reduction measures need be taken".[304]

We note that by doing so the 1996 Final Report itself - which only deals with fresh, chilled and frozen product - regards heat treatment as one of the policy options to be imposed on fresh, chilled or frozen product and thereby confirms the link we discerned above[305] between the prohibition, in effect, imposed by Australia on fresh, chilled and frozen product, on the one hand, and the heat treatment requirements currently prescribed in Australia, on the other. We note, moreover, that at the interim review meeting Australia stated that its quarantine measure currently in place is not the same as any of the seven options identified in the 1996 Final Report. However, Australia confirmed that its current measure most closely resembles the first of the five options further addressed in the 1996 Final Report ("[p]ermit the importation of product effectively heat treated for pathogens of concern").

8.98 We note, however, that the 1996 Final Report makes no substantive assessment of the risk or the risk reduction related to the heat treatment requirements in effect imposed by the measure at issue (and more generally referred to in the first option outlined above [306]). On the contrary, the 1996 Final Report itself states that there is insufficient data on whether or not heat treatment inactivates the disease agents in dispute:

> "For many of the disease agents, data on thermal resistance are not available as the necessary investigations have not been undertaken. Most fish pathogens would be expected to be readily inactivated by heat, but there are notable exceptions such as IPNV ... There are insufficient data to be confident that all of the agents that may be present would be inactivated, but it could be expected there would be a significant reduction in titre of the agents that may survive the heat treatment".[307]

In Section 1.4.2 of the 1996 Final Report, addressing "risk analysis factors" on a disease-by-disease basis, heating as a risk reduction factor is not even addressed.[308] In Section 2, a technical review of

[304] Ibid., p.62.
[305] Para. 8.95.
[306] At the interim review stage, Australia made clear that the first option set out in the 1996 Final Report ("[p]ermit the importation of product effectively heat treated for pathogens of concern") is not the same as the heat treatment requirements Australia currently imposes (in the 1988 Conditions). See para. 8.175.
[307] 1996 Final Report, pp.57-58. In this respect, see also the answers by experts advising the Panel (Burmaster and Rodgers) to Panel Question 13, e.g., Rodgers stating : "... comparative data for evisceration, heat treatment and full cooking are scarce [he then refers to one 1994 study by Whipple and Rohovec and concludes]... Most of the other studies related to inactivation by heat are largely concerned with incubation and cultivation temperatures in artificial media, not to reduction of pathogen levels in tissue".
[308] 1996 Final Report, pp.37-49.

data for 24 salmonid diseases, the 1996 Final Report mentions heat treatment as a potential risk reducing factor, but then makes the following statement for 13 out of the 24 diseases it examined:

> "Treatments, (e.g., heating, disinfection)
>
> We are unaware of any published information on such treatments which might reduce the risk".[309]

In its submissions to this Panel, Australia reiterated this view as follows:

> "The susceptibility of microorganisms to inactivation by heat treatment can be characterised by particular parameters (D and Z values), which are specific for each organism or strain of organisms. For most fish pathogens, these parameters have not been determined".[310] (underlining added)

With respect to the disease IPNV, the 1996 Final Report even concludes that it is resistant to heat treatment.[311] For other diseases the 1996 Final Report mentions that both freezing and heating may have risk reduction effects.[312] This was addressed in more general terms by the 1995 BRS Report:

> "Imported flesh heated to low temperatures [as allowed under the 1988 Conditions[313]] presents essentially the same risks as fresh or frozen flesh".[314]

Indeed, according to evidence referred to by Canada[315], some disease pathogens not only survive but even grow when heat-treated at the lower temperature range allowed under the 1988 Conditions.[316] In conclusion, the 1995 BRS Report explicitly questioned the rational basis of requiring heat treatment before importation:

> "The current process of heating salmonid finfish to inactivate potential exotic pathogens does not have a rational basis in view of the thermal stability of a number

[309] Ibid., p.148 (*Edwardsiella tarda*), p.167 (*Vibrio anguillarum* and *V. ordalii*), p.171 (*Vibrio salmonicida*), p.178 (*Yersinia ruckeri*), p.207 (Pacific salmon anaemia virus), p.229 (*Enterocytozoon salmonis*), p.234 (*Loma salmonae*), p.239 (*Ceratomyxa shasta*), p.245 (*Henneguya salminicola*), p.249 (*Kudoa thyrsites*), p.258 (*Parvicapsula spp.*), p.263 (PKX), p.268 (Rosette Agent). For other diseases, according to the 1996 Final Report, only some evidence is available that heat treatment is "likely" to reduce risk, (e.g., p.152 for *Piscirickettsia salmonis*, p.160 for *Renibacterium salmoninarum*, p.183 for ENV, p.187 for *Herpesvirus* salmonis Type 1, p.212 for salmon leukaemia virus). The 1996 Final Report concludes for only 4 disease agents that heat treatment will have a significant effect on or inactivate the disease agent (p.194 for IHNV, p.216-217 for salmon pancreas disease virus, p.223 for VHSV and p.253 for *Myxobolus cerebralis*).

[310] Australia's comment to Panel Question 13 to the experts, Australian comments, p.12.

[311] 1996 Final Report, p.53: "IPNV is a very stable virus. It can withstand heating and cooling and is expected to persist in the environment for long periods".

[312] For example, with respect to the disease agent *Piscirickettsia salmonis*: "*Piscirickettsia salmonis* does not survive well in freshwater, but can survive for weeks in sea water. It is adversely affected by both high (>20°C) and low temperatures (freezing)" (1996 Final Report, p.53); see also, to a more limited extent, with respect to, e.g., *Aeromonas salmonicida* (at pp.140-141: "Freezing and thawing will significantly reduce levels of culturable organisms. The effect of these factors on non-culturable forms of the pathogen in the product is not known") and ENV (pp.182-183: "Little is known of the liability to freezing of ENV at -20 C, however MacMillan and Mulcahy (1979) succeeded in inducing VEN with blood that had been frozen at -70 C").

[313] Para. 8.11.

[314] 1995 BRS Report, p.37 (confirming the 1995 Humphrey Report, Section 9.5.5).

[315] Evidence referred to by Canada in its oral statement at the second substantive meeting, not submitted to the Panel, but not contested by Australia.

[316] See also comment in the 1996 Final Report (at pp.343-344) on how protein can act as a protectant of organisms during heat treatment and survival of spores.

> of pathogens of high quarantine importance, especially at the lower temperature ranges".[317]

8.99 We thus consider that Canada has raised a presumption (i.e., made a *prima facie* case) that there is no "rational relationship between the measure and the risk assessment"[318] in that nowhere in the 1996 Final Report - the only risk assessment forwarded by Australia - can a rational basis be found to support the sanitary measure maintained by Australia, i.e., the heat treatment requirements in effect imposed by the measure at issue. Canada has, therefore, raised a presumption that there is no risk assessment that "reasonably supports or warrants"[319] the measure at issue. We also consider that Australia, in turn, has not provided evidence to rebut that presumption. We thus find that the measure at issue - in so far as it applies to the salmon products further examined - is not "based on" a risk assessment in accordance with Article 5.1. To that extent we find that Australia, by maintaining the measure at issue, acts inconsistently with Article 5.1. Given our earlier finding - that a violation of the more specific Article 5.1 can be presumed to imply a violation of the more general provisions of Article 2.2[320] - we find that Australia, to that extent, also acts inconsistently with Article 2.2.

8.100 We note Australia's statement that its policy of allowing imports of salmon products heat-treated in accordance with the 1988 Conditions will be reviewed and that for these purposes an import risk analysis is scheduled. It is possible that this risk analysis provides a rational basis for the measure at issue. However, as of today and on the basis of the risk assessment before us, we do not detect such basis.

(c) Summary

8.101 We have found above that the measure in dispute is not based on a risk assessment in accordance with Article 5.1:

> (1) in so far as the measure at issue applies to those salmon products in dispute other than from adult, wild, ocean-caught Pacific salmon (i.e., other than those covered by the 1996 Final Report) in that for these products no risk assessment in accordance with Article 5.1 has been submitted[321]; and
>
> (2) in so far as the measure at issue applies to those salmon products in dispute from adult, wild, ocean-caught Pacific salmon (which we have defined as "the salmon products further examined"), to the extent it in effect and from a sanitary perspective imposes certain heat treatment requirements, is not reasonably supported or warranted by a risk assessment.[322]

Because of these inconsistencies with Article 5.1, we also found that - to the same extent - Australia, by maintaining the measure at issue, acts inconsistently with Article 2.2.

8.102 We note that if we were to have found that the measure in dispute is based on a risk assessment in accordance with Article 5.1 and if, for that reason, Australia could have adopted a measure to achieve its appropriate level of protection against these risks, we would then be called upon to examine in this case whether the determination and application of this level of protection is consistent with Articles 5.5 and 5.6. In the alternative, therefore, we shall next examine these provisions.

---

[317] 1995 BRS Report, p.37 (confirming the 1995 Humphrey Report, Section 9.5.5).
[318] Appellate Body Report on *EC - Hormones*, op. cit., para. 193, p.78.
[319] Ibid., para. 208.
[320] Para. 8.52.
[321] Para. 8.56.
[322] Para. 8.99.

4. Canada's claims under Article 5.5

8.103 Article 5.5 provides:

> "With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves".

Article 5.5 must be read in context. An important part of that context is Article 2.3 [323], which provides as follows:

> "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade".

8.104 We recall that both Australia (especially in the 1996 Final Report and the drafts preceding that report) and Canada (during our proceedings), focused on adult, wild, ocean-caught Pacific salmon and that we, in turn, did the same. For these reasons, the evidence and arguments before us which are relevant to our examination under Articles 5.5 and 2.3 are centred on adult, wild, ocean-caught Pacific salmon. On that basis we decided in paragraph 8.60 to confine our examination of this dispute under Articles 5.5 and 2.3 to those salmon products at issue from adult, wild, ocean-caught Pacific salmon, which we have defined as "the salmon products further examined".

(a) Determination of the appropriate level of sanitary protection

8.105 Canada claims that Australia has not determined its "appropriate level of sanitary ... protection" with respect to the importation of dead salmon and that this, as such, already violates Article 5.5. According to Canada, Australia provided different and contradictory expressions of its appropriate level of protection, defining this level, *inter alia*, as "no significant risk", "very low risk" or "possibility of risk". According to Canada, "possibility of risk" is equivalent to "zero-risk", a level which is, as recognized by Australia itself, unattainable.

8.106 Australia submits that the SPS Agreement does not require Australia to quantify its appropriate level of protection for salmonids. For Australia, the determination of the level of protection deemed appropriate is a sovereign decision to which no minimum or maximum thresholds are attached. According to Australia, the appropriate level of protection with respect to salmonids was determined in regard to risks of both introduction of the diseases of concern and the consequences associated with these diseases. Even though in this case the likelihood of occurrence might be small, the consequences of introduction are, for Australia, of an unacceptable magnitude. Australia further notes that the most descriptive expression of its appropriate level of protection in the area of quarantine is contained implicitly in previous quarantine decisions and the risk management measures applied. In the light of Australia being an island state free of many pests and diseases, Australia submits that it has consistently adopted a high, conservative approach with respect to the

[323] Appellate Body Report on *EC - Hormones*, op. cit., para. 212.

appropriate level of protection. Australia adds that its economy is highly dependent on agricultural production and exports (80 per cent of Australia's agricultural production is exported) and that this, as well as economic and non-economic factors in the domestic context, is factored into its quarantine decision-making.

8.107 We note that paragraph 5 of Annex A provides the following definition:

> "*Appropriate level of sanitary or phytosanitary protection* - 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.
>
> NOTE: Many Members otherwise refer to this concept as the 'acceptable level of risk' ".

We further note that several provisions of the SPS Agreement other than Article 5.5 mention the concept of an "appropriate level of sanitary or phytosanitary protection".[324] However, nowhere does the SPS Agreement explicitly impose an *obligation* on WTO Members to identify or quantify such level. We consider, rather, that any sanitary measure applied to a given situation inherently reflects and achieves a certain level of protection with respect to that situation and that this level of protection - implied in the sanitary measure selected by a Member - can be presumed to be at least as high as the level of protection considered to be appropriate by that Member.[325] In this case, the measure at issue implies and reflects a certain level of sanitary protection achieved by Australia with respect to the salmon products at issue, including those further examined. Given that no evidence to the contrary was provided by Australia, we assume that this level of protection is the level of protection considered to be appropriate by Australia. In other words, we assume that this level is Australia's "appropriate level of sanitary protection". We see no need to clearly define or quantify that level for present purposes. We only note that Australia, *inter alia*, submitted that it is a high or "very conservative"[326] level of sanitary protection aimed at reducing risk to "very low levels" [327], "while not based on a zero risk approach".[328] We also note that Australia's primary reason to impose such conservative level of protection is the magnitude of the biological, environmental and economic consequences of the introduction of the diseases at issue, while it acknowledges, on the other hand, the "small" likelihood of such introduction.[329]

(b) Arbitrary or unjustifiable distinctions in levels of sanitary protection which result in discrimination or a disguised restriction on trade

8.108 The relevant part of Article 5.5 imposing an obligation on WTO Members reads:

> "... each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade".

---

[324] Sixth preamble to the SPS Agreement, Articles 3.3, 4.1, 5.3, 5.4, 5.6, 9.1, 10.2, 12.4 and paragraph 3(c) of Annex B.

[325] In this respect, see the Panel Reports on *EC - Hormones*, op. cit., respectively at para. 8.74, and para. 8.77: "However, the fact that an ADI [i.e., a quantified 'Acceptable Daily Intake' of a substance] or MRL [i.e., a quantified 'Maximum Residue Level' of a substance] can *reflect* a level of protection (without *stricto sensu* itself being a level of protection), does not exclude, as the European Communities has argued, that an ADI or MRL can also be a sanitary *measure* in the sense of the SPS Agreement" (emphasis in original).

[326] Australia, First Submission, para. 351.

[327] Ibid.

[328] Australia, Rebuttals, para. 16.

[329] Australia, Rebuttals, para. 216. See also Australia's statement at the experts meeting: "Australia is willing to accept only a low likelihood of the entry, establishment or spread of diseases of quarantine concern, if the consequences from the entry of a pest or disease are expected to be significant" (Transcript, para. 81).

In this respect, the Appellate Body in *EC - Hormones* stated the following:

> "Close inspection of Article 5.5 indicates that a complaint of violation of this Article must show the presence of three distinct elements. The first element is that the Member imposing the measure complained of has adopted its own appropriate levels of sanitary protection against risks to human life or health in several different situations. The second element to be shown is that those *levels of protection* exhibit arbitrary or unjustifiable differences ("distinctions" in the language of Article 5.5) in their treatment of different situations. The last element requires that the arbitrary or unjustifiable differences result in discrimination or a disguised restriction of international trade. We understand the last element to be referring to the measure embodying or implementing a particular level of protection as resulting, in its application, in discrimination or a disguised restriction on international trade". [330]

The Appellate Body then added:

> "We consider the above three elements of Article 5.5 to be cumulative in nature; all of them must be demonstrated to be present if violation of Article 5.5 is to be found".[331]

We thus consider that three elements are required in order for a Member to act inconsistently with Article 5.5:

- the Member concerned adopts different appropriate levels of sanitary protection in several "different situations";
- those levels of protection exhibit differences which are "arbitrary or unjustifiable"; and
- the measure embodying those differences results in "discrimination or a disguised restriction on international trade".

8.109 We recall that Article 5.5 needs to be read in the light of Article 2.3.[332] As noted by the Appellate Body in *EC - Hormones*:

> "When read together with Article 2.3, Article 5.5 may be seen to be marking out and elaborating a particular route leading to the same destination set out in Article 2.3".[333]

Indeed, even though Article 5.5 deals with arbitrary or unjustifiable *distinctions in levels of protection* imposed by one WTO Member for different situations and Article 2.3 addresses, rather, sanitary measures which (1) arbitrary or unjustifiably *discriminate between* WTO Members or (2) are applied in a manner which would constitute a *disguised restriction* on trade; the third element under Article 5.5 also requires that the *measure* in dispute results in discrimination or a disguised restriction on trade. We conclude, therefore, that if we were to find that all three elements under Article 5.5 - including, in particular, the third element - are fulfilled and that, therefore, the more specific Article 5.5 is violated, such finding can be presumed to imply a violation of the more general Article 2.3. We do recognize, at the same time, that, given the more general character of Article 2.3, not all violations of Article 2.3 are covered by Article 5.5.

8.110 We recall, moreover, that the Committee on Sanitary and Phytosanitary Measures has been given a mandate by Article 5.5, second sentence, to "develop guidelines to further the practical implementation of this provision", but that no such guidelines have to date been developed.

---

[330] Op. cit., para. 214, emphasis in original.
[331] Ibid., para. 215.
[332] Para. 8.103.
[333] Op. cit., para. 212.

8.111 Canada claims that the measure in dispute meets each of the three elements contained in Article 5.5 and therefore violates Article 5.5. Australia disagrees and submits that its measure is fully consistent with Article 5.5. We next examine each of the three elements under Article 5.5.

(i) Distinctions in levels of protection for "different situations"

Arguments of the parties

8.112 For Canada the "different situations" to be compared under Article 5.5 are, at a minimum, those that involve at least some of the same 24 disease agents at issue. Canada submits that many of these disease agents also occur in non-salmonids whose entry into Australia is *not* prohibited. To avoid a distinction in levels of protection in these different situations, Canada argues, Australia would have to impose similar sanitary measures for the importation of all products known to be capable of hosting any of the 24 diseases of concern.

8.113 Canada argues, for example[334], that Australia makes the following distinctions in levels of sanitary protection (also outlined in Annex 1 of our report):[335]

> (1) an import ban on uncooked salmon for human consumption to protect against risk of introduction of, *inter alia*, the disease agent *Aeromonas salmonicida* (atypical strain), according to the 1996 Final Report "one of the most serious threats to Australian fish" [336], as opposed to allowing imports of, *inter alia*, uncooked Pacific herring, cod, haddock, Japanese eel and plaice for human consumption, all of which are known to host the same disease (as well as other diseases of concern to Australia);
>
> (2) an import ban on uncooked salmon for human consumption to protect against risk of introduction of, inter alia, the disease agents VHSV and IPNV [337] which according to the 1996 Final Report itself have not even been detected in the salmon products further examined[338], as opposed to allowing imports of, *inter alia*, uncooked Pacific herring, Atlantic and Pacific cod, haddock and European eel for human consumption, all of which are known to host VHSV (as well as other disease agents of concern to Australia), and uncooked cod, European and Japanese eel and Dover sole for human consumption, all of which are known to host IPNV (as well as other disease agents of concern to Australia);
>
> (3) an import ban on uncooked salmon for human consumption to protect against risk of introduction of, *inter alia*, four specific disease agents (*Aeromonas salmonicida* (atypical strain), Erythrocytic necrosis virus, Infectious haematopoietic necrosis virus and VHSV), as opposed to allowing imports of herring in whole, frozen form for use as bait which are known to host the same diseases[339];

---

[334] In its submissions, Canada also referred to other examples but particularly addressed four comparisons. We shall therefore, in turn, concentrate on these four comparisons.

[335] The descriptive part of our report (at para. 4.201) also sets out four comparisons put forward by Canada under Article 5.5. However, in the findings section we only address the first three of these comparisons. The first two comparisons set out in our findings are brought together in the descriptive part - on request by Canada - as one comparison. However, for purposes of our findings we consider it more appropriate to set out these two comparisons separately since they deal with different fish products, different diseases and different arguments as to disease occurrence.

[336] 1996 Final Report, p.38.

[337] Respectively "Viral Haemorrhagic Septicaemia Virus" and "Infectious Pancreatic Necrosis Virus".

[338] 1996 Final Report, respectively at p.45 and p.44.

[339] According to Canada, Pacific herring is host to all four disease agents, whereas Atlantic herring only to one of them (Erythrocytic necrosis virus).

> (4) an import ban on uncooked salmon for human consumption to protect against risk of introduction of, *inter alia*, five specific disease agents (*Aeromonas salmonicida* (atypical strain), *Yersinia ruckeri*, *Edwardsiella tarda*, IPNV and *Vibrio anguillarum*), as opposed to allowing imports of live ornamental finfish which are known to host the same diseases.[340]

Canada argues that it does not matter that no risk assessment has so far been made by Australia for the other products compared under Article 5.5. For Canada, the point is that for uncooked salmon Australia takes an extremely cautious approach whereas for non-salmonids Australia is, in Canada's words, "gambling".

8.114 Australia argues that the "different situations" envisaged in Article 5.5 may occur in regard to (1) the same product and the same diseases where there might be identical or similar adverse health effects and consequences or (2) different products with the same adverse health effects and consequences. With respect to the distinction made between importation of salmonids and non-salmonids, Australia acknowledges that non-salmonid product or live fish imported into Australia could represent a risk of entry of diseases of concern. It argues, however, that it is currently undertaking import risk analyses and reviewing its measures related to non-salmonids. An import risk analysis on the importation of bait and feed fish is scheduled to commence in April 1998. The import risk analysis for ornamental fish was started in 1997. Australia also argues that to restrict the importation of non-salmonids before having completed these risk analyses would run counter to other provisions of the SPS Agreement, in particular the obligation to base sanitary measures on a risk assessment. Australia submits that the imposition of similar measures to different products may in fact result in different levels of protection in respect of the same disease agent since the likelihood of disease entry is likely to be different for various commodities. Australia also argues that it imposes the measure in dispute because of the range of disease agents that potentially could be present in the salmon products further examined, not because of any one particular disease agent.

"Different situations"

8.115 In defining the scope of "different situations" under Article 5.5, we note the following statement in the Panel Reports on *EC - Hormones*:

> "We note that both parties in dispute agree that the scope of "different situations" contained in Article 5.5 includes situations which deal with the *same substance* as well as situations which involve the *same adverse health effect*. For this reason, considering the lack of guidelines by the Committee on Sanitary and Phytosanitary Measures and without further defining or limiting the scope of "different situations", we find that, for the purposes of this dispute, we can compare situations where the same substance or the same adverse health effect is involved as "different situations" in the sense of Article 5.5".[341]

The *EC - Hormones* panels then found that they could compare natural hormones with synthetic hormones under Article 5.5 as "different situations", even though these are different substances, because "the situations thus compared involve at least the *same adverse health effect*, namely carcinogenicity".[342] The same conclusion was reached with respect to a comparison between five of

[340] According to Canada, freshwater ornamental finfish host *Aeromonas salmonicida* (atypical strain), *Yersinia ruckeri*, *Edwardsiella tarda* and IPNV, whereas marine ornamental finfish host *Vibrio anguillarum*.

[341] Panel Reports, op. cit., para. 8.176 (US complaint) and para. 8.179 (complaint by Canada), emphasis in original.

[342] Ibid., paras. 8.208-9 at para. 8.208 (US complaint) and paras. 8.211-2 at para. 8.211 (complaint by Canada), emphasis in original.

the six hormones at issue and the antimicrobial growth promoters carbadox and olaquindox.[343] Dealing with this very issue on appeal, the Appellate Body stated the following:

> "Clearly, comparison of *several* levels of sanitary protection deemed appropriate by a Member is necessary if a panel's inquiry under Article 5.5 is to proceed at all. The situations exhibiting differing levels of protection cannot, of course, be compared unless they are comparable, that is, unless they present some common element or elements sufficient to render them comparable. If the situations proposed to be examined are *totally* different from one another, they would not be rationally comparable and the differences in levels of protection cannot be examined for arbitrariness".[344]

8.116 In the *EC - Hormones* cases the measure at issue intended to protect human health against risks arising from contaminants in foods. It thus fell under the definition of a sanitary measure in paragraph 1(b) of Annex A and had to be based on a risk assessment in the sense of the second definition of paragraph 4 of Annex A. Such sanitary measure and risk assessment should, according to paragraph 4, address "the potential for adverse effects" on health; not the non-health related consequences. Other situations with "the same adverse health effect" were, therefore, found to be comparable under Article 5.5. In this dispute, the measure at issue is intended to protect animal health as a sanitary measure defined in paragraph 1(a) of Annex A and is to be based on a risk assessment in the sense of the first definition in paragraph 4 of Annex A. According to this first definition in paragraph 4, such risk assessment has to take into account risks arising not only from the "entry, establishment or spread of a pest or disease", but also from the "associated biological and economic consequences".

8.117 On these grounds - and in particular referring to the interpretation given by the Appellate Body to the concept of "different situations" in Article 5.5, requiring that such situations should "present some common element or elements sufficient to render them comparable"[345] - we find that in the circumstances of this dispute, we can compare situations under Article 5.5 if these situations involve either a risk of "entry, establishment or spread" of the same or a similar disease or of the same or similar "associated biological and economic consequences" and this irrespective of whether they arise from the same product or other products. In other words, we are of the view that the treatment provided by Australia to the salmon products further examined can be compared under Article 5.5 with the treatment it provides to other salmon products or non-salmonids which represent a risk of entry, establishment or spread of the same or a similar disease or a risk of the same or similar associated biological and economic consequences.

8.118 At the interim review stage, Australia argued that for "different situations" to be comparable under Article 5.5 both the disease *and* the consequences need to be the same. Australia thereby referred to the definition of risk assessment where these two factors are linked by the word "and", not "or". We note, however, that at this stage of our examination we only address the question whether two situations can be compared under Article 5.5. We do not examine nor decide at this point whether the risk (both in the sense of risk of entry, establishment or spread of the disease and the associated consequences) linked to these two situations is the same or has been addressed inconsistently. This issue needs to be examined under the second element of Article 5.5.

8.119 To have "different situations" under Article 5.5, we do not consider that the other products compared to the salmon products further examined need to be potential hosts to *all* disease agents of concern for these salmon products. To the extent that both the other products and the salmon products further examined are known to be hosts to one of these disease agents or - for the salmon products - give rise to an alleged concern for that disease agent, they can be associated with the same kind of

[343] Ibid., paras. 8.220-1 (US complaint, where only carbadox was at issue) and paras. 8.223-4 (complaint by Canada, where both carbadox and olaquindox were discussed).
[344] Op. cit., para. 217, emphasis in original.
[345] Op. cit., para. 217.

risk, namely a risk of entry, establishment or spread of that disease. Indeed, if we were to find that only products which are known to be host to *all* 24 disease agents of concern to Australia can be compared to the salmon products further examined, it would then be sufficient for a WTO Member imposing a sanitary measure - in order to avoid the application of Article 5.5 - to list a series of disease agents allegedly of concern to it, the totality of which is not known to occur in any other product.[346] In our view, even if the salmon products further examined were to be host to more disease agents than the other products they are compared to, does not affect the comparability of these products as "different situations" under Article 5.5. This factor may, however, be a reason to justify a distinction in levels of protection imposed for these different situations under the second element of Article 5.5 (i.e., arguments that such distinction is not "arbitrary or unjustifiable").

8.120 We next have to determine whether the four comparisons we outlined in paragraph 8.113 compare situations for which a risk arises of entry, establishment or spread of the same or a similar disease or of the same or similar associated biological and economic consequences. We recall that our examination of this dispute under Article 5.5 is limited in scope to those salmon products at issue from adult, wild, ocean-caught Pacific salmon, which we defined as the salmon products further examined. We shall, therefore, only compare those salmon products to the other products set out in the four comparisons.

8.121 We note, first, that Australia expressed a *concern* for each of the specific disease agents, put forward under each of the four comparisons, with respect to the salmon products further examined.[347] We recall, second, that neither the parties to the dispute nor the experts advising the Panel[348] contest the fact that with respect to all four comparisons these specific disease agents have actually been detected (i.e., are *known to occur*) in the products compared to the salmon products further examined. Third, according to the experts advising the Panel, the biological and economic consequences of a disease introduction (i.e., the consequences of a disease once established in a country) will generally be the same or similar in a given country, irrespective of the product introducing the disease. Therefore, as soon as two situations have a disease agent or a concern for a disease agent in common, also the associated potential biological and economic consequences can be presumed to be the same or at least to be similar.[349] Nothing in the 1996 Final Report (in particular its Section 3 which addresses the economic and other impacts of salmonid disease introduction into Australia) indicates differently. Since (1) the two situations in each of the four comparisons have, therefore, at least one disease agent in common - or, as far as the salmon products are concerned, represent at least an alleged concern for that disease agent - and (2) also the consequences associated with these diseases can, according to the experts advising the Panel, be presumed to be at least similar, we consider that

[346] In response to an Australian comment at the interim review stage, this does not, of course, exclude that a Member may, in some cases, have good reasons to be concerned about a series of disease agents which may occur in a given product but which do not occur in any other product.

[347] All the diseases put forward by Canada under Article 5.5 figure in the list of 24 diseases of concern to Australia with respect to salmon products. This list was provided in Australia's answer to Panel Question 2 and is reproduced in Table 3 in the descriptive part.

[348] Answers by the experts advising the Panel to Panel Question 8.

[349] Answers by the experts advising the Panel to Panel Question 6 ("Canada contends that for any given disease agent, the *consequences* of the disease becoming established in an importing country would be the same regardless of the original imported source. In your view, is this statement technically/scientifically correct?"): Burmaster answers, p.4 ("Yes; I cannot think of a counter-example to this principle", expanded in Transcript, para. 259); Rodgers answers, p.7 ("This statement is probably generally correct ..."; Rodgers then goes on to say that the nature of the original import may have a bearing on the possible consequences. However, the consequences he addresses do not relate to those arising after the introduction of the disease but rather to the risk of such introduction occurring, the consequences of allowing imports of these different products irrespective of whether they introduce diseases or regional differences in the importing country); Wooldridge answers, pp. 10-11. ("Once a given disease is established country-wide in an importing country, then in my opinion the consequences from that point on will be the same whatever the original imported source or manner of establishment"; Wooldridge notes, however, that a difference in import distribution may lead to a difference in short term consequences of disease establishment due to regional differences in susceptibility to the disease in the importing country); Winton did not answer Question 6.

for each of these comparisons the two situations can be compared under Article 5.5 as "different situations".

8.122 The four comparisons examined under Article 5.5 and the respective diseases under each of these comparisons, with a reference to where the occurrence of these diseases in the other products has been confirmed[350], are outlined in Annex 1 to our report.

Difference in levels of protection

8.123 We next examine whether there is, for each of these "different situations"[351], a distinction in levels of sanitary protection. As noted earlier[352], the appropriate level of sanitary protection will normally be reflected in the sanitary measures imposed for a specific situation. We consider, moreover, that the level of protection achieved by a specific sanitary measure will also depend on the degree of risk against which that measure is intended to protect. In that sense, we agree with Australia that imposing the same sanitary measure for different situations does not necessarily result in the same level of protection. Indeed, in many situations (e.g., situations representing different risks) the same sanitary measure might result in different levels of protection. On the other hand, different sanitary measures for different situations might ensure the same level of protection. Indeed, one given situation might only represent a small risk for which a lenient sanitary measure will achieve a high level of protection, whereas another situation might pose very high risks requiring a very strict and different sanitary measure in order to meet that same high level of protection.

8.124 To determine whether Australia makes a distinction in the levels of protection it considers to be appropriate for the situations compared, we thus need to examine the sanitary measures Australia currently imposes for these different situations. Since we have found that these situations are comparable as "different situations" under Article 5.5 (because they have at least one disease agent in common and, presumably, also represent the same or similar biological and economic consequences[353]) and since we will consider the potential difference in the degree of risk posed by these different situations under the second element of Article 5.5, we will for present purposes assume that if there is a difference in the sanitary *measures* imposed for the different situations we compare under Article 5.5, this difference does reflect a distinction in *levels of protection* achieved in - and considered to be appropriate by - Australia.

8.125 For the above reasons[354], we consider that even though Australia has not yet conducted import risk analyses for the other products compared under Article 5.5, Australia does, nevertheless, have a level of protection it considers to be appropriate for these other products. Australia currently has a sanitary regime, imposing specific sanitary measures or refraining from such regulation, for these other products. This sanitary regime (whether or not specific measures are enacted) reflects a level of protection. To have a specific level of protection, there is no need to first complete a risk assessment.

8.126 The arguments submitted by Australia - that imposing similar measures for both the salmon products and the other products compared, without first completing a risk analysis for these other products, would run counter to the obligation to base sanitary measures on a risk assessment; and that situations can only be compared under Article 5.5 if for both an appropriate risk assessment is

[350] When addressing "disease occurrence" in Annex 1, we focus on whether or not the specific disease agent has been detected in the product concerned. We realize that doing so we simplify the comparison and that a better comparison could be made if more data was available. However, according to our mandate, we have to make an objective assessment of the evidence put before us (Article 11 of the DSU). Our approach should, therefore, not be read to imply that risk assessments should be limited to disease agents that have actually been detected nor that they cannot take into account evidence related to scientific research.

[351] Para. 8.113 and Annex 1 to our report.

[352] Para. 8.107.

[353] Para. 8.121.

[354] Paras. 8.123 and 8.124.

available - are unconvincing. First, as we just noted, for any given situation a level of protection applies. Article 5.5 directs us to compare for different situations the related levels of protection as they are currently considered to be appropriate by Australia and this whether or not the sanitary measures enacted to achieve that level are based on a risk assessment. Of course, such comparison would be easier and more accurate if for both situations an appropriate risk assessment were available. However, according to Article 5.5 and our mandate set out in Article 11 of the DSU (to make an "objective assessment of the matter before [us], including an objective assessment of the facts of the case"), we are called upon in this case to make this comparison and to do so on the basis of the evidence before us. We cannot conduct our own risk assessment. Nor do we attempt to do so in this report. The fact that one of the experts advising the Panel stated that "if you are trying to say which [of two products] is the most risky, then you need to know something about and possibly do a full assessment for [the other] product"[355] and that "it would be sensible to assess that which you have prioritized initially to have the highest risk first, but until you have done the risk assessment, you actually cannot be sure you have got that right"[356], does not change our position. Nor do we disagree with these statements. Indeed, for a scientist to say with scientific certainty that one product represents a higher risk than the other, there may be a need to have two, more or less, complete sets of data, including two risk assessments. And even on that basis a scientist would probably not be able to state with absolute certainty that one product is riskier than the other. Our mandate is different. We are not asked to make a scientific risk comparison nor to state with scientific certainty that one product is riskier than the other. We can only weigh the evidence put before us and, on the basis of the rules of burden of proof we adopted[357], including the use of factual presumptions, decide whether sufficient evidence is before us - evidence which has not been rebutted - in order to state that it can be presumed that one product is riskier than the other. Second, the obligations contained in Article 5.1 (risk assessment) and Article 5.5 are complementary, not mutually exclusive. We consider, therefore, that a WTO Member cannot justify the inconsistency with one Article on the ground that such inconsistency avoids an additional inconsistency with another Article. Third, in order to impose sanitary measures for the other products compared to the salmon products further examined, a complete risk assessment is not always required. Article 5.7 allows for the provisional adoption of sanitary measures in cases where relevant scientific evidence is insufficient.[358] Finally, we note that the Appellate Body in *EC - Hormones* when addressing Article 5.5 also compared one situation (the treatment provided by the European Communities for five of the six hormones at issue) to another situation (the treatment provided by the European Communities to carbadox and olaquindox) even though the European Communities had not submitted a risk assessment for the latter situation.[359]

8.127 Assessing now the sanitary regimes imposed for the products compared, we recall, first, that for the salmon products further examined (the first situation in all four comparisons we outlined in paragraph 8.113), Australia currently imposes an import prohibition.[360] Considering this sanitary measure, we assume that the level of protection determined to be appropriate by Australia for these

[355] Wooldridge, Transcript, para. 278.
[356] Ibid., para. 291.
[357] Paras. 8.40 ff.
[358] Article 5.7 provides: "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time".
[359] Op. cit., para. 218 and para. 226 ff. It would, of course, be easier and provide a more accurate comparison if for both the situations compared a full risk assessment is available (see Transcript, paras. 271 ff.). However, in our view, the absence of a full risk assessment for either situation does not, in particular for straightforward comparisons, prevent scientists, and on that basis panels, to state in more general terms what is most likely to represent a higher level of risk (see, e.g., Winton, Transcript, paras. 280-283 and the quotes in paras. 8.136 ff.).
[360] Paras. 8.19 and 8.95.

salmon products is very high.[361] We next examine the sanitary regime for the other products compared to these salmon products.

8.128 In the first comparison[362], the salmon products further examined are compared to uncooked Pacific herring, cod, haddock, Japanese eel and plaice for human consumption. The second comparison[363], assesses these salmon products as opposed to uncooked Pacific herring, Atlantic and Pacific cod, haddock and European eel for human consumption. In the third and fourth comparison, respectively, the import of herring in whole, frozen form for use as bait and the import of live ornamental finfish is addressed.[364] Answering Panel Question 4, Australia states that the sanitary measures currently applied to the importation of the aquatic animals and related products other than salmonids addressed in these four comparisons are listed in the 1996 Final Report:

> "Import requirements for aquatic animals and their products other than salmonids:
>
> All goods entering Australia are subject to quarantine. They may be inspected on arrival and may be sampled and tested at the importer's expense regardless of whether or not prior permission to import is required and granted.
>
> The specific policies applying to the importation of aquatic animals (other than salmonids), their products and related materials, are as follows:
>
> - Live, freshwater, ornamental fish may be imported with prior written approval. Approval is restricted to fish on Schedule 6 of the *Wildlife Protection (Regulation of Exports and Imports) Act 1982* and there are pre-entry and post-entry requirements including a minimum period of 14 days in post-arrival quarantine premises.
> - Live, marine, ornamental fish may be imported subject to examination on arrival for species identification, clinical health and presence of other materials of quarantine concern. Approval is restricted to fish on Schedule 6 of the *Wildlife Protection (Regulation of Exports and Imports) Act 1982.*
> - Animals imported for scientific or display purposes must be held in premises approved for the purpose under the *Quarantine Act 1908*. Permission must also be obtained from DEST, under the *Wildlife Protection (Regulation of Exports and Imports) Act 1982* for the importation of fish species other than those on Schedule 6 of that Act.
>
> ...
> - Other live aquatic animals may be imported subject to risk assessment and approval on a case by case basis. Permission must also be obtained from DEST under the *Wildlife Protection (Regulation of Exports and Imports) Act 1982.*
> - Meals derived from aquatic animals, for example fish and prawn meal, require prior written permission for importation subject to suitable processing of the product and inspection on arrival.
>
> ...
> - Other non-viable aquatic animal products, for example mussels, are allowed entry subject to inspection and confirmation of non-viability and freedom from visible contamination.

[361] Paras. 8.123 and 8.124.
[362] Para. 8.113 and Annex 1 to our report.
[363] Ibid.
[364] Ibid.

- Clothes, footwear and used fishing gear that have had contact with fish or fish farms overseas are subject to inspection on arrival and treatment if required".[365]

In its answer to Panel Question 4, Australia adds that its quarantine measures for aquatic animals are under active review and that it expects that changes to import policies may occur when current and proposed studies have been completed. Australia further submits that other SPS measures related to internal quarantine restrictions, human health and residue matters and SPS measures related to non-fish vertebrates were not canvassed in its answer to our question. It also notes that ornamental fish are the main type of live aquatic animals imported. Approval of imports of ornamental fish is restricted to fish on Schedule 6 of the *Wildlife Protection (Regulation of Exports and Imports) Act 1982*. They are inspected on arrival to ensure that they are healthy, to confirm the identification of the species and to ensure that there are no other materials or issues of quarantine concern present. Freshwater ornamental fish have a compulsory quarantine detention period of either 14 or 28 days in approved quarantine premises. However, with respect to the uncooked non-salmonid products compared under the first two comparisons outlined above and fish used as bait, at issue in the third comparison, neither the 1996 Final Report nor Australia in its submissions before us, mention any specific sanitary measures.

8.129 On the basis of the information thus provided, we note that in any event the aquatic animals and products compared to the salmon products further examined under any of the four comparisons, are allowed for importation into Australia. On the other hand, the salmon products further examined cannot be imported. We further recall that in the circumstances of this dispute and for the purposes of our examination under the first element of Article 5.5, we would assume that a difference in the sanitary measures imposed for the different situations compared, does reflect a distinction in appropriate levels of protection.[366] We thus assume in this case that the rather substantial difference in sanitary measures imposed by Australia for the salmon products further examined (an import prohibition) as opposed to those imposed for the other four situations (where imports are allowed, often without control; ornamental finfish only after control), does reflect a difference in the levels of protection considered to be appropriate by Australia for each of the four comparisons in the sense of the first element of Article 5.5.

(ii) "Arbitrary or unjustifiable" differences in levels of protection

8.130 For Canada, no possible justification can be offered for the distinctions in the foregoing levels of protection. Canada argues that expert reviews commissioned by Australia, in particular the 1995

[365] 1996 Final Report, pp.5-6, italics in original.
[366] Paras. 8.123 and 8.124.

Humphrey Report[367], the 1995 BRS Report[368] and Technical Paper No. 3 (1992)[369] confirm that these distinctions are arbitrary and unjustifiable.

8.131 With respect to the distinctions made between the salmon products further examined, on the one hand, and whole, frozen herring for use as bait (third comparison) and live ornamental finfish (fourth comparison), on the other hand, Canada adds that the likelihood of disease establishment arising from the latter imports will be greater than that arising from uncooked salmonids for human consumption. This because, according to Canada, the sequence of events required for disease establishment to occur through bait fish or ornamental finfish is greatly compressed. As far as bait fish is concerned, Canada argues that it will undergo much less rigorous inspection than fish for human consumption; that bait fish is not cooked subsequent to entry into Australia as most salmon products for human consumption would be; and that - unlike salmon products for human consumption which would only be found in the aquatic environment as a result of unlikely chance events - bait fish are imported for the specific purpose of being introduced into the aquatic environment. With respect to ornamental finfish, Canada submits that several critical risk-reduction steps, including product preparation (evisceration etc.), internal inspection and physical/chemical treatment such as freezing and cooking are absent. For Canada, the greater risk posed by live ornamental finfish is also confirmed by empirical evidence: unlike dead, eviscerated product, for which there are no documented cases of disease transmission anywhere in the world, live ornamental finfish imports are known to have introduced exotic diseases, including into Australia.[370]

8.132 Australia contends that the reports cited by Canada are only draft documents or reports written by independent consultants, used for public discussion purposes, which do not represent Australian government policy. For Australia, these reports are part of a review process of existing quarantine policies with the objective to determine appropriate and consistent quarantine measures for aquatic animals and their products. They are part of the practices and processes of government in Australia and were undertaken at a stage of policy formulation. Australia further submits that the quotations referred to by Canada have been taken out of context. With respect to the 1995 Humphrey Report, Australia argues that it went on to say that given Australia's disease status, restrictions on the importation of salmonids are reasonable and that a risk assessment process may be required. According to Australia, it did not say that the measures on salmon are unwarranted: it saw salmonids as a higher risk species, recommended minimum restrictions and stated that all fish should be the

[367] Humphrey, J.D., Australian Quarantine Policies and Practices for Aquatic Animals and their Products: a review for the Scientific Working Party on Aquatic Animal Quarantine, Bureau of Resource Sciences, 1995, Canadian Ex. A-22: "Major inconsistencies exist under existing quarantine regulations, whereby all fish are permitted entry, except for fresh or frozen salmon" (at p.88); "All non-living finfish animals or products derived therefrom destined for human consumption should be considered for importation. The arbitrary distinction between salmonid and non-salmonid fish should be repudiated" (at pp.119-120).

[368] Nunn, M.J., Aquatic Animal Quarantine in Australia: Report of the Scientific Working Party on Animal Quarantine, Bureau of Resource Sciences (BRS), 1995, Canadian Ex. A-21, p.34: "... there is currently a major inconsistency whereby fresh or frozen products derived from finfish other than salmonids may be imported without specific quarantine restrictions, whereas salmonid flesh is prohibited unless treated in a manner to inactivate potential pathogens"; "in view of the absence of documented examples of exotic disease incursions resulting from imports of products of aquatic animals for human consumption, and the international acceptance of evisceration as a means of substantially reducing the risk of disease transfer in finfish for human consumption, the present restrictions on the importation of salmonid flesh for human consumption cannot be justified and should be revised"; "all non-living finfish or products derived therefrom destined for human consumption should be considered for importation" and "the arbitrary distinction between salmonid and non-salmonid fish should be repudiated".

[369] Quarantine, Health and Movement, Technical Paper No. 3, in Draft National Strategy on Aquaculture: Technical Papers for Discussion, Australian and New Zealand Fisheries and Aquaculture Council, December 1992, Canadian Ex. A-19, p.2: "The arbitrary separation of aquaculture/recreational species from others (especially ornamental species) has little, if any, scientific basis ...".

[370] Canada refers to the 1995 Humphrey Report, p.88 and a study by Langdon, J.S., of the Fish Health Reference Laboratory, entitled: "Diseases of Introduced Australian Fish in Fish diseases: refreshers course for veterinarians", May 23-27, 1988, Canadian Ex. B-32, p.225 at p.231.

subject of a case-by-case study.[371] Australia submits that such case-by-case process has commenced. With respect to the 1995 BRS Report, Australia contends that it made the same recommendations as the 1995 Humphrey Report: the quarantine restrictions, in excess of evisceration, are justified, but quarantine restrictions on both salmonids and non-salmonid aquatic animals should be reviewed and brought into consistency.[372]

8.133 In examining the second element under Article 5.5, we recall, first of all, that each of the four comparisons have at least one disease agent in common - or at least, for the salmon products further examined, an alleged concern for that disease agent - and that, therefore, for each of these comparisons the two situations compared can be assumed to represent the same or a similar disease risk as well as the same or similar associated biological and economic consequences. However, we further recall that Australia effectively bans the import of the salmon products further examined, but allows the import of the other four categories of fish or fish products. It might, therefore, be expected that some justification for this distinction in sanitary measures and corresponding levels of protection exists, such as a *higher* risk related to imports of the salmon products further examined. If not, these distinctions could be considered to be "arbitrary or unjustifiable" in the sense of the second element of Article 5.5.

8.134 Since we have more evidence before us which relates to the third and fourth comparison, we start our examination with these two comparisons. That is: a ban on the salmon products further examined compared to, respectively, allowing imports of herring in whole, frozen form for use as bait and allowing imports of live ornamental finfish. We note, however, that the arguments, reports, studies and expert opinions submitted to us in this respect - rather than pointing in the direction of a *higher* risk related to the salmon products further examined, in order to justify the stricter sanitary measures imposed for these products - all provide evidence that the two categories of non-salmonids, for which more lenient sanitary measures apply, can be presumed to represent at least as high a risk - if not a higher risk - than the risk associated with the salmon products further examined.

8.135 We recall that the experts advising the Panel stated that the biological and economic consequences of a disease introduction (i.e., the consequences of a disease once established in a country) will generally be the same or similar in a given country, irrespective of the product introducing the disease.[373] With respect to the products we decided to compare under Article 5.5, no evidence to the contrary is before us. In particular, nothing in the 1996 Final Report (especially its Section 3 which addresses the economic and other impacts of salmonid disease introduction into Australia) represents evidence to the contrary. We shall thus assume that the consequences of disease introduction in Australia are the same or similar irrespective of whether the disease is introduced by imports of the salmon products further examined or by imports of herring used as bait or live ornamental finfish.

8.136 First, we note the following excerpts from relevant reports and studies submitted to us which address the relative risk related to salmon products (including, or for some studies even specifically addressing, the salmon products further examined) as opposed to bait fish or live ornamental fish. We note that these reports do not form part of Australia's formal risk assessment nor represent Australia's official government policy. However, to the extent they constitute relevant available scientific information which was submitted to the Panel, we consider it our task to take this evidence into account. We consider that, for purposes of our examination, the scientific and technical content of these reports and studies is relevant, not their administrative status (i.e., whether they are official government reports or not).[374] As to Australia's comment made at the interim review stage that we

[371] Australia refers to the 1995 Humphrey Report, pp.89 and 120.
[372] Australia refers to the 1995 BRS Report, p.35.
[373] Para. 8.121.
[374] Para. 7.5.

seem to accord a lesser evidentiary status to the 1996 Final Report, we recall that this report does not address the relative risk related to the different products we compare under Article 5.5.

Technical Paper No. 3 (1992):

"The existing range of controls encompasses the whole spectrum of possibilities from a complete ban on live fish and raw products from salmonids, to virtually no restrictions on the basis of health for marine aquarium fish. The arbitrary separation of aquaculture/recreational species from others (especially ornamental species) has little, if any, scientific basis and has led to the present anomalous situation cited above.

...

Non-salmonid freshwater finfish - ... These requirements [imposed by Australia on this category of fish, see para. 128 above] are patently inadequate to exclude many serious diseases, especially those which may remain latent or become pathogenic when transferred to another species ... Undoubtedly, the conditions for the importation of freshwater aquarium fish are in urgent need of upgrading".[375] (underlining added)

1995 BRS Report:

"The Working Party noted the consultant's conclusion (Section 9.1.2) on the disease risk of different imports. It agreed that live aquatic animals pose the highest risk of introducing exotic disease. It noted in particular that live ornamental finfish are a special case because they are known or potential vectors of diseases of high quarantine importance, are traded widely internationally, and are imported in large numbers into Australia each year

...

The Working Party noted the consultant's conclusion (Section 9.1.2.3) that the use of live finfish for bait or for food for carnivorous finfish constitutes a major risk of disease transmission, and of introducing exotic disease if the bait fish or feed fish is imported.

...

The Working Party noted the consultant's conclusions (Section 9.1.2.5) on inconsistencies in current policy on the importation of non-living aquatic animals for human consumption. It acknowledged that processing can significantly reduce the risk of entry of exotic pathogens in such products. It also acknowledged that detailed epidemiological information may be needed from the exporting authority to assess the risk of importing such products".[376] (underlining added)

"The Working Party agreed with the consultant's conclusions (Section 9.2.3.2) on the potential of ornamental finfish to be vectors of diseases ... The Working Party agreed with the consultant's conclusion (Section 9.2.3.3) that there are two broad risk categories with regard to ornamental finfish imports [a higher risk category and a lower risk category] ... The Working Party noted that goldfish *Carassius auratus*, guppies *Poecilia reticulata* and gouramis *Trichogaster trichopterus* present special

[375] Technical Paper No. 3 (1992), pp.2-3.
[376] 1995 BRS Report, pp.4-5. See also the 1995 Humphrey Report, pp.87-91.

cases for immediate inclusion in the higher risk category of living finfish imports because:

- they are recognised vectors of exotic diseases of high quarantine importance;
- they are farmed, or likely to be farmed in open systems or management, with direct access to natural waters; and
- large numbers are currently imported into Australia.

The Working Party noted with concern the consultant's conclusion that there is a major inconsistency whereby certain higher risk species nominally imported for ornamental purposes are subject to minimal quarantine, but other species of equal or lesser risk require much higher standards of quarantine".[377] (underlining added)

"The Working Party noted that finfish and aquatic invertebrates are imported for bait and fish feed, and that the volume of such imports is increasing. The Working Party noted that some major diseases of aquatic animals have spread internationally through the practice of importing bait fish. From first principles, it agreed with the consultant's conclusion (Section 9.8.1) that this activity constitutes a high risk of introducing exotic pathogens".[378] (underlining added)

1995 Draft Report:

[addressing salmon "disposed of as fish bait or burley" as a risk factor] "This practice [disposal of salmon as fish bait or burley] is thought to present the greatest risk of disease introduction ... Fish remains, used as bait, would present as much risk as burley containing uncooked fish product. Some of the bait would be taken by caught fish but some may be lost in the water or eaten by fish that are not landed".[379] (underlining added)

[providing "product conclusions"] "It has been concluded that the more processing the product receives the lower risk that the product presents. In general, value added products present less risk because processing removes tissues that are more likely to harbour pathogens and to be discarded prior to cooking".[380] (underlining added)

We note, moreover, that, according to statistics provided by Canada (and not contested by Australia), during the period between 1988 and 1995 57,663,000 freshwater live ornamental fish and 1,193,000 salt water live ornamental fish have been imported into Australia.[381] With respect to imports of bait, a Report of the National Task Force on Imported Fish and Fish Products stated the following: "[b]ait users, both commercial and recreational, import fish and fish products. According to the import survey, *commercial bait users are extremely dependent upon the import of bait*. This dependence varies between different industries".[382] (emphasis added)

8.137 The evidence outlined above points in the direction of a *higher* risk of disease introduction associated with imports of bait fish and live ornamental fish than the risk posed by imports of salmon products for human consumption. Nevertheless, Australia imposes far stricter sanitary measures for the latter category than it does for the former. Whether or not this evidence is part of official Australian government policy does not, in our mind, change the scientific weight to be given to it.

[377] Ibid., pp.17-19. See also the 1995 Humphrey Report, pp.101 ff.
[378] Ibid., p.40. See also the 1995 Humphrey Report, p.123.
[379] 1995 Draft Report, p.33.
[380] Ibid., p.214.
[381] Annex A-H to Canada's first submission.
[382] Report of The National Task Force on Imported Fish and Fish Products, A report into the implications arising from aquatic animal imports, DPIE, December 1996, p.23, see also at pp.24-26 and 30.

We consider, therefore, that Canada, as party challenging the measure at issue under Article 5.5, has raised a presumption (i.e., made a *prima facie* case) that the distinctions in levels of protection imposed by Australia for, on the one hand, the salmon products further examined and, on the other hand, herring in whole, frozen form for use as bait and live ornamental finfish, are "arbitrary or unjustifiable" in the sense of the second element in Article 5.5.

8.138 Second, we note the following opinions of experts advising the Panel which confirm this *prima facie* case of "arbitrary or unjustifiable" distinctions:[383]

> Burmaster:
>
> [answering Panel Question 10 and commenting on Canada's claim that "the likelihood of disease establishment is higher for imports of whole, uneviscerated bait fish and for live fish known to host that disease agent than it is for imports of uncooked salmon for human consumption"] "This seems highly likely to me, but I have no independent information to support or refute such an opinion".[384] (underlining added)
>
> Rodgers:
>
> [answering Panel Question 9] "The importation of several other groups [the Panel Question refers to "imports of aquatic animals or aquatic animal products, other than salmonids"] would pose a potential risk of disease introduction that would probably be at least as high, if not higher, than that posed by the importation of uncooked salmon from Canada. These groups would include any live ornamental fish, bait fish and trash fish for feeding aquacultured species. It is not possible to predict though, without an import risk analysis study, which of these represents the highest risk. However, importation of live fish for stocking of open waters containing indigenous fish, the feeding of trash fish or bait fish directly to aquacultured species as a feed supplement or substitute would probably be the most important in terms of risk. Escapees from a closed system into an open waterway could also be a problem. The arrival of furunculosis into Australia via imported goldfish or into Norway via salmon smolts and the first reported outbreaks of VHS in turbot from Scotland and Ireland help to support the hypotheses of live fish importations and feeding respectively".[385] (underlining added)
>
> [answering Panel Question 10] "It is probably true to say that for a given disease agent, the likelihood of disease establishment is higher for imports of whole, non-eviscerated bait fish and for live fish than it is for imports of uncooked salmon for human consumption".[386] (underlining added)
>
> Winton:
>
> "... the subsets of pathogens in these different species [salmon products for human consumption, bait fish and live ornamental fish] will be different. Ornamental fish will have their own subset of pathogens. But in a general sense, live fish that are

[383] We only refer to three of the four experts advising the Panel since only three of them have expressed an opinion on this issue.

[384] Burmaster answers, p.5. See also Burmaster, Transcript, para. 279.

[385] Rodgers answers, p.13.

[386] Rodgers answers, p.14. Rodgers then goes on to address what he calls the "actual level of risk", looking at risk reduction factors which might be present (e.g., import of live fish for scientific purposes only) or be taken (e.g., control measures) with respect to live fish or bait. However, these factors do not affect the risk comparison made here since Australia has no risk reduction factors in place for bait fish nor any stringent control measures for live ornamental finfish, see para. 8.128.

> introduced carry probably, in my view, the highest risk of any category. We have documented examples of ornamental fish carrying both Notifiable Diseases of the OIE and non-notifiable other fish diseases in international trade. Second level, might well be those fish used as bait. Again Dr. Rodgers' point is good, we may not have ever sampled them adequately to know, but in an example from the North American coast, for example, number of years ago, everyone assumed that herring were sent around as safe products up and down the coast and used as bait. We now know that Pacific herring, and in fact Atlantic herring in the Baltic and North Sea are probably the major reservoir for *viral haemorrhagic septicaemia* virus, and probably constitute a much higher risk than a certified population dead salmonids or eviscerated salmonids. So I would put them in the second most risky category. The most safe of the three groups would be uncertified uncontrolled open-ocean salmonids such as I have talked about here".[387] (underlining added)
>
> [answering Panel Question 24] "Members of the FDC [Fish Diseases Commission] have reviewed the scientific evidence and are not aware of a known expansion of range for a fish pathogen due to the movement of eviscerated fish; conversely, there are many cases of disease transmission associated with shipment of infected live fish, live eggs, or even uneviscerated fish used to feed other aquatic animals that are documented in the scientific literature".[388] (underlining added)
>
> [remarks on Panel Question 12] "The FDC considers that the risk of transmission of fish diseases by movement of eviscerated fish products is probably lower than the risk from certain other activities (movement of aquarium fish, ballast water in ships, etc.) and thus does not justify trade restrictions".[389] (underlining added)

8.139 We note, moreover, that Australia has not submitted any evidence which contradicts the above-mentioned reports and opinions referred to by Canada which constitute evidence that the salmon products further examined effectively pose *less* risk than whole, frozen herring used as bait or live ornamental finfish. Nor has Australia, in its turn, put forward *positive* evidence of a possible justification for the distinctions in levels of protection it currently imposes.[390] On the contrary, at our meeting with the experts advising the Panel Australia seemed to agree that in general terms (and without prejudice to Australia's position that risk assessments must be undertaken before risks can be compared) live fish can be expected to pose the highest risk, thereafter bait fish and only after that salmon products for human consumption.[391]

---

[387] Transcript, para. 267. See also Winton, Transcript, para. 179: "there is such a large body of scientific evidence associating movements of live fish and eggs with diseases, and the *absence* of scientific data associating any other products for human consumption that the preponderance of data seem to be that the risk is quite low". At the experts meeting, Winton provided further explanation as to why bait fish and live fish ornamental fish pose higher risks: "One, the fish that go directly in the water course bypass some of the exposure methods that might be imagined, some of which are not so likely that would accompany human consumption products, and, secondly, because some of these fish are known to be carriers of diseases and if they are particularly uncertified or unexamined, could be carrying that disease at a level as high or higher than that of an eviscerated product" (Winton, Transcript, para. 281). See also Winton, Transcript, paras. 42 and 203.

[388] Winton answers, p.3.

[389] Winton answers, p.5.

[390] When asked to justify this difference in treatment, Australia limited its answer to a statement that risk analyses are scheduled or taking place for bait fish and live ornamental fish (Australia's answer to additional Panel Question 9 of 23 January 1998).

[391] At the meeting with experts advising the Panel Australia noted the following: "As a sweeping generalization, everyone agrees with these kind of three levels of risk. What Australia is saying is that you have got to do more than that. You have got to do more than sweeping generalizations if you are looking at product which may have a different intended purpose. So therefore, Australia contends that whether ornamental fish, or whether bait fish we need to do a risk assessment ... So in short, we agree with generalizations, but the specifics are really what we are

8.140 As to Australia's argument that imports of salmon products pose higher risks than imports of bait fish or live ornamental finfish because salmon products may carry a series of other, additional diseases appearing on the list of 24 diseases of concern, we recall that the salmon products further examined are only those in dispute (*inter alia*, only Canadian salmon) from adult, wild, ocean-caught Pacific salmon. According to Canada[392], the disease agents known to occur[393] in this category of Canadian salmon are limited to four: *Renibacterium salmoninarum*, IHNV, salmon leukaemia virus and *Henneguya salminicola*. Australia has not contested this. The expert advising the Panel on this issue stated that also the following two disease agents are reported to occur in adult, wild, ocean-caught Pacific salmon: *Kudoa thyrsites* and *Parvicapsula sp.*[394] However, only one of these two additional diseases (*Parvicapsula sp.*) appears on Australia's list of 24 diseases of concern to it. In total only five of the 24 diseases of concern to Australia have thus been detected in the salmon products further examined.[395] Moreover, none of the four disease agents referred to by Canada under the third comparison and *known to occur* in herring for use as bait (*Aeromonas salmonicida* (atypical strain), Erythrocytic necrosis virus, Infectious haematopoietic necrosis virus and VHSV), are - on the basis of the evidence before us - reported to occur in the salmon products further examined.[396] The same is true for the five disease agents addressed under the fourth comparison (*Aeromonas salmonicida* (atypical strain), *Yersinia ruckeri*, *Edwardsiella tarda*, IPNV and *Vibrio anguillarum*): all of them are *known to occur* in live ornamental finfish, but none of them has been reported in the salmon products further examined.[397] Since, moreover, both herring used as bait and live ornamental finfish are known to be host to one of the disease agents of greatest concern to Australia (*Aeromonas*

---

dealing with" (Transcript, para. 285). See also Australia's statement in Transcript, para. 181 ("On relative terms, as Dr. Winton said, well, gametes and all the rest pose greater risk, but nevertheless, it can happen").

[392] According to Rodgers, one of the experts advising the Panel, one should, indeed, give particular importance to Canada's views on disease prevalence. At our meeting with experts advising the Panel, Rodgers noted that "the most accurate up to date information concerning disease prevalence in an exporting country is usually held by that exporting country themselves, providing that country is of course recognised as a competent authority. In this case of course, Canada is a well respected, has a well respected monitoring system in place for this type of situation" (Transcript, para. 19).

[393] We focus on those diseases "known to occur" (i.e., for which there is evidence that they may occur in the specific product), not those more generally "of concern" to Australia. In this respect Wooldridge, when addressing the question of which diseases are appropriate to include in a risk assessment, stated the following: "those diseases which one may legitimately look at are *any that one has evidence could be in the product*, and that might not simply be the information notified to the OIE, but it might be from a literature research or personal reports of communications" (Transcript, para. 107, emphasis added). See also Rodgers, Transcript, para. 193 ("I think most monitoring programmes and most national legislation is based on the understanding that to take action you must actually isolate the organism itself"). However, we agree with Australia in the sense that the fact that we focus on those diseases which have been *detected* in the salmon products further examined, does not mean that there is absolute certainty that other diseases do not occur in these products (see Transcript, paras. 244-253 and 327). See also footnote 1 to Annex 1 of our report.

[394] Rodgers' answer to Panel Question 7, Rodgers answers, p.8. At the meeting with experts advising the Panel, Rodgers limited his answer from four to only three additional diseases, confirming that the fourth one has only been detected in juveniles, not adult fish (Transcript, para. 230). In our report we only mention two of the three since at the interim review stage, Australia pointed out that the third additional disease referred to by Rodgers, namely "marine anaemia", is also known as "salmon leukaemia virus", a disease which is listed in the 1996 Final Report and which is one of the four diseases of which Canada acknowledges that it occurs in salmon products further examined. This disease is therefore not an "additional disease".

[395] In this respect it is interesting to note that according to Winton and Rodgers, wild ocean-caught Pacific salmon during their ocean phase would probably, in a general sense, represent less of a disease risk than fresh water fish or cultured fish in an uncontrolled water supply (Transcript, paras. 261-263).

[396] This is reflected in the chart attached in Annex 1. We note, in particular, Winton's reply to the question whether bait fish represent higher risk than the salmon products further examined: "I could make that statement with a high level of certainty for Pacific herring in North America. As bait fish those fish contain a significantly and quantifiably higher incidence and prevalence of infection than do Pacific salmon" (Transcript, para. 283).

[397] See chart in Annex 1.

salmonicida)[398], a disease which has not been reported in the salmon products further examined, we consider that - on the basis of the evidence before us - Australia has not been able to substantiate its argument that the salmon products further examined represent a higher risk than herring used as bait or live ornamental finfish.

8.141 We thus consider that Australia has *not* been able to rebut the *prima facie* case of "arbitrary or unjustifiable" distinctions established by Canada. We find, therefore, that, as of today and on the basis of the evidence provided to us, the distinctions in levels of sanitary protection reflected in Australia's treatment of, on the one hand, the salmon products further examined and, on the other hand, herring in whole, frozen form for use as bait and live ornamental finfish, are "arbitrary or unjustifiable" in the sense of the second element of Article 5.5.

8.142 In paragraph 8.126 we have dealt with Australia's argument that risk assessments must be undertaken for all situations examined under Article 5.5 before the risk arising from these situations can be compared. Moreover, our finding that the foregoing distinctions in levels of protection are "arbitrary or unjustifiable" does not imply any judgment as to whether the current Australian measures imposed on the salmon products further examined - or the appropriate level of sanitary protection these measures reflect - are warranted. Our finding only relates to the *distinctions* made by Australia in the levels of protection it applies to different situations. It does not give any value judgment on any of these levels of protection taken separately.

8.143 Since we already found that the third and fourth comparison put forward by Canada under Article 5.5 involve distinctions in levels of protection which are "arbitrary or unjustifiable", we see no need to further examine the justifiability of the distinctions made by Australia in the first and second comparison. We shall not, therefore, make further findings with respect to these comparisons.

(iii) Distinctions in levels of protection which result in "discrimination or a disguised restriction on international trade"

8.144 Canada submits that Australia's arbitrary and unjustifiable distinctions in its appropriate levels of protection result in a disguised restriction on international trade. In its interpretation of "a disguised restriction on international trade" in the sense of the third element of Article 5.5, Canada referred, prior to the Appellate Body Report on *EC - Hormones*, to the following statement of the Appellate Body in its Report on *US - Standards for Reformulated and Conventional Gasoline ("US Gasoline*"):

> "... "disguised restriction", whatever else it covers, may properly be read as embracing restrictions amounting to arbitrary or unjustifiable discrimination in international trade taken under the guise of a measure formally within the terms of an exception listed in Article XX. Put in a somewhat different manner, the kinds of considerations pertinent in deciding whether the application of a particular measure amounts to "arbitrary or unjustifiable discrimination", may also be taken into account in determining the presence of a 'disguised restriction' on international trade. The

[398] 1995 Draft Report, p.i: "The IRA considers 24 diseases and judges *Aeromonas salmonicida* to pose the greatest risk of introduction" and 1996 Final Report, p.38: "*A. salmonicida* has a wide range of hosts and would present one of the most serious threats to Australian fish". The quotes do not distinguish typical from atypical strains of *Aeromonas salmonicida*. However, at the interim review stage, Australia submitted that only the typical strain of *Aeromonas salmonicida* (not the atypical strains, which have been detected in herring for (continued) use as bait and live ornamental finfish) is of the greatest concern to it and that the we confused the two different strains in our interim report. In reply, Canada stated that any so-called "confusion" is created by Australia's own 1996 Final Report and referred to the following statement at pp.140-141: "Atypical isolates are of larger concern and cause heavier losses than typical ones in some salmon-culturing areas, for example Atlantic Canada. Similar scenarios must be expected if a virulent-typical or atypical-strain were established into Australian waters".

> fundamental theme is to be found in the purpose and object of avoiding abuse or illegitimate use of the exceptions to substantive rules available in Article XX".[399]

For Canada, this reasoning of the Appellate Body with respect to Article XX of GATT 1994 was equally applicable to Article 5.5 and the relationship between arbitrary or unjustifiable distinctions in levels of protection and the resulting disguised restrictions on international trade. Canada submitted that the distinctions made by Australia in its levels of protection for the salmon products further examined and for, *inter alia*, whole, frozen herring for use as bait and live ornamental finfish were arbitrary and unjustifiable and resulted in an import ban on these salmon products, i.e., a restriction on international trade in the guise of a sanitary measure.

8.145 Prior to the Appellate Body Report on *EC - Hormones*, Australia submitted that it did not disagree with Canada's legal interpretation of "a disguised restriction on international trade" contained in Article 5.5. Later, Australia argues that the direct application of Appellate Body findings in regard to interpretations of Article XX of GATT 1994 to Article 5.5 has been rejected by the Appellate Body in *EC - Hormones*. Australia further argues that Canada's assertion of a "disguised restriction on international trade" does not contain any evidence that the measure at issue results in a disguised restriction on international trade.

8.146 With respect to the interpretation of the third element under Article 5.5, i.e., the need for the distinction in levels of protection to result in "discrimination or a disguised restriction on international trade", we recall the Appellate Body's findings in *EC - Hormones*:

> "214. ... The last element requires that the arbitrary or unjustifiable differences result in discrimination or a disguised restriction of international trade. We understand the last element to be referring to the measure embodying or implementing a particular level of protection as resulting, in its application, in discrimination or a disguised restriction on international trade.
>
> 215. We consider the above three elements of Article 5.5 to be cumulative in nature; all of them must be demonstrated to be present if violation of Article 5.5 is to be found. In particular, both the second and third elements must be found. The second element alone would not suffice. The third element must also be demonstrably present: the implementing measure must be shown to be applied in such a manner as to result in discrimination or a disguised restriction on international trade. The presence of the second element - the arbitrary or unjustifiable character of differences in *levels of protection* considered by a Member as appropriate in differing situations - may in practical effect operate as a "warning" signal that the implementing *measure* in its application *might be* a discriminatory measure or *might be* a restriction on international trade disguised as an SPS measure for the protection of human life or health. Nevertheless, the measure itself needs to be examined and appraised and, in the context of the differing levels of protection, shown to result in discrimination or a disguised restriction on international trade".[400] (italics in original, underlining added)

With respect to the reference made by Canada in this case to the Appellate Body's findings in *US - Gasoline*, the Appellate Body in *EC - Hormones* stated the following:

> "... in view of the structural differences between the standards of the *chapeau* of Article XX of the GATT 1994 and the elements of Article 5.5 of the *SPS Agreement*,

[399] Appellate Body Report, adopted 29 April 1996, WT/DS2/AB/R, p.25.
[400] Op. cit., paras. 214-215.

> the reasoning in our Report in *United States - Gasoline*, quoted by Panel, cannot be casually imported into a case involving Article 5.5 of the *SPS Agreement*".[401]

Specifically addressing the question of whether the measure at issue in *EC - Hormones* "results in discrimination or a disguised restriction on international trade", the Appellate Body stated the following:

> "In our view, the degree of difference, or the extent of the discrepancy, in the levels of protection, is only one kind of factor which, along with others, may cumulatively lead to the conclusion that discrimination or a disguised restriction on international trade in fact results from the application of a measure or measures embodying one or more of those different levels of protection. ... It is well to bear in mind that, after all, the difference in levels of protection that is characterizable as arbitrary or unjustifiable is only an element of (indirect) proof that a Member may actually be applying an SPS measure in a manner that discriminates between Members or constitutes a disguised restriction on international trade, prohibited by the basic obligations set out in Article 2.3 of the *SPS Agreement*. Evidently, the answer to the question whether arbitrary or unjustifiable differences or distinctions in levels of protection established by a Member do in fact result in discrimination or a disguised restriction on international trade must be sought in the circumstances of each individual case".[402] (underlining added)

After examination of this issue, the Appellate Body in *EC - Hormones* concluded as follows:

> "Our conclusion, therefore, is that the Panel's finding that the "arbitrary or unjustifiable" difference in the EC levels of protection in respect of the hormones at issue on the one hand and in respect of carbadox and olaquindox on the other hand, "result in discrimination or a disguised restriction on international trade", is not supported either by the architecture and structure of the EC Directives here at stake or of the subsequent Directive on carbadox and olaquindox, or by the evidence submitted by the United States and Canada to the Panel. ...".[403] (underlining added)

8.147 At our second substantive meeting, Canada added the following factors which it claims prove that the measure at issue, implementing the level of protection imposed by Australia for the salmon products further examined, results in a disguised restriction on trade. First, Canada refers to Australia's unwillingness to tolerate even a *potential* presence of disease agents in salmonids (resulting in a ban on uncooked product) whereas it does accept imports of non-salmonids where the presence of the same agents has been *confirmed*. Second, Canada asserts that there was an abrupt change in conclusions from the 1995 Draft Report, suggesting that imports of the salmon products further examined should be allowed, to the 1996 Final Report, which advocates that the ban should be maintained. Third, Canada argues that the 1996 Final Report excluded relevant information which was considered in the 1995 Draft Report. Fourth, Canada highlights what it considers to be the absence of any scientific basis for the measure at issue. Fifth, Canada notes Australia's failure to specify the pathogens addressed by its measure. Sixth, Canada argues that despite Australia's professed concerns for the health of its salmonid populations, Australia does not control the internal movement of fish (including salmon), hosts to the disease EHN.[404] Seventh, Canada submits that the measure at issue is not being applied to achieve an appropriate level of protection, but that Australia is using "appropriate level of protection" as a shield for a trade-restrictive measure.

8.148 Australia responds that Canada equates the second with the third element under Article 5.5, an interpretation rejected by the Appellate Body in *EC - Hormones*. Australia submits that it has

---

[401] Ibid., para. 239.
[402] Ibid., para. 240.
[403] Ibid., para. 246.
[404] "Epizootic Haematopoietic Necrosis", also referred to as EHNV, i.e., EHN Virus.

undertaken a risk assessment on Pacific salmon and on that basis decided to maintain quarantine restrictions. On a range of other aquatic animal products, it is undertaking a structured program of risk assessments. Australia further argues that it is a significant importer of aquatic animal products, including smoked and canned salmon from Canada; that many of these imports compete directly against domestic products in the Australian market; and that Australia is also a significant producer and exporter of non-salmonid aquatic products. For Australia, these are the particular circumstances pertaining to Australia's quarantine measures on different aquatic products. According to Australia, most of the factors referred to by Canada are attempts to infer motives from Australia's decisions. Australia argues that inferences of motive or intent are not borne out by the facts and do not constitute evidence of trade discrimination or a disguised restriction. Recalling that the 1995 Draft Report did not recommend that fresh, chilled or frozen salmon should be imported free of quarantine conditions, Australia submits that the difference between the 1995 Draft Report and the 1996 Final Report represents a small degree of difference between two highly conservative options. As to the change in recommendations made by these two reports, Australia refers to a reappraisal of scientific and other data in the context of Australia's appropriate level of protection.

8.149 We recall, first, the *arbitrary distinctions in levels of protection* imposed by Australia for comparable situations[405] (namely, for the salmon products further examined as opposed to that for herring used as bait and live ornamental finfish). The evidence before us showed that imports of herring for use as bait and live ornamental finfish - rather than posing less risk and thus warranting less stringent sanitary measures - can be presumed to represent a *higher* risk than that related to imports of the salmon products further examined.[406] This evidence led us to find that the difference in levels of protection is "arbitrary or unjustifiable".[407] In this respect, we note that the Appellate Body in *EC - Hormones* stated the following:

> "the arbitrary or unjustifiable character of differences in *levels of protection* considered by a Member as appropriate in differing situations - may in practical effect operate as a "warning" signal that the implementing *measure* in its application *might* be a discriminatory measure or *might* be a restriction on international trade disguised as an SPS measure for the protection of human life or health". (emphasis in original)[408]

In this dispute, we do consider that the arbitrary character of the differences in levels of protection is a "warning signal" that the measure at issue results in "a disguised restriction on international trade".

8.150 Second, we recall that the arbitrary difference in levels of protection thus imposed by Australia for comparable situations is a *rather substantial difference*, namely an import prohibition for the salmon products further examined as opposed to tolerance of imports of herring for use as bait without control and of live ornamental finfish after control.[409] In this respect, we note the Appellate Body's statement in *EC - Hormones* that

> "the degree of difference, or the extent of the discrepancy, in the levels of protection, *is only one kind* of factor which, along with others, may cumulatively lead to the conclusion that discrimination or a disguised restriction on international trade in fact results from the application of a measure". (emphasis added)[410]

[405] I.e., "different situations" in the sense of the first element of Article 5.5, see paras. 8.115 ff.
[406] Paras. 8.136 ff.
[407] Para. 8.141.
[408] Appellate Body Report, op. cit., para. 215.
[409] Para. 8.129.
[410] Appellate Body Report, op. cit., para. 240.

In this dispute, we do consider that the rather substantial difference in levels of protection is one of the factors we should take into account in deciding whether the measure at issue results in "a disguised restriction on international trade", as argued by Canada.

8.151 We consider that an additional "warning signal" is present in this dispute which is similar in nature to the two outlined above in the sense that it is not conclusive in its own right. We recall our finding that the sanitary measure in dispute, to the extent it in effect and from a sanitary perspective imposes certain heat treatment requirements, is not reasonably supported or warranted by a risk assessment and, therefore, not "based on" a risk assessment in accordance with Article 5.1.[411] On that ground, we also found that the measure at issue, to that extent, violates the Article 2.2 requirement that sanitary measures be based on scientific principles and not be maintained without sufficient scientific evidence.[412] We consider that these two findings of inconsistency (with both Articles 5.1 and 2.2) constitute another "warning signal" which may, together with other factors, lead to the conclusion that the measure at issue results in a "disguised restriction on international trade". Indeed, considering these violations of Articles 5.1 and 2.2 it would seem that the measure at issue constitutes an import prohibition, i.e., a restriction on international trade, "disguised" as a sanitary measure. We do stress, however, that this additional "warning signal" as such cannot be sufficient to conclude that the measure results in a "disguised restriction on international trade".

8.152 In our view, the three "warning signals" outlined above are supported by three other factors more substantial in nature. These factors are derived from the architecture and structure of the measures which embody the different levels of protection we examined under the first and second element of Article 5.5. All three suggest that the measure implementing the level of protection for the salmon products further examined (i.e., the measure at issue), in its application and in the context of the implementing measures imposed by Australia for the other products compared under Article 5.5, results in "a disguised restriction on international trade".

8.153 First, in this particular case, the arbitrary and rather substantial distinctions in *levels of sanitary protection* imposed by Australia (and referred to in the first two "warning signals" set out above) are expressed in two substantially different implementing *measures*, namely, (1) an *import prohibition* for the salmon products further examined, as opposed to (2) *tolerance of imports* of herring for use as bait without control and of live ornamental finfish after control.[413] Nevertheless, under the first element of Article 5.5, we considered the products to which these measures apply to be comparable (as "different situations" under Article 5.5).[414] More importantly, under the second element of Article 5.5 we also found that the risk arising from these products can be presumed to be the same (and that the risk related to imports of herring for use as bait and live ornamental finfish might even be greater than that arising from the salmon products further examined).[415] The fact that Australia, therefore, applies substantially different implementing measures to products which can be presumed to represent the same risk, suggests that Australia is effectively *discriminating* between, on the one hand, the salmon products further examined (imports of which are prohibited) and, on the other hand, herring used as bait and live ornamental finfish (imports of which are allowed).[416] Since, in our view, the concept of "disguised restriction on international trade" in Article 5.5 includes, among other things, restrictions constituting an arbitrary or unjustifiable discrimination between certain products - in particular in the event this discrimination results from measures imposed on or in

[411] Para. 8.99.
[412] Ibid.
[413] Para. 8.129.
[414] Para. 8.121.
[415] Para. 8.137.
[416] According to the Report of The National Task Force on Imported Fish and Fish Products, DPIE, December 1996, at p.24, Table 3.8, whole frozen herring for use as bait is mainly imported into Australia from New Zealand, USA and Holland. At our interim review meeting Australia noted that Canada is also a significant producer and exporter of herring and that it has the same access to the Australian market as any other supplier. Australia further submitted that Canada also exports live ornamental fish to several destinations, including Australia.

connection with the importation of these products (*in casu*, an import prohibition *versus* allowing imports), we consider that this factor can also be taken into account in our decision as to whether the measure at issue results in "a disguised restriction on international trade".

8.154 The second additional factor we consider to be relevant suggests elements of domestic protection.[417] In our view, the 1995 Draft Report and the 1996 Final Report constitute an important part of the "architecture" of the measure in dispute.[418] The measure at issue has been maintained as a direct result of the 1996 Final Report's conclusions. The 1996 Final Report, in turn, is based on earlier drafts, including, in particular, the 1995 Draft Report. The 1995 Draft Report reached the following conclusion: "It is the conclusion of this draft IRA [Import Risk Analysis] that the importation of eviscerated, headless, wild, ocean-caught Pacific salmon from Canada and the USA should be permitted, under specified conditions".[419] The 1995 Draft Report then added: "The results of this analysis should be reviewed in the light of any significant advances in knowledge on scientific and technical matters relevant to quarantine issues".[420] However, the 1996 Final Report reached a different conclusion from that reached in the 1995 draft: "... it is recommended that the present quarantine policies for uncooked salmon products remain in place".[421] This recommendation, in effect, meant that the import prohibition on salmon products further examined should be maintained. The change in recommendations between the 1995 Draft Report and the 1996 Final Report was, therefore, one from allowing fresh, chilled or frozen product under specified conditions to prohibiting its importation or requiring heat treatment, hence its transformation into a different product. Even though we requested Australia on several occasions to clarify this rather substantial change in conclusions, we consider that Australia has not provided us with information as to what happened or what evidence was obtained in the period between the issuance of the two reports - in particular during the risk communication phase which took place subsequent to the circulation of the 1995 Draft Report - that can sufficiently explain the change in recommendations (less than two years after the 1995 Draft Report) put forward in the 1996 Final Report.[422] Australia itself confirmed that the reversal is not due to a change in its appropriate level of protection.[423] For Australia, the reversal was made because of new scientific information (e.g., on spread of prawn viruses), a re-appraisal of existing scientific information and the attendant uncertainties associated with the estimates and a re-assessment of the consequences of disease introduction, in particular the potential environmental impact and the socio-economic impact on recreational fisheries in Australia. However, the experts advising the Panel all stated that in between the 1995 Draft Report and the 1996 Final Report no new

[417] In this regard we also note that in Australia's submissions before this Panel, Australia noted that when QP86A was imposed "[i]n Australia there was a desire to protect recreational fisheries based on salmonids and to protect the potential development of a salmonid aquaculture industry". Moreover, according to an Industry Commission Research Project on Australian Atlantic Salmon: Effects of Import Competition, 20 December 1996, at p.5: "Atlantic salmon farming began in Australia in 1985, with considerable encouragement from the Tasmanian Government ... Tasmanian production has grown from an initial harvest of 20 tonnes in 1986-87 to around 7000 tonnes in 1995-96".

[418] As noted by Australia in its answer to original Panel Question 16: "The May 1995 draft import risk analysis must be seen as part of a process which would lead to a final report to be put to the Director of Quarantine for decision. The May 1995 draft put forward a proposal as a basis for comment and further discussion".

[419] 1995 Draft Report, p.iii.

[420] Ibid.

[421] 1996 Final Report, p.70.

[422] Para. 7.18.

[423] At the meeting with experts advising the Panel, Australia stated the following: "... the experts themselves have underlined at the point that the science and the methodology are dynamic and evolving, a point which of course we have made in our submissions. I would note however, that *the one thing that is not changing, is Australia's appropriate level of protection*. Australia has adopted a structured approach to the development of quarantine policies, including the assessment and management of risk" (Transcript, para. 79, emphasis added).

scientific evidence relevant to the problem at hand has been produced.[424] In the words of the 1995 Draft Report there were therefore, according to the experts advising the Panel, *a priori* no "significant advances in knowledge on scientific and technical matters relevant to quarantine issues" which could warrant this rather substantial change in the 1995 Draft Report's conclusions. With respect to the other factors invoked by Australia, we note that none of them are clearly referred to in the 1996 Final Report or, even less, mentioned by the 1996 Final Report to be the reason for the reversal of the 1995 conclusions. Without making any conclusive statement in this respect, we nonetheless consider, however, that on the basis of the evidence before us the decisive reason for reversing the 1995 Draft Report's conclusion - that the salmon products further examined should be allowed into Australia under specified conditions - might well have been inspired by domestic pressures to protect the Australian salmon industry against import competition.[425] We acknowledge that this element, in itself, does not constitute sufficient proof that the measure results in "a disguised restriction" on trade, but consider that it can, nonetheless, be taken into account cumulatively with the other factors we address.

8.155 Third, we recall that Australia bans the import of the salmon products further examined because of a "low" *potential* of introduction of 24 diseases, only five of which have been detected in these salmon products.[426] When it comes to imports Australia thus imposes very strict sanitary measures in order to uphold an allegedly very conservative level of protection for its fish population. However, some elements before us make us doubt whether Australia applies similarly strict standards when it comes to the internal movement of salmon products within Australia or Australia's internal monitoring and prevention mechanism for fish diseases more generally.

8.156 Canada refers, for example, to the disease Epizootic haematopoietic necrosis (EHN). This fish disease is one of the five "Diseases Notifiable to the OIE" which means that, according to the OIE, it is "considered to be of socio-economic and/or public health importance within countries" and is "significant in the international trade of aquatic animals and aquatic animal products".[427] EHN is *reported to occur* in salmon populations in Victoria, but not in other parts of Australia such as Tasmania, Western Australia, Queensland and the Northern Territory.[428] Australia agrees with this. Nevertheless, Australia does not impose any restrictions on the internal movement of fish products. We acknowledge Australia's argument that EHN is not a serious disease of salmonids, that an OIE listing of a disease agent has, according to Australia, no scientific relevance as to evaluations of the severity of that disease agent and that the biological consequences related to the introduction of EHN

[424] Transcript, paras. 298-303. See also, in this respect, Rodgers, Transcript, paras. 33-34 ("Now for me, I take it to mean that all these reports actually reach a similar scientific conclusion ... The problem for me seems to be the change in emphasis and conclusion in the 1996 Final Report, which seems to consider the scientific advice but then reaches a political decision, following public consultation") and Wooldridge, Transcript, para. 55 ("... the Final Report does not make clear where any factual errors in the Draft may have occurred which may have altered the assessed risks. And since it came to the opposite conclusion to that in the Draft, this clarity for any factual changes is essential. It is very difficult to see from this whether different conclusions to an adequate assessment would be valid").

[425] Canada argues, for example, that "[f]ollowing the release of the May 1995 Report, Tasmanian salmon producers lobbied furiously against it. They even hired a lobbying firm ... to reverse the conclusion ..." (Canadian oral statement, second substantive meeting, p.33). In response, Australia argues that lobbying activities by the full range of stakeholders (including overseas governments and other interests) reflect the open and transparent arrangements pertaining in democratic systems of government and are neither implicitly or explicitly proscribed nor discouraged by WTO provisions. In such circumstances Australia submits that there is no justification for inferences of motives that lobbying by one particular group influenced or affected the processes leading to the recommendations of the 1996 Final Report.

[426] Para. 8.140.

[427] OIE Code, Section 1.1, Definitions, p.7, emphasis on defined terms omitted. Part 3 of the OIE Code dealing with "Other Significant Diseases", further states that "the list of notifiable diseases of aquatic animals includes only major diseases of proven aetiology and limited geographic range", p. 109.

[428] EHN has not been reported to occur in Canadian salmon either. Australia pointed out, at the interim review stage, that EHN is not considered to be exotic in New South Wales and South Australia.

are not comparable to those arising from the introduction of exotic disease agents such as IHNV.[429] Yet, we see no benefit in trying to compare the risk arising from EHN as opposed to that arising from the diseases of concern to Australia with respect to the salmon products further examined, nor to compare the different measures imposed by Australia to deal with these risks. We note, however, that the other reasons provided by Australia to justify the absence of any internal restrictions on the movement of salmon products, in particular from Victoria to other parts of Australia (no significant trade of fresh salmon into Tasmania from mainland Australia and minimal consequences related to the introduction of salmon diseases in Western Australia where little salmon culture is conducted, Queensland where only a small salmon population exists in isolated mountain areas or the Northern Territory where no salmon is present) would seem to be equally valid in support of allowing *imports* of salmon products into specific parts of Australia.[430]

8.157 Moreover, when we asked Australia, more generally, whether it has sanitary measures to prevent the spread of, or detect and monitor, fish diseases *within* Australian borders which are equally stringent as those imposed to protect Australian fish populations against *imports*, Australia recognized that "aquatic animal disease control within Australia is in its infancy compared to its terrestrial counterpart, as in other countries", but that it had been "identified as a major national priority as demonstrated by the recent [1997] Government response to the National Task Force on Imported Fish and Fish Products Report".[431] However, the stringent restrictions on *imports* of salmon products were first imposed more than 20 years ago.

8.158 We consider that the elements outlined under this third additional factor, though probably not conclusive as such, can also be taken into account, cumulatively with other factors, in our decision on whether the measure at issue results in "a disguised restriction on international trade".

8.159 On the basis of all "warning signals" and factors outlined above, considered cumulatively, we consider that Canada has raised a presumption (i.e., established a *prima facie* case) that the distinctions in levels of protection imposed by Australia for, on the one hand, the salmon products further examined and, on the other hand, herring in whole, frozen form for use as bait and live ornamental finfish, in its application - i.e., by means of the measure at issue which implements the level of protection for the salmon products further examined - results in "a disguised restriction on international trade", in the sense of the third element of Article 5.5. We consider that Australia, in turn, has not provided sufficient evidence to rebut that presumption. We thus find that, to that extent, the third element under Article 5.5 is fulfilled.

(iv) Summary

8.160 We have found above:

(1) that Australia imposes different appropriate levels of sanitary protection in several "different situations", namely with respect to all four comparisons set

[429] See, however, Winton, Transcript, paras. 208-211, on EHN, stating (at para. 209) that it is part of a "pool of strains of very closely related viruses which can have devastating effects for which there is a limited geographic distribution but a fairly wide species distribution". EHN does not occur on the list of 24 diseases of concern to Australia with respect to salmon products, according to Australia, because it is not exotic and it does not occur in North America.

[430] We note that in this respect Article 6 of the SPS Agreement provides: "Members shall ensure that their sanitary ... measures are *adapted to the sanitary ... characteristics of the area - whether all of a country, part of a country*, or all or parts of several countries - ... to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, *inter alia*, the *level of prevalence of specific diseases* or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations".

[431] Australia's answer to additional Panel Question 12 of 8 December 1997, answers, p.10, referring to: Australian Quarantine - A Shared Responsibility, The Government Response, Minister for Primary Industries and Energy, August, 1997.

out in paragraph 8.113 (the salmon products at issue from adult, wild, ocean-caught Pacific salmon compared to other products);

(2) that these levels of protection exhibit differences which are "arbitrary or unjustifiable" in so far as they relate to, on the one hand, the salmon products at issue from adult, wild, ocean-caught Pacific salmon and, on the other hand, herring in whole, frozen form for use as bait and live ornamental finfish; and

(3) that these differences between the treatment provided to, on the one hand, the salmon products at issue from adult, wild, ocean-caught Pacific salmon and, on the other hand, herring in whole, frozen form for use as bait and live ornamental finfish result, by means of the measure at issue, in "discrimination or a disguised restriction on international trade".

Since all three elements of Article 5.5 are present in this case, we find that Australia, by maintaining the measure at issue, acts inconsistently with its obligations under Article 5.5. Given our earlier finding - that a violation of the more specific Article 5.5 can be presumed to imply a violation of the more general Article 2.3[432] - we find that Australia, to that extent, also acts inconsistently with Article 2.3.

5. Canada's claims under Article 5.6: Measures not more trade restrictive than required to achieve the appropriate level of protection

8.161 In the alternative, Canada submits that -- in the event we were to find that no distinctions are made by Australia in its levels of protection or that any such distinctions are not arbitrary or unjustified - the measure at issue is nevertheless more trade restrictive than required to achieve Australia's appropriate level of protection with respect to the salmon products further examined, contrary to Article 5.6.

8.162 Canada argues that Australia has breached its obligations under Article 5.6 in two respects. First, Canada submits that Australia's sanitary measures for non-salmonids (in particular the four categories of fish or fish products examined under Article 5.5[433] are significantly less trade restrictive than those imposed for the salmon products further examined and this even though the risks posed by these non-salmonids are equal to or greater than those presented by the salmon products further examined. For Canada, there is no technical or economic reason why similar measures to those currently imposed for these non-salmonids could not reasonably be extended to the salmon products further examined. Second, Canada argues that, even if there were a plausible explanation for Australia maintaining far more trade restrictive measures in respect of salmon than in respect of non-salmonids, the current measure imposed for the salmon products further examined (an import ban) is the most trade restrictive measure available to Australia. Canada further submits that, as Australia's own risk assessment (the 1996 Final Report) concedes that the levels of risk presented by the five options it considered (including the option finally selected, namely heat treatment) cannot be distinguished, each of these options must, therefore, logically achieve Australia's appropriate level of protection, i.e., the level of protection currently achieved by the measure in dispute. For Canada, there is, for example, no difference in the level of risk between the current restriction (imposing heat treatment without having assessed its effectiveness) and evisceration, the standard suggested by the OIE. Since all four alternative options are far less trade restrictive than the sanitary measure currently imposed (an import ban), Canada concludes that Australia breaches its obligations under Article 5.6.

8.163 According to Australia, the measure at issue has been determined, through a risk assessment, to be necessary to achieve its appropriate level of protection. Australia submits that the risk

[432] Para. 8.109.
[433] Para. 8.113 and Annex 1.

assessment established that there was no other measure reasonably available to Australia, considering the risks posed by the salmon products further examined and taking into account technical and economic feasibility, that would achieve the appropriate level of protection and which would be significantly less restrictive to trade. Australia submits that Canada has not come forward with directly relevant scientific evidence that might warrant an alternative conclusion. Australia argues that the different options set out in the 1996 Final Report provide a continuum of risk and that each of these options would achieve a distinct level of protection. Australia submits that it has documented the different options considered and reached the conclusion that while different options might reduce risk, they would not reduce the risk to a level sufficient to achieve Australia's appropriate level of protection. According to Australia, Canada's claim that the current heat-treatment requirements have not been sufficiently assessed or that Australia opted for the most trade-restrictive measure available, does not constitute evidence that a significantly less trade restrictive measure is available that would achieve Australia's level of protection. Australia argues, moreover, that it has not taken the most trade-restrictive measure possible for salmon since significant quantities of heat-treated salmon can enter Australia. According to Australia, Canada has not addressed issues associated with economic or technical feasibility of different options. With respect to its measures imposed on non-salmonids, Australia argues that the fact that some of these other situations involve a disease agent which is the same as one of the 24 disease agents potentially present in the salmon products further examined, does not make these other situations comparable to that of these salmon products. Australia further submits that if conformity with Article 5.6 required Australia to adopt the same sanitary measures for non-salmonids as it imposes for the salmon products further examined, Australia would then arbitrarily restrict trade - and risk breaching its obligations under the SPS Agreement - since no risk assessments for these other products have as yet been conducted. Australia argues that, because no such risk assessments have been made, it is not in a position to determine whether the measure currently applied to the salmon products further examined would achieve the appropriate level of protection for these other non-salmonid products.

8.164 Article 5.6 reads as follows:

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

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 sanitary or phytosanitary protection and is significantly less restrictive to trade".

8.165 Article 5.6 must be read in context. As noted earlier[434], an important part of the context of Article 5 is Article 2. We consider that Article 5.6 should, in particular, be read in light of Article 2.2, which provides in relevant part:

> "Members shall ensure that any sanitary ... measure is applied only to the extent necessary to protect ... animal ... life or health". (underlining added)

[434] Para. 8.103.

Given that we already found earlier that the measure in dispute is inconsistent with Article 2.2[435], we shall not further address the legal relationship between Articles 5.6 and 2.2.

8.166 We recall that our examination of this dispute under Article 5.6 is limited in scope to those salmon products at issue from adult, wild, ocean-caught Pacific salmon which we have defined as the salmon products further examined.[436]

8.167 In this dispute, Article 5.6 requires that the measure at issue (*in casu*, QP86A as implemented or confirmed by the 1988 Conditions, the 1996 Requirements and the 1996 Decision and this in so far as it prohibits the importation into Australia of fresh, chilled or frozen salmon, in particular to the extent it - in effect and from a sanitary perspective - imposes certain heat treatment requirements[437] is "not more trade-restrictive than required to achieve [Australia's] appropriate level of sanitary ... protection, taking into account technical and economic feasibility". According to the footnote to Article 5.6, the measure at issue shall be considered to be "more trade-restrictive than required" if there is another sanitary measure which:

(1) is "reasonably available taking into account technical and economic feasibility";
(2) "achieves [Australia's] appropriate level of sanitary ... protection"; and
(3) is "significantly less restrictive to trade" than the sanitary measure contested.

We consider that these three elements are cumulative in nature. Only when Canada has raised a presumption (i.e., established a *prima facie* case), not sufficiently rebutted by Australia, that all three elements are present, can the measure at issue be found to be inconsistent with Article 5.6.

8.168 In examining the three elements under Article 5.6, we recall that the 1996 Final Report (Section 1.5.4) identifies five potential quarantine policy options:

> "The quarantine policy options, in no particular order of merit, are as follows:
>
> 1. Permit the importation of product effectively heat treated for pathogens of concern
>   - product might be heat treated prior to export, or
>   - heat treated on arrival prior to general distribution
> 2. Implement the recommendations of the BRS report "Aquatic Animal Quarantine in Australia: Report of the Scientific Working Party on Aquatic Animal Quarantine" in part or in full [allowing imports of salmon but, inter alia, with certain certification and inspection requirements and only as eviscerated, filleted flesh] .
> 3. Permit the importation of retail-ready fillets, for distribution in raw form under specified conditions.
> 4. Implement the recommendations of AQIS's draft IRA, that is, permit the importation of headless, gilled, eviscerated product under specified conditions.
> 5. Permit importation of product that complies with current international standards for trade in salmon product for human consumption, that is, OIE recommends that product be eviscerated and that no other risk reduction measures need be taken".[438]

[435] Para. 8.99.
[436] Para. 8.60.
[437] Paras. 8.19 and 8.95 ff.
[438] 1996 Final Report, p.62. These options are set out in more detail in pp.63-65 of the 1996 Final Report.

The 1996 Final Report then concludes that an unacceptable risk persists for imports of the salmon products it examined. However, in order to reduce this risk to an acceptable level the conclusion it then reaches is that the measure in place should be maintained:

> "On the basis of the large number of disease agents in question; the many unknowns about them; the impossibility of detecting covertly infected animals at inspection; the multiple, complex pathways through which imported product could enter Australian waterways; the presence of potential host species in Australian waterways; the possibility of diseases establishing in Australia; the substantial economic impacts that could result to the salmonid aquaculture industry from disease establishment; the potential loss of amenity and economic impact on recreational fishing and associated business; the potential environmental impacts on listed endangered and vulnerable species; and the ineradicability of disease, it is recommended that the present quarantine policies for uncooked salmon products remain in place".[439] (underlining added)

By recommending that the measure in place for uncooked products be maintained, the 1996 Final Report, in effect, confirmed the measure at issue to the extent it imposes certain heat treatment requirements.[440]

8.169 Canada refers to the four other options provided in the 1996 Final Report as valid alternatives under Article 5.6. It advocates, in particular, evisceration (i.e., the fifth option outlined in the 1996 Final Report).

8.170 We next examine whether any of these alternatives meets each of the three elements required under Article 5.6.

(a) an alternative measure "reasonably available taking into account technical and economic feasibility"

8.171 The first element of Article 5.6 requires that the alternative measure be "reasonably available taking into account technical and economic feasibility". We note that all four alternative options outlined above were presented in the 1996 Final Report itself as options which merit consideration and this in contrast to two other options - removal of all quarantine restrictions and banning the importation of all salmon products - which were thought of as options which could not "reasonably be considered as appropriate, having regard to associated quarantine risks" and were therefore "not discussed further".[441] In our view, this implies that the 1996 Final Report put forward the four alternatives we examine as technically and economically feasible policy options. Nothing in the 1996 Final Report - nor any other evidence before us - implies that any of these four alternatives would be technically or economically unfeasible. We thus consider that Canada has raised a presumption that the four alternative options outlined in the 1996 Final Report are "reasonably available taking into account technical and economic feasibility". Australia has not come forward with any argument or evidence to rebut that presumption. We find, therefore, that in the present dispute the first element under Article 5.6 is fulfilled.

(b) an alternative measure which "achieves [Australia's] appropriate level of sanitary ... protection"

8.172 We next address the second element of Article 5.6. The alternative measure needs to achieve Australia's appropriate level of sanitary protection. We fully agree with Australia that the determination of its *level* of sanitary protection is a decision to be made by Australia, not by any other

[439] Ibid., p.70.
[440] At the interim review meeting, Australia confirmed that the heat treatment requirements currently imposed are - in the interim and until further risk assessments are carried out - those contained in the 1988 Conditions.
[441] 1996 Final Report, p.62.

WTO Member or international organization. The SPS Agreement (in paragraph 5 of Annex A) defines this level as the level of protection "*deemed appropriate by the Member* establishing a sanitary ... measure", *in casu*, the level deemed appropriate by Australia. However, this decision on what level of protection is appropriate has to comply with the SPS Agreement (e.g., Articles 5.4 and 5.5). The same applies to Australia's decision as to which sanitary *measure* will achieve Australia's *level of* protection. It is for Australia to decide on this, but, again, in so doing it has to act consistently with the SPS Agreement, in particular Articles 2, 5.1 to 5.3 and 5.6. Our examination under Article 5.6 is not aimed at a *de novo* review of what sanitary measure Australia should have chosen to achieve its appropriate level of protection. On the other hand, we cannot completely defer this decision to Australia and thus not give effect to Article 5.6. Our mandate under Article 11 of the DSU requires us to "make an objective assessment of the matter before [us], including an objective assessment of the facts of the case".[442]

8.173 In order to decide whether any of the alternative measures meet Australia's appropriate level of protection for the salmon products further examined, we first have to examine more closely what that level of protection is.[443] In this respect, we recall our earlier consideration that the *level of* protection implied or reflected in a sanitary *measure* or regime imposed by a WTO Member can be presumed to be at least as high as the level of protection considered to be *appropriate* by that Member. In this dispute, the level of protection implied in the measure currently imposed - in effect and from a sanitary perspective certain heat treatment requirements - can thus be presumed to be at least as high as Australia's appropriate level of protection for the salmon products further examined.[444] To determine whether any of the alternative measures meet Australia's appropriate level of protection, we should thus examine whether these alternatives meet the level of protection currently achieved by the measure at issue.

8.174 After summing up the five available options, the 1996 Final Report states the following:

> "These options and derived variations represent a continuum of the estimated levels of quarantine risk. Option 5 represents the higher end and option 1 the lower end of the risk continuum; the other options lie between. The difference in level of risk between each option is incremental and cannot be quantified".[445] (underlining added)

In the conclusion to Section 1 of the 1996 Final Report (Section 1.6), the five options are repeated and a similar general assessment is made:

> "These options provide for varying levels of risk which cannot be quantified. Heat treatment (Option 1) provides the highest level of security; the international standard of evisceration only (Option 5) provides for the lowest level of security".[446] (underlining added)
>
> "The risk of disease entry and establishment that would follow adoption of Options 1 to 4 appears to be small based on the known epidemiology of the disease agents and past experience. However, there is a degree of uncertainty attached to this judgement of the level of risk because of gaps in and inherent shortcomings of the available data.

---

[442] Appellate Body Report on *EC - Hormones*, op. cit., paras. 110-119, in particular para. 117.

[443] We noted earlier that we saw no need to clearly define or quantify this level (para. 8.107). We recall, however, Australia's statement that its level of protection with respect to the salmon products further examined is high or "very conservative" and aimed at reducing risk to "very low levels", "while not based on a zero risk approach" (Ibid.). We also recall that QP86A itself provides that salmon products may enter Australia only if they have been subject to "such treatment as in the opinion of the Director of Quarantine is *likely to prevent* the introduction of any infectious or contagious disease" (emphasis added, para. 8.10).

[444] Para. 8.107.

[445] 1996 Final Report, pp.62-65, at p.62.

[446] Ibid., p.69.

> It is extremely difficult to distinguish and describe the level of risk that each option presents from the continuum of risk that are covered by these options. For Options 1, 2, 3 and 4, this is particularly so and it is hard to determine if any of the suggested quarantine requirements, which are additional to those identified in Option 4, would have a substantial impact on the overall risk".[447] (underlining added)

8.175 The measure currently in place imposes, in effect, certain heat-treatment requirements defined in the 1988 Conditions. Heat treatment is referred to more generally in Option 1. At the interim review stage, Australia submitted that Option 1 is not the same as the 1988 Conditions in that the level of protection in Option 1 is higher than that achieved by the 1988 Conditions because Option 1 calls for inactivation of the disease agents, a result not required in the 1988 Conditions.[448] Since Option 1 was never formally recommended by the 1996 Final Report and, therefore, not further defined, we have no evidence on which to decide whether Option 1 is the same as the 1988 Conditions. We recall, however, that to determine whether any of the alternative measures meet Australia's appropriate level of protection, we should examine whether these alternatives meet the level of protection currently achieved by the measure in place (in effect, the heat treatment requirements in the 1988 Conditions) and - in the event Option 1 is different from the measure in place - not that reflected in Option 1.[449] Since, according to Australia, the level of protection achieved by the measure in place *is lower* than that reflected in Option 1, if we were to find evidence that alternative options can be presumed to meet the level of protection reflected in Option 1, these alternatives can *a fortiori* be presumed to achieve the lower level of protection currently achieved by the measure in place.

8.176 According to the 1996 Final Report, Option 2 (adopting the 1995 BRS Report's conclusions) is likely to represent the option with a degree of risk most similar to that achieved under Option 1.[450] We shall, therefore, focus our attention on Option 2 and examine, in particular, whether that option would also achieve the level of protection currently achieved by the measure at issue. Four factors lead us to conclude that there are alternatives to the measure currently in place which would meet Australia's appropriate level of protection, i.e., meet the level of protection achieved today by the measure in dispute.

8.177 First, Australia itself, in the 1996 Final Report, acknowledges that "[t]he risk of disease entry and establishment that would follow adoption of Options 1 to 4 appears to be small".[451] The 1996 Final Report goes even further and states that "it is hard to determine if any of the suggested quarantine requirements, which are additional to those identified in Option 4, would have a substantial impact on the overall risk". According to Australia itself there is, therefore, only a minimal, if any, difference in the level of sanitary protection linked to the alternative Options 2 to 4 and that reflected in Option 1 - and thus *a fortiori*[452] than that achieved by the measure at issue.

8.178 Second, on several occasions the 1996 Final Report states that "[h]eat- treatment (Option 1) provides the highest level of security".[453] However, as we found earlier[454], neither the 1996 Final Report, nor any other study before us, establishes that heat treatment actually reduces risk to the greatest extent. The 1996 Final Report does not even address heat treatment as a risk reduction factor for 13 of the 24 diseases of concern. According to the 1996 Final Report and other studies and expert

[447] Ibid., p.70. For similar statements see Section 4 of the 1996 Final Report ("A Response to Key Issues Raised in Submissions to the Revised Draft Import Risk Analysis"), pp.325, 327 and 385.

[448] However, answering a question from the Panel at the interim review meeting, Australia stated that of the options set out in the 1996 Final Report, Option 1 comes closest to the measure currently in place.

[449] Para. 8.173.

[450] 1996 Final Report, at p.62: "Option 5 represents the higher end and option 1 the lower end of the risk continuum; the other options lie between".

[451] Ibid., p.70.

[452] Para. 8.175 *in fine*.

[453] Ibid., p.69, also pp.62 and 70.

[454] Para. 8.99.

opinions we received, some disease agents are known to survive heat treatment or even grow when heat treatment is limited to the lower temperatures currently allowed under the 1988 Conditions; and for some disease agents freezing seems to reduce risk to the same extent as heating.[455] Australia's main reason in the 1996 Final Report to not accept the "small" risk related to Options 2 to 4[456], namely that "there is a degree of uncertainty attached to this judgement of the level of risk because of gaps in and inherent shortcomings of the available data", seems, therefore, to apply more to heat treatment (Option 1) than to any of the other options. Indeed, all risk reduction factors proposed by, for example, the 1995 BRS Report (Option 2) have been examined; not only in the 1995 BRS Report itself, but most of them, if not all, also in the 1995 Draft Report (Option 4). Both the 1995 BRS Report and the 1995 Draft Report, on the basis of an extensive examination of data, conclude that imports of the salmon products further examined under specified conditions represent negligible risk and should be allowed. Both reports also question the rational basis of the current heat-treatment requirements.[457] In our view, the above elements suggest (1) that the level of protection currently achieved by the heat-treatment requirement (which has, as we found earlier, not been "based on" a risk assessment[458] is unclear and possibly not as high or conservative as Australia submits and (2) that, therefore, the level of protection which would be met, in particular, by Option 2 (the 1995 BRS Report recommendations), according to the 1996 Final Report posing risk most similar to the measure currently imposed, and Option 4 (the 1995 Draft Report recommendations), both Options having based their recommendations on a thorough scientific analysis, would also achieve Australia's current level of protection (reached by the heat-treatment requirement imposed) and might even exceed it.

8.179 Third, we recall that Australia confirmed that its level of protection for the salmon products further examined remained unchanged between the 1995 Draft Report (recommending that imports of these salmon products be allowed) and the 1996 Final Report (suggesting maintenance of the prohibition). We further recall that Australia has not convinced us of the reasons why this rather substantial change in conclusions reached by these reports occurred.[459] We recall, in particular, that the experts advising the Panel unanimously stated that no relevant new scientific evidence occurred between the two reports which could explain the reversal.[460] If this is true, there would seem to be no reason (i.e., no new scientific evidence) why the recommendations of the 1995 Draft Report (Option 4) would no longer meet Australia's (unchanged) level of protection. On this ground, there would, a fortiori, be no reason why Option 2, according to Australia the most stringent alternative, would not achieve Australia's level of protection.

8.180 Fourth, with respect to what Australia identifies as the most liberal option, i.e., Option 5 which would "[p]ermit importation of product that complies with current international standards", namely evisceration, the OIE expert advising the Panel stated the following:

> "The FDC [Fish Diseases Commission of the OIE] considered this point carefully and is unanimous in the opinion that <u>evisceration of fin fish (e.g. salmonids in this case) provides a very high level of safety against transmission of disease and that none of the notifiable or other significant diseases are likely to be transported with such products.</u>

[455] Para. 8.98.
[456] 1996 Final Report, p.70.
[457] Para. 8.98.
[458] Para. 8.99.
[459] Para. 8.154.
[460] Transcript, paras. 298-303.

> Thus the FDC has judged that eviscerated products fall outside the concern of the FDC".[461] (underlining added)
>
> "The differing health conditions in various member countries (both exporting and importing) are a concern; however, it is impractical to have different recommendations for each country. This is why the FDC has tried to set minimum standards that can be applied worldwide but encouraged countries to engage in bilateral negotiations where there are differences of opinion regarding quality of fish health services, presence of other pathogens of concern, etc. This flexibility, however, extends only to live fish, live gametes, and uneviscerated fish. As stated above, the FDC currently regards eviscerated fish to represent a minimal risk that does not warrant restriction of trade".[462]

Given the repeated reference made in the SPS Agreement to the relevant international organizations, in this dispute the OIE, and the recommendations they produce (e.g., Articles 3.1 and 5.1) [463], as well as to the more general objective of harmonization (e.g., Articles 3.4 and the sixth preamble), we consider that appropriate weight should be given to this opinion on Option 5.[464] However, in so doing we do not endorse evisceration as a measure which would meet Australia's level of protection nor do we disregard the evidence before us in regard to the relative effectiveness of evisceration, depending on the disease concerned and the tissues in which it can be found.[465] Since Option 2 is, according to Australia, still more risk-reducing than Option 5, this opinion *a fortiori* applies to support the contention that Option 2 could, indeed, be said to meet the level of protection actually met by the measure in force.

8.181 On the basis of all four factors outlined above, considered cumulatively, we consider that Canada has raised a presumption that there are other measures available, in particular Option 2 set out in the 1996 Final Report, which would "achieve [Australia's] appropriate level of sanitary ... protection" in the sense of the second element under Article 5.6 and that Australia has not provided sufficient evidence to rebut that presumption. We find, therefore, that in the present dispute the second element under Article 5.6 is fulfilled. We make this finding on the basis of the evidence before us which, in our view, constitutes a presumption - which has not been rebutted - that there are alternative measures available which would meet Australia's appropriate level of protection. Our finding does, therefore, not endorse any of the alternative options we examined. It does not imply that Option 2 would actually achieve Australia's appropriate level of protection nor does it imply that Option 2 would be the only option which could achieve that level.

---

[461] Winton's answer to Panel Question 24, Winton, answers, p.3. See also Winton, Transcript, paras. 100-101, 305, 326 and 43 ("The OIE Fish Diseases Commission has not considered eviscerated fish to represent a significant risk. But I agree with Dr. Rodgers that probably there is no trade that has zero risk ... in our view, as a series of experts and based on our evaluation of the scientific literature, we do not find scientific evidence that such eviscerated products have constituted a risk in the past. Should such scientific data be forthcoming, we would perhaps modify the types of products or the types of diseases and it is a very dynamic process, and we probably will never get it completely right").

[462] Winton's answer to Panel Question 25, Winton, answers, p.3.

[463] Paras. 8.44 ff. and 8.49.

[464] Another expert advising the Panel expressed a similar opinion on the effectiveness of evisceration: Rodgers, Transcript, para. 21: "The question of evisceration is also relevant here obviously. I think that we are all in agreement generally that it is an effective means of reducing the level of risk although the level of reduction would largely depend on tissue location of the disease-causing agent and the effectiveness of the evisceration process. Nevertheless, we do not know of any specific cases where fish diseases have been transmitted from one area to another by imported eviscerated salmonids, or in fact other eviscerated fish, any other species of eviscerated fish". See also Rodgers, Transcript, para. 307.

[465] In this respect, we refer to the general agreement among parties and experts advising the Panel on this issue that some eviscerated product might still contain some of the disease agents of concern, e.g., in muscle, remnant kidney tissue, bone, skin or blood (see, e.g., Transcript, paras. 21, 90, 99-101, 203-204, 234 and 305-307).

(c) an alternative measure which is "significantly less restrictive to trade" than the sanitary measure contested

8.182 We finally address the third element under Article 5.6: the alternative measure needs to be "significantly less restrictive to trade" than the measure contested. Canada argues that all four alternative options set out in the 1996 Final Report are significantly less trade restrictive. In its request for access to the Australian market, Canada examined in particular headless, eviscerated product and advocated that these products could be safely imported.[466] We recall that the measure imposed by Australia (in effect, certain heat treatment requirements) *prohibits* the importation into Australia of fresh, chilled or frozen salmon, including the salmon products further examined.[467] All four alternative options outlined above would *allow* imports of the salmon products further examined, albeit under specific conditions (e.g., the salmon products would have to be retail-ready fillets, eviscerated, headless or gilled, etc...). We consider that even imposing the most stringent of these specific conditions would still be significantly less restrictive to trade than an outright prohibition. As opposed to any of the other conditions, heat treatment actually changes the nature of the product and limits its use. Heat-treated salmon can obviously no longer be consumed as fresh salmon. Eviscerated, headless or filleted salmon, on the other hand, can either be consumed as fresh salmon or cooked salmon.[468] We consider, therefore, that Canada has raised a presumption that all four alternatives outlined in the 1996 Final Report are "significantly less restrictive to trade" than the measure in dispute and that Australia has not rebutted this presumption. We thus find that in the present dispute the third element under Article 5.6 is fulfilled.

(d) Summary

8.183 We have found above that all three elements required in Article 5.6 in order to find a violation of Article 5.6 are present in this dispute. We thus find that Australia by maintaining the measure at issue acts inconsistently with Article 5.6.

6. Canada's claims under Articles 2 and 3: "Basic Rights and Obligations" and "Harmonization"

8.184 Since we have found that the measure in dispute is inconsistent with the requirements of Articles 5.1, 5.5 and 5.6 and is, on that ground, also inconsistent with the requirements of Articles 2.2 and 2.3, we see no need to further examine Canada's other claims under Article 2 nor its claims under Article 3.

E. ARTICLE XI OF GATT 1994

8.185 Since we have found that the measure in dispute is inconsistent with the requirements of the SPS Agreement, we see no need to further examine whether it is also inconsistent with Article XI of GATT 1994.

[466] 1996 Final Report, p.7.
[467] Para. 8.19.
[468] Out of a total of 66,234 tonnes of Canadian salmon exports in 1996, 50,838 tonnes were fresh and frozen salmon; the rest was canned salmon. As opposed to canned or heat-treated salmon, Canada submits that "recent trends indicate consumer preference for fresh and frozen salmon" (Canada, First Submission, para. 31). Australia seems to recognize this when it states that: "For [Australian] farmed Atlantic salmon [the main salmon species commercialized in Australia] supply to both the domestic and export market is predominantly of whole fresh fish" (Australia, Second Submission, para. 58).

IX. CONCLUSIONS

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

(i) Australia, by maintaining a sanitary measure which is not based on a risk assessment, has acted (both in so far as the measure applies to salmon products at issue from adult, wild, ocean-caught Pacific salmon and the other categories of salmon products in dispute), inconsistently with the requirements contained in Article 5.1 of the Agreement on the Application of Sanitary and Phytosanitary Measures and, on that ground, has also acted inconsistently with the requirements contained in Article 2.2 of that Agreement;

(ii) Australia, by adopting arbitrary or unjustifiable distinctions in the levels of sanitary protection it considers to be appropriate in different situations (on the one hand, the salmon products at issue from adult, wild, ocean-caught Pacific salmon and, on the other hand, whole, frozen herring for use as bait and live ornamental finfish), which result in discrimination or a disguised restriction on international trade, has acted inconsistently with the requirements contained in Article 5.5 of the Agreement on the Application of Sanitary and Phytosanitary Measures and, on that ground, has also acted inconsistently with the requirements contained in Article 2.3 of that Agreement;

(iii) Australia, by maintaining a sanitary measure (with respect to those salmon products at issue from adult, wild, ocean-caught Pacific salmon) which is more trade-restrictive than required to achieve its appropriate level of sanitary protection, has acted inconsistently with the requirements contained in Article 5.6 of the Agreement on the Application of Sanitary and Phytosanitary Measures.

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, the action is considered *prima facie* to constitute a case of nullification or impairment", we conclude that to the extent Australia has acted inconsistently with the SPS Agreement it has nullified or impaired the benefits accruing to Canada under the SPS Agreement.

9.2 We *recommend* that the Dispute Settlement Body request Australia to bring its measure in dispute into conformity with its obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures.

ANNEX 1

The Four Comparisons Under Article 5.5

COMPARISON 1	Disease of concern	Disease occurence[469]	Treatment of imports
Canadian adult, wild, ocean-caught Pacific salmon, for human consumption		This disease agent has <u>not been detected</u> in Canadian adult, wild, ocean-caught Pacific salmon[470]	banned
Pacific herring, Cod, Haddock, Japanese eel, Plaice, for human consumption	Aeromonas salmonicida (atypical strain)	This disease agent has been <u>detected</u> in uncooked:[471] Pacific herring Cod Haddock Japanese eel Plaice	 allowed access allowed access allowed access allowed access allowed access

[469] When addressing "disease occurrence" in this Annex, we focus on whether or not the specific disease agent has been detected in the product concerned. We realize that doing so we simplify the comparison and that a better comparison could be made if more data was available. However, according to our mandate, we have to make an objective assessment of the evidence put before us (Article 11 of the DSU). Our approach should, therefore, not be read to imply that risk assessments should be limited to diseases that have actually been detected nor that they cannot take into account evidence related to scientific research.

[470] Final Report, p.136; Canadian answer to original Panel Question 2, p.4.

[471] Final Report, p.138 (wide statement); Australian answer to original Panel Question 3, p.6 (for eel); Australian answer to additional Panel Question 3 of 8 December 1997, p.6 (for all fish products compared).

ANNEX 1 (cont'd)

The Four Comparisons Under Article 5.5

COMPARISON 2	Diseases of concern	Disease occurrence	Treatment of imports
Canadian adult, wild, ocean-caught Pacific salmon, for human consumption	Viral haemorrhagic septicaemia virus (VHSV) Infectious pancreatic necrosis virus (IPNV)	These disease agents have not been detected in Canadian adult, wild, ocean-caught Pacific salmon[472]	banned
Pacific herring, Atlantic and Pacific cod, Haddock, European and Japanese eel and Dover sole, for human consumption		VHSV has been detected in uncooked:[473] Pacific herring Atlantic cod Pacific cod Haddock European eel	 allowed access allowed access allowed access allowed access allowed access
		IPNV has been detected in uncooked: [474] Cod European and Japanese eel Dover sole	 allowed access allowed access allowed access

[472] For VHSV, Final Report, p.45; for IPNV, Final Report, pp.44 and 197; Australia agrees with this in its answer to original Panel Question 2, pp.4-5.

[473] For Pacific herring: Winton, Transcript, para. 236; For Pacific cod and Pacific herring: Final Report, pp.45 and 222; For Pacific cod and herring in general: Australian answer to original Panel question 3, p.7; For Atlantic cod and Haddock: Australian answer to Panel Question 20 put forward at the meeting with experts advising the Panel; For eel: Australian answer to additional Panel question 3 of 8 December 1997, p.6.

[474] For cod, sole and eel: Australian answer to additional Panel Question 3 of 8 December 1997, p.6.

ANNEX 1 (cont'd)

The Four Comparisons Under Article 5.5

COMPARISON 3	Diseases of concern	Disease occurrence	Treatment of imports
Canadian adult, wild, ocean-caught Pacific salmon for human consumption	*Aeromonas salmonicid*a (atypical strain) Erythorcytic necrosis virus	Only IHNV has been detected in Canadian adult, wild, ocean-caught Pacific salmon[475]	banned
Whole, frozen herring for use as bait	Infectious haematopoietic necrosis virus (IHNV) Viral haemorrhagic septicaemia virus (VHSV)	Pacific herring[476]: All four disease agents have been detected[477] Atlantic herring: only Erythorcytic necrosis virus has been detected[478]	allowed access

COMPARISON 4	Diseases of concern	Disease occurrence	Treatment of imports
Canadian adult, wild, ocean-caught Pacific salmon, for human consumption	*Aeromonas salmonicida* (atypical strain) *Yersinia ruckeri* *Edwardsiella tarda*	None of these disease agents has been detected in Canadian adult, wild, ocean-caught Pacific salmon	banned
Live ornamental finfish	Infectious pancreatic necrosis virus (IPNV) *Vibrio anguillarum*	All five disease agents have been detected in Live ornamental finfish[479]	allowed access

[475] According to Canada, IHNV is known to occur in these salmon products (Canadian answer to original Panel Question 2, p.4). However, according to the 1996 Final Report, at p.43, IHNV has only been recovered once and this was regarded as "an unusual event".

[476] See, in general terms, Winton, Transcript, para. 283, answering the question whether one can say without having done a full risk assessment that bait fish represent higher risk than salmon products: "I could make that statement with a high level of certainty for Pacific herring in North America. As bait fish those fish contain a significantly and quantifiably higher incidence and prevalence of infection than do Pacific salmon".

[477] For *Aeromonas salmonicida*: see Comparison 1, footnote 2; for Erythorcytic necrosis virus: see 1996 Final Report, p.43 and p.182 and Australian answer to original Panel Question 2, p.6; for IHNV: see Australian answer to Panel Question 20 put forward at the meeting with experts advising the Panel; for VHSV: Australian answer to original Panel Question 2, p.7, Winton, Transcript, paras. 236 and 267.

[478] Table 6 in Canada's First Submission, pp.79-80. According to Winton, Atlantic herring in the Baltic and North Sea are probably also a major reservoir for VHSV (Transcript, para. 267).

[479] Table 7 in Canada's First submission, p.82 and Australian answer to Panel Question 20 put forward at the meeting with experts advising the Panel. See also Winton, Transcript, para. 267.

ANNEX 2

PANEL ON AUSTRALIA - MEASURES AFFECTING IMPORTATION OF SALMON PANEL ESTABLISHED AT THE REQUEST OF CANADA

Transcript of the Joint Meeting with Experts, Held on 4 February 1998

Chairman

1. Let me first of all begin by welcoming the scientific experts and the parties to this meeting, let me start by informing you that this meeting is being recorded. Therefore, when you take the floor, please be sure to turn on your microphone by pressing the green button. A red light is visible on the microphone when it is on. Equally important, please turn off your microphone when you have finished speaking; this system only permits one microphone to be on at a time. I think there is one other thing in that context, if you could also speak reasonably slowly and clearly because there will have to be a transcript prepared afterwards and it will help to facilitate that process.

2. Now the purpose of this meeting is to permit the experts to expand on their written responses to the Panel's questions, highlighting the main points, and to permit a full exchange of views between the experts, the parties and the Panel.

3. Now I would like to take the opportunity to thank the experts for having agreed to serve as advisers to the Panel, and for having responded within such a short period of time to the Panel's questions. As you know, we do have to operate under time constraints and we must produce reports within certain periods. This puts considerable pressure, not only on use but on you as well and I am grateful to you for responding as you have.

4. For your information, that is to say for the information of the experts, following today's meeting and a second meeting tomorrow with the parties to the dispute, the Panel must then proceed to prepare its report. The first part of this report summarizes the facts of the case and the arguments of the parties and will be provided in draft form to the parties for their comments. An element of this first factual part of the report will be a compilation of your written responses to the Panel's questions, and this will be circulated to you and you will be given the opportunity to make any necessary corrections to this summary of your responses. Subsequently, the Panel must provide first a complete, interim report to the parties and then its Final Report, and we intend to include a transcript of today's meeting as an annex to the report, it will probably appear at the interim or even the final stage because I doubt that the transcript will be ready in time to go out with the factual part, in any case it will appear and will be a verbatim record of what has taken place today. So I thought you might like to be aware of that before we actually launch into the proceedings.

5. Now I must stress that the process of this Panel, the proceedings in the Panel meeting are confidential and everything which is said in this room is subject to the WTO rules of dispute settlement and the Panel's working procedures. When the Panel has concluded its work and a Final Report is circulated to all WTO Members, that report is normally considered to be a public document, including the summary of your responses to the Panel's questions and the transcript of this meeting, so we expect that the Final Report will be circulated in that form in, probably late May.

6. In terms of this meeting, the Panel intends to proceed as follows: I will first give the experts the floor, one-by-one, to make any general introductory remarks which they believe to be appropriate. There is no need to repeat at length what is already in your written responses, but I would invite you to highlight your main points in the areas where you see the most important issues and points of contention. Should you wish to comment on any points made by another expert, please feel free to do so. I would also draw your attention to a number of additional questions that were sent out by the Panel, they were additional to the first round of questions. Perhaps if you could take the opportunity of your opening statements to

address the ones that concern you - they are not all of them for all experts -but please address those which concern you. It would be helpful if you could do that in your initial statements.

7. When this is concluded we will then open the floor open to the parties and begin with Canada. Canada will be given the opportunity to put questions and comments on the experts' views and the experts will then be invited to respond. We would like to take the questions one-by-one in order to ensure an orderly process, but should Australia have any follow-up question directly linked to one that has just been raised by Canada, it would then have the opportunity to raise that question at the same time so that we do not subsequently crisscross backwards and forwards between the subjects - if we get into a subject let us deal with it and dispose of it. Similarly, after the responses from the experts to Canada, Australia will be given the opportunity to raise their questions and comments on experts views. If Canada has any directly related follow up questions, they would be permitted to insert those as well. Again, the experts will have the opportunity to respond to each question as they are raised. Now I would emphasize that it is really up to the experts how they respond to these questions, this is not an interrogation or court of law, they should feel relaxed about it and obviously offer their expertise as they see fit. I have to say that my experience with these sort of sessions in the past, has been that they have been conducted very satisfactorily from the point of view of the expert advice, there is no real, no element of interrogation in any way.

8. That said, the primary focus today, is the discussion with the experts and I would ask the parties to refrain from the sort of statements and re-battle arguments which they will have the opportunity to deliver tomorrow. Tomorrow, however, will be the final opportunity for submissions from the parties but today the priority is to give time to the experts and the scientific factual issues under discussion with them.

9. Subsequent to the interventions of the parties, the Panel may wish to raise some further questions or seek some further additional clarification, and finally, I will give the experts an opportunity to take the floor again individually for any final statements which you may wish to make, so that you may stress what views and conclusions you consider most important. I would ask all of you, both experts and parties to try and be as succinct and to the point as possible and to avoid, for example any lengthy repetition of what has already been submitted in writing. So, with these remarks, I would now turn to the experts themselves, they are identified by name-plates and I will name them as I give the floor to them. I would ask, when we get to the parties, if whoever is going to speak from the parties would identify themselves, would introduce themselves as they take the floor, not just only for the benefit of the experts and ourselves but also so that we can identify them for the purpose of the transcript.

10. That said, unless there are any questions on procedure, I would propose now to invite the experts to take the floor. I will offer it to them in alphabetical order for want of any other basis, so perhaps I could begin by welcoming Dr. Burmaster to this meeting and to invite him to take the floor.

11. If you which to make a presentation or make use of the slide machine there is a portable microphone, but if you do not then please you will find it is better there.

Dr. Burmaster

12. Good morning and thank you it is a great pleasure to be here this morning and I must say that this is my first such experience so please bear with me as I work along to assist the Panel as best I can. I guess I have one or two comments only that I would like to make now, to supplement my written statement from last November.

13. The first is that I said in November, and I continue to say now, that a risk assessment for this type of issue, I believe should be done in quantitative fashion; that it should involve a numerical calculations as best as is known and with stated uncertainties. At its heart, I believe a risk assessment should be conducted with numerical arguments and to persist on that, I would think that it would use probability distributions and those probability distributions could take a number of different forms - there is no unique correct way to do this style of analysis - but I do believe that however one put together the information that it would include probabilistic descriptions of the variability of what we do know about events and the nature of fish diseases and transmission of fish diseases and so on. It should also somehow state

numerically as best as possible the degree of certainty or the degree of uncertainty in human knowledge associated with those calculations. I have been asked from time to time what would be the minimal, the minimum requirements of such a risk assessment and coming as I do from the United States, I would say that we, in the United States, have adopted a sort of generally, a four step process for risk analysis. The first step would be hazard identification, the second would be dose response assessment, the third would be the exposure assessment and the forth and final step of the risk assessment would be risk characterization. Typically, in the States, the hazard identification step is done qualitatively; one identifies the nature of the problem and in this instance what diseases might occur and what species of fish may be susceptible to those diseases. That would be a discussion qualitative in nature. But then, and the remaining steps, dose response assessment, exposure assessment and risk characterization, those steps would all be quantitative steps done with numerical calculations to display the probabilities of occurrence, the probabilities of dose response, the probabilities of exposure and the probabilities of risk characterization. That would conclude the risk assessment steps and then to go on, there would be additional steps: risk communication and risk management steps such as you and other risk managers might undertake.

14. On the second question that came up, here we have, in this situation, multiple fish diseases, potentially multiple fish diseases and potentially multiple target species of fish. The question has arisen if there are ten diseases of fish - ten different diseases - and five different fish species, to make up a hypothetical argument, do we have to multiply those and do fifty, ten times five, different risk assessments? I think, as a practical matter one need not have to do fifty different risk assessments. I think that there are ways to sort through that, it may be that you would have to do one or two or smaller number of risk assessments not a full number of fifty. Let me stop there and thank you.

Chairman

15. Thank you very much Dr. Burmaster, let me now welcome Dr. Rodgers and invite him to give his opening comments and you have the floor Sir.

Dr. Rodgers

16. Thank you Mr. Chairman, I will be a little more expansive than Dr. Burmaster, because I think my particular background expertise involves fish diseases, fish disease transmission and prevalence so there are some relevant points to make in these sections. But before I make some comments, I would like to thank the Panel for the opportunity to address them and also I hope so far my answers have proved useful to them in their understanding of the background to the case. I personally found it a fascinating exercise which at times for me has been both difficult and frustrating. Not necessarily because of the nature of the problem but certainly the 20 kilos or so of paper which arrived on my doorstep to evaluate and assess, which is almost one kilo for each year of the dispute, which is not too bad going really.

17. My own answers to the questions posed for the experts have tried to clarify any contentious points, if you like, within which is a very complex scenario. I have also tried to be non-technical where at all possible using fact to support my own personal opinion, which again, I hope has helped the Panel so far. Consequently, I think my answers and possibly those of the other experts should be taken as a whole and not taken out of context and dissected down into phrases because as I say it is a very complex situation we find ourselves in but, having said that, I recognise that in certain cases it is almost inevitable that phrases are taken out of context. With hindsight, I particularly enjoyed answering questions such as eight and fourteen because at the end of the day both parties seem to agree that my answers were supportive of their own particular stances so that puts me in a better position today.

18. I will try to summarize the answers that I have already given by making some general comments related to selected relevant points, as I see them, perhaps some of the more important points, while at the same time responding to the supplementary questions which were sent to us some weeks ago. Although I will not necessarily name the supplementary questions by number. The original sections were divided -the original questions rather - were divided into three sections, those related to risk assessment procedures, fish diseases, transmission and prevalence, and also the OIE procedures. I will deal with them in traditional reverse order because I did not attempt to answer the OIE section at all, because I did not really have

enough working knowledge of the OIE to comment. I also do not propose to dwell too much on the section concerning fish diseases because the responses from the parties were largely in agreement with some, what I would call minor, exceptions, although they themselves may not agree that the exceptions were minor.

19. Essentially though, what I would say about the disease section is that the most accurate up to date information concerning disease prevalence in an exporting country is usually held by the exporting country itself, providing that country is of course recognised as a competent authority. In this case of course, Canada has a well respected monitoring system in place for this type of situation. The degree of scientific confidence in disease detection with existing methods relies really on the lowest limits of detection of each particular test, or series of identification methods. However, this can lead to difficulties in isolating certain fish viral pathogens and also certain bacterial strains. In addition there is a cut off sensitivity point for most diagnostic methods which leads to the carrier state in particular being difficult to detect, except with the most sensitive methods that are available. Nevertheless, any deficiencies in sensitivity for existing methods are generally accepted by the scientific community both in terms of the supportive science and also by the legislative policies that actually stipulate their use in regular surveillance programmes. It is also true to say that regularly tested stocks are normally considered as a lesser risk than occasionally or untested stocks, since regular monitoring will provide a background database if you like, of information over time. However, post harvesting testing for disease in fish, tested for human consumption is very rarely undertaken at all.

20. As far as actual disease transmission is concerned, this of course combines many biological, behavioural and environmental factors which are interrelated - we cannot get away from that fact. As such, the epidemiological factors relevant to disease transmission would not necessarily be the same for each disease since they are complex and numerous, although the general aspects would be common. Perhaps the most relevant factor to my mind, in this particular case is the introduction of potential pathogens into an already stable environment. Since the natural balance of an indigenous fish population could be altered perhaps irreversibly, this is one factor which perhaps is overriding in this particular case of transmission. However, having said that, there is a generally accepted lack of information about the occurrence of fish diseases in wild fish and the potential interactions between wild fish and the mechanisms of disease introduction themselves.

21. The question of evisceration is also relevant here obviously. I think that we are all in agreement generally that it is an effective means of reducing the level of risk although the level of reduction would largely depend on tissue location of the disease-causing agent and the effectiveness of the evisceration process. Nevertheless, we do not know of any specific cases where fish diseases have been transmitted from one area to another by imported eviscerated salmonids, or in fact any other species of eviscerated fish.

22. Also the post-harvest organoleptic examination for grading purposes should remove unsightly looking fish such as those which may have ulcers or extensive haemorrhaging or some sort of superficial damage. These conditions could occur as a result of disease, although again, carrier subclinically infected fish could still remain after such an examination.

23. Now, I do not propose to comment any further on the consequences of disease entry because I think in general again we are in agreement as to which main step-wise criteria need to be fulfilled for this to happen. However, we should bear in mind that early detection of disease entry and subsequent eradication following any disease establishment would be very difficult in any country. The only supplementary question which does not fall easily within the three main sections that the original questions were divided into was directed specifically at myself, which basically asks what is "steelhead trout" or "rainbow trout", so if I may I will deal with it at this point before I move on to the risk assessment section. Essentially steelhead trout and rainbow trout are salmonids *not* salmon and they are the same species, that is they are *Oncorhynchus mykiss*). There are some salmon within the same genus of *Oncorhynchus* but they are true salmon such as coho salmon and sockeye salmon. The main difference between steelheads and rainbows is their ability to migrate. The steelhead trout is the *anadromous*, migrating fish compared to the rainbow trout which is the non-*anadromous*, non-migrating equivalent. These fish were originally

placed in the genus *Salmo* as the Atlantic salmon still are, but rising taxonomic evidence, if you like, in 1989 led to the change being made because these fish were considered more closely related to the *Oncorhynchus* genus than the *Salmo* genus which contains more Atlantic European species, and at that time all specific drainage trout were placed into the genus *Oncorhynchus*.

24. That brings me to the final section, which is perhaps for us as experts the most contentious section on risk assessment procedures, and in particular, the comparison between the two reports as presented to us. For me the 1996 Final Report is generally less specific than the 1995 Draft Report. It is also more confusing in layout but includes the product of a communication exercise which the Draft Report does not. In fact, we are led to believe it was never within the original remit of the Draft Report to contain a risk communication exercise. Neither report can be classified as a quantitative risk assessment exercise, but the Draft Report, for me, is a clear qualitative assessment of importation risks. Although both reports largely rely on interpretation of the same risk assessment data, the Final Report reaches a different risk analysis conclusion which is a result, for me, of public consultation. In general, the 1995 Draft Report is acceptable for me and meets the minimum requirements as a qualitative risk assessment.

25. As far as the 1996 Final Report is concerned, of course it is based on the earlier Draft Report, that was the intention, and also includes the results of a risk communication exercise which should make it equally acceptable. I think we have the luxury, if you like, of being able to compare the two reports and when you do, there does, for me, appear to be something lacking in the Final Report which is surprising because, following the 1995 Report it should have all the basic elements in place. This missing element seems specifically related to its clarity and its detail and the underlying methodology which almost appears to be a straight forward literature review without conclusion.

26. To be honest, I got completely lost in the Final Report looking for sections which were possibly out of place and this, in my opinion, makes it less transparent then the original Draft Report. It assesses risks on a disease-by-disease basis but in a textural form and does not assign any probabilities that would be needed to reach a conclusion. In this respect, therefore, I think, it possibly does fall short of determining any probability based on the information available. This concept of probability is embodied in OIE guidelines which indicate that the risk factors should be used to estimate the probability of an adverse event occurring with point estimates of probability distributions, employed to represent the values either quantitatively or qualitatively.

27. Therefore, taken alone without reference to the Draft Report, it is probably not acceptable overall as a risk assessment exercise, although it does include more components. There seems to have been a change in style, content and approach in the Final Report following the risk communication step. I personally think this has devalued the report as a whole, which is after all supposed to be the published face of the whole analysis process.

28. If you are concerned with several diseases, effectively the risks are identified by drawing up a list of the potential diseases of concern that would be associated with the importation of a particular fish product, followed by an examination of the consequences of their entry and establishment. Now, although many risk factors are common between different diseases, each disease may have unique factors to consider and each of these will have a variable quality and quantitative of available data that will need to be dealt with separately, which does make it necessary to assess risks on a disease-by-disease basis. But following on from what David Burmaster said, of course you might be able to analyze a higher risk disease in order to arrive at an answer, rather then having actually to look at every individual disease in turn.

29. So where does all that leave us? I got a little confused, and its probably relevant at this point to make an overall summary, purely from a scientific point of view, as I see it. This means effectively that we can now bring in the 1997 risk assessment which was submitted by Canada, that uses a quantitative method to consider the data already available in 1995 for the two most serious diseases of concern, namely those caused by *Aeromonas salmonicida* and *Renibacterium salmoninarum*. To illustrate the point, we fortunately do not have to look, in my mind, into greater depth at the report because we could be here until tomorrow, but rather look at the overall conclusions of the various reports following the various risk assessment components. Here I will read, I am sorry, I will have to quote from the various reports.

30. In the 1995 Draft Report AQIS concludes that "wild, ocean-caught Pacific salmon from Canada and the USA that have been eviscerated and had their heads removed, when consumed in the domestic or restaurant setting, are considered to present a negligible risk of disease introduction and establishment". It also states that "it is considered extremely unlikely that the importation of headless, eviscerated, wild, ocean-caught Pacific salmon would introduce infection into Australian fish populations" (and here it is referring to *Aeromonas salmonicida* in particular), and that "the risk of disease introduction is acceptably low, having regard to the potential serious consequences of such an event".

31. In the 1996 Final Report there is a reference which says "there are risks of exotic disease agents occurring in salmon products; however, the risk of establishment of an exotic disease is low if suitable risk management interventions are made".

32. In the 1997 Canadian Risk Assessment (the so-called Vose Assessment), there is a statement which says "the risk of native salmonid infection with *Aeromonas salmonicida* or *Renibacterium salmoninarum* from Canadian salmon is exceedingly small" and that "the information available to Australia at the time of writing their reports was sufficient to enable them to conclude that the furunculosis and BKD risk posed by Canadian salmon must be considered negligibly small" there is also a final statement which says "head-on and heads-off, chilled and frozen eviscerated Canadian ocean-caught Pacific salmon all present negligible risk of disease introduction".

33. Now for me, I take it to mean that all these reports actually reach a similar scientific conclusion, unless negligible in one report refers to a different level of risk in another report, which is quite possible, I do not know whether Marion Wooldridge or David Burmaster can comment at a later stage on the difference between phrases such as "negligible", "extremely unlikely", "acceptably low", "low", "exceedingly small" and "negligibly small". The interesting thing is that both the original qualitative 1995 AQIS Draft Report and the quantitative 1997 Vose Assessment use the same concluding phrase, "negligible risk". What neither of them have is risk communication.

34. The problem for me seems to be the change in emphasis and conclusion in the 1996 Final Report, which seems to consider the scientific advice but then reaches a political decision, following public consultation, as I have said. Now the OIE revised guidelines state that the importing countries shall decide whether the risk determined in the import analysis is acceptable or not, but that the importing country must be prepared to justify their decision. The question of scientific advice versus final political decision, for me, is a very difficult one to address, since the existence of risk, irrespective of the level, may be ultimately unacceptable.

35. The SPS agreement includes the requirement to undertake a risk assessment in these circumstances by stating "the measure be based on a risk assessment, as appropriate to those circumstances, and that the risk assessment takes into account the techniques developed by the relevant international organizations", which for aquatic animal health, is the OIE. In their relevant recommendations at no time is there a requirement to undertake a quantitative exercise. The OIE state that "a risk analysis must be able to deal with the complexities of real life situations and that no single method is applicable in all cases. For this reason, countries wanting to conduct import risk analysis may find it necessary to design their own methodology or their own process for carrying out such an exercise".

36. In summary, from a purely scientific point of view, I agree personally with the AQIS recommendation in the 1995 Draft Report based on a qualitative exercise. I also agree with the disease summaries of the BRS Review and the most recently commissioned quantitative exercise from Canada, which taken together accept that there is a risk and that risk is "low", "exceedingly small" or "negligible" which ever phrase you want to use. There appears to be no argument that a risk exists, none at all. But the key fact for me, is *not* whether the risk assessment exercises should be qualitative or quantitative, or even whether one report is better than another, because at the end of the day, using similar phrases they all reach a similar conclusion. For me, the key fact is what you do with that information that identifies a certain level of risk, the next step if you like, which in this case, identifies a negligible level of risk. The final decision, after a risk communication exercise which considers additional factors, is going to be a political decision, not a scientific decision. That decision can agree or not with the scientific advice, which

identifies as I have said a certain level of risk. Whether that risk is then acceptable, following socio-economic and internal political considerations (to which, fortunately, in this case I am not a party), is not really for me today to say. What I would say though is that additional fears about the acceptability of such a low level of risk should be allayed by considering a series of risk reduction factors. But those risk reduction factors should be accepted by both parties. In this way, the application of such a series of measures may demonstrate that the extent to which risk is reduced is sufficiently great that an accurate assessment of the initial unrestricted risk is unnecessary and here again I quote from the OIE manual. For me, risk assessment is a piece of the process that helps decision makers arrive at a final conclusion, is not an answer in itself.

37. That is all I would like to say except to finally conclude by congratulating both parties on their presentations because analysing and finding the necessary scientific information for this exercise is not easy. I know from experience how difficult it can be, and I would make a plea if you like for them, as the New Zealanders have done to a certain extent, to make that information available following the Panel decision, irrespective of what that decision is, for everybody, because it is extremely valuable information that should be used, possibly through the auspices of the OIE in some way, for anybody else coming after to help support subsequent risk assessment exercises. Thank you Mr. Chairman.

Chairman

38. Well thank you very much Dr. Rodgers, perhaps I could continue now with the order and turn the floor over to Dr. Winton. You have the floor.

Dr. Winton

39. Well I would like to begin by thanking the Panel for the invitation to attend, I have found this a very interesting exercise. I would also like to state that both parties in this dispute, I regard as friends and I have scientific colleagues in both countries and the amount of effort and time that has been expended is substantial and I second Dr. Rodgers comments that a lot of very good information has been generated in this exercise. I tried to restrict my comments to that of the OIE Fish Diseases Commission for two reasons: partly because I consider this to be a dispute among friends and not to take sides, but secondly because Dr. Blancou the Director-General of the OIE, feels that the OIE should be impartial in these matters and so I have tried to restrict my comments pretty much to areas in which I believe the Fish Diseases Commission has some role.

40. First of all, the Fish Diseases Commission of the OIE and the OIE itself is not necessarily the repository of all information or all judgement on these things. We do not, in fact, sit in judgement, we gather information to the best of our ability through a network of colleagues, reference laboratories and friends, but much of the information generated by both parties and by Dr. Rodgers has been useful to us and we are in the process of learning about this ourselves. We found several of these exercises to really be quite in advance on what we estimated risk assessments might be in the areas of fish diseases, because the Fish Diseases Commission has adopted very much the risk assessment approaches drafted by the OIE itself for large animals and Dr. Wooldridge can comment more about that. But it is an evolving area, it is an area where new scientific information is required in order to develop quantitative assessments, if you do not know survival curves of pathogens, it is difficult to estimate some of the factors that have to go into a quantitative risk assessment, and certainly the OIE recognizes that.

41. The Fish Diseases Commission has, as I said, adopted the approach of the OIE and that is that a risk assessment should be the method by which disputes can be resolved between parties, particularly in the case here of the fish disease. We generally had imagined that such risk assessments would be quantitative to maximum extent possible, and I think, as Dr. Rodgers and Dr. Burmaster have indicated, this is possible. I think the New Zealand and to some extent the Australian and certainly the more recent Canadian reports have gone a long ways towards showing what can be done in the areas of risk assessment.

42. The Fish Diseases Commission has not tried to address every possible disease risk between any possible trading partners because virtually every case has unique elements. Those unique elements have to do with the species in the exporting and the importing countries, the volume of trade, the type of product that might be in trade, etc. But what the Fish Diseases Commission has tried to do is to establish a group of diseases for which there is general agreement that these are significant diseases in worldwide trade. The Fish Diseases Commission has also imagined that the most significant areas of risk involve live fish, live gametes and secondly, uneviscerated products.

43. The OIE Fish Diseases Commission has not considered eviscerated fish to represent a significant risk. But I agree with Dr. Rodgers that probably there is no trade that has zero risk. I think as Dr. Burmaster and Dr. Wooldridge have pointed out, you have a balance between benefits and risks, the only no risk option is no trade. So if there is going to be trade, you can always construct some scenario by which some agent might pass. In an effort to balance this, the Fish Diseases Commission has created a list of Notifiable Diseases which we believe there is general agreement on and a method, or set of standard protocols by which certifications can be obtained for international trade to proceed, primarily in the case of aquaculture products. Outside of that sphere, is a huge grey area which includes the dispute here in question, wild fish or eviscerated fish. For that the OIE Fish Diseases Commission has really not much to say other than, in our view, as a series of experts and based on our evaluation of the scientific literature, we do not find scientific evidence that such eviscerated products have constituted a risk in the past. Should such scientific data be forthcoming, we would perhaps modify the types of products or the types of diseases and it is a very dynamic process, and we probably will never get it completely right.

44. In response to some of the questions then about the Fish Diseases Commission and detailed minutes, etc., and how this body works there are five elected members of the Fish Diseases Commission. We are often joined by one of two experts, Dr. Beers for example attended, I think two years ago one of the sessions and we appreciated his input at that time. We try to invite experts periodically to provide input in areas in which we think we are weak. We are admittedly weak in areas of risk assessment and we rely on the OIE and other authorities such as we have here with us to provide guidance in that area. We are also somewhat weak in areas of crustacean and shellfish diseases and we will invite experts to assist us in some of these areas. But we do have a large network of reference laboratories and colleagues to provide that information. We do not keep detailed minutes of our debates and consultations, they are essentially a consensus agreement, if the five members do not agree, we simply do not do anything for a while until we do agree or we get new information. The minutes that we do provide are somewhat summary in nature and are presented to the general session at which each member country has a voting delegate. So we serve really as a technical body to the OIE itself.

45. I think that ... understand that the OIE Fish Diseases Commission as a subgroup of the OIE is developing essentially as we go and I think this dispute actually has been very informative to us. The OIE code and manual for terrestrial animals and animal diseases has been around for quite a while. Over twenty years ago this approach was imagined to be extended to aquatic animals for which trade was increasing and the Fish Diseases Commission was created. Until the GATT Treaty, the Uruguay Round of GATT, the OIE was not given as much authority in these issues. But following the Uruguay Round of GATT OIE was seen to some extent as a reference body and the Fish Diseases Commission was increased to five members to increase its geographic distribution and to some extent its expertise. We do not represent geographic areas per se and certainly not countries, but we assemble information on the epidemiological situation in various parts of the world and for that some geographic input is important. Certainly we could use experts from other areas of the world including Australia or New Zealand. Presumably our network of reference laboratories, of which we have two in Australia, are important sources of information.

46. I think that I can comment on one or two of the additional questions that the Panel has raised. Dr. Rodgers has expertly answered the question on salmon and steelhead. This is an areas that is of a little bit of debate, the geneticist will tell you that all members of the genus *Oncorhynchus* are probably closely related, but by convention Pacific salmon are really those traditional species of Pacific salmon that migrate to the ocean and that the rainbow trout, the *anadromous* form, the steelhead, is seen as a trout, to some extent, so it is in fact a salmonid but perhaps not a Pacific salmon in most people's general agreement.

47. To the other questions, most of which involve risk assessment, I would certainly defer to Dr. Wooldridge or Dr. Burmaster. The 1996 Final Report of Australia, in many ways took into account some of the risk assessment techniques developed by the OIE in that this is an evolving process. We imagined that a risk assessment might be necessary, but in fact the OIE right now is moving along and refining and adapting its techniques, and in fact I think has gone quite a ways farther then some of us who are not familiar with risk assessment methods might have imagined. To that extent, the 1996 Final Report, as Dr. Rodgers I think mentioned, falls short of a quantitative assessment, one that Dr. Burmaster perhaps had argued for. Yet I certainly acknowledge the fact that there are large gaps in the scientific information by which a quantitative risk assessment can be fully done. But I think that the New Zealand Report and perhaps some others have made a good effort given the existing scientific information of trying to quantify those risks, and whether the probability is one in a hundred thousand tones or one in fifty thousand tones, I am sure there is some margin of error. But the idea at least that you can begin to assess probability estimates, I think is important and I think that all of us will be looking towards that approach in the future. At that point I think that will conclude my comments.

Chairman

48. Thank you very much Dr. Winton. Perhaps I could now invite Dr. Wooldridge to take the floor.

Dr. Wooldridge

49. Good morning, thank you very much for inviting me here. I would like to just first of all say I think I have got friends in both parties here, so I reiterate some of Jim Winton's comments. What I have tried to do is look at this with an unbiased approach and actually look at the methodology that has been used. So first of all I am going to go through a few comments, a brief summary of what I think about this, and then I am going to specifically focus on the questions, the additional questions after that.

50. First of all I must apologise for having labelled my written answer to question 17 as an answer to question 16. However, it appears that this was realized by all parties and therefore caused no major problems.

51. I then spoke about the terminology in my original written report and I think that what David Burmaster has said does show that there are different terminologies in use. But I will just reiterate the terminology which I am coming from again, which is that a risk analysis comprises hazard identification, risk assessment, risk management and risk communication. A risk assessment may, in my opinion, be a either qualitative or quantitative, but either way the essential components are: identified and defined hazards and identified and defined unwanted outcomes, a clearly set out and biologically feasible pathway or sequence of events from the hazard of interest to the unwanted outcome for which the risk is being assessed, and information to assess the *probability* of the steps in the pathway occurring, from which can then be assessed the overall probability of the outcome occurring. In addition, all information must be referenced, and the whole assessment transparent.

52. In my opinion, it is not simply enough to demonstrate the *possibility* of an outcome occurring, as I said in my written report and as Jim also reiterated, I think you can always find a feasible way in this question, at any rate, of the possibility occurring and that I do not believe is enough.

53. Just a few words here on the OIE guidelines, which I did in fact refer to, I did mention in one of my answers, which I think was to question 29. They are currently undergoing a rewrite as many of you will probably know, and because I was actually involved in that rewriting, it was a little bit difficult for me to separate out what the original guideline said and what I knew was going to come up very soon. There are in fact, many areas which are similar and one is that quantitative assessments are not required in either the original or the new guidelines and that once you have assessed the risk then the acceptability of that risk does depend upon local factors which then need to be highlighted and brought out when trying to decide what the appropriate risk management strategies are. Basically, the draft guidelines for risk analysis and risk assessment coming out from the OIE hope to reflect the best methodology currently available, which means that it will always be to a certain extent out of date unless it is rewritten all the time

and my own personal feeling is that we do not and should not use outdated technology and methodologies simply because they are in older guidelines if we can actually demonstrate an improvement on those methodologies and that would be in fact, an argument for changing the guidelines, which is what is happening.

54. Anyway, to go back to the question in hand here, in my opinion, the Draft 1995 Report fulfils these requirements of qualitative risk assessment. It contains a clearly set out and transparent qualitative risk assessment. The Final Report is the result of the process of risk communication. In my opinion, the process of risk communication has two major functions relevant here: (i) to uncover errors in the factual information used, and (ii) to gather opinions on the level of acceptable risk amongst all those concerned. Factual changes may affect the assessed or scientific risk, that is the probability of something actually happening. Opinions will not - or at least they should not, in a well executed risk analysis -affect the assessed risk, they should be used only in management decisions as to whether assessed risk is accepted or not, and that is a value judgement depending upon local requirements and conditions. The two issues should be clearly separated, so that the accepted risk can be agreed - or challenged, if necessary - and the issues relevant to the locally acceptable risk level can be understood, and modified be negotiation, if necessary.

55. In my opinion, the Final Report, also qualitative in nature, is far less clear or transparent than the Draft. Like Dr. Rodgers, I had difficulty in differentiating between the various parts in it, in particular between assessed and acceptable risk, and the effect risk communication had on these two different things. In particular, the Final Report does not make clear where any factual errors in the Draft may have occurred which may have altered the assessed risks. And since it came to the opposite conclusion to that in the Draft, this clarity for any factual changes is essential. It is very difficult to see from this whether different conclusions to an adequate assessment would be valid. However, since it looks only at the possibility of the unwanted outcomes of infection and disease importation, rather than the probability, in my opinion, it does not in any event fulfil the essential requirements of a risk assessment. As I said in my written report, I am not a fish pathologist or a fish expert in any way and so I am unable to assess whether the data given to assess the risks is accurate and complete. As I stated, this will affect the final outcome and the final conclusions from either assessment and this is where Dr. Rodgers and Dr. Winton actually have a far greater input.

56. I initially stated that a risk assessment may be qualitative or quantitative and that a quantitative assessment is often initially undertaken. Now, and I also said that frequently you can not do a quantitative assessment based on two reasons. Partly the fact that often you would not have the data to actually complete it satisfactorily, but I also put the corollary on that, that when you start doing one you often find that there is a lot more data around then you initially thought. Secondly, very often because time constraints and requirements for action dictate that in the given circumstances a qualitative assessment, which is generally much quicker, is the thing that is required or the only thing that can be done. There is a third reason too, and that is that if you actually do a qualitative assessment more rapidly, and everybody agrees with the result, there is actually no point in carrying on and doing a quantitative assessment, and mainly this is where, if one concludes that an assessed risk is negligible, from a qualitative assessment, and this assessment is agreed as being correct, and if, in addition, all concerned also agree that this negligible level is acceptable, then there is unlikely to be a requirement for a quantitative assessment. Now, from this point of view, it really does not matter what people mean by negligible if everybody says "yes it is negligible and we are happy with that" then fine - nobody is arguing, there is no dispute and there is no problem. The problem, of course, does come when there is a dispute and people do wonder what is meant by 'negligible', and yes, it does mean at lot of different things to a lot of people which is why, when I get to my summary, I actually advise that one way around that is to carry on with a quantitative assessment.

57. Anyway, where it is not the case that everybody has actually agreed on a decision that there are negligible risks, or where further demonstration of a low level of probability is required, as I say, a quantitative assessment is in my opinion the next obvious process to attempt. This is what New Zealand have done, and I cannot actually see any reason Australia did not *attempt* to undertake the same kind of assessment - selecting the disease which, qualitatively they assessed as the most risky in their Draft Report. In my opinion, as I have stated in my written evidence, the basic New Zealand method and much of the

data is equally applicable. In addition, and more importantly the attempt to undertake a quantitative assessment, whether you get all the data or not, and whether you can in fact feed everything into to the model and come out with a quantitative answer, clarifies your thought processes, and will, as a result, highlight those specific data inadequacies if and where they exist. This also helps to remove the subjectivity of a qualitative assessment and separate clearly the issue of assessed risk from acceptable risk.

58. In summary, I do not accept Australia's contention that it is impossible to attempt to undertake a quantitative assessment in this situation. In my opinion this is the obvious way forward. The specific method used to estimate the probability of the unwanted outcome can then be examined completely separately from the issue of whether that probability is acceptable or not. One example of this is the David Vose risk assessment, one could do a separate risk assessment if that was felt appropriate. It seems to me that it is the obvious way to go forward when any dispute of this sort arises, is to attempt to actually clarify everything through stages by doing this quantitative assessment, which I would say is the next obvious step.

59. I will just now go through the answers to the specific questions that came up this last week. Questions 1, 2 and 3 on that paper were either not addressed to me or not in my field. Question 4: Section 2 of the 1996 Final Report describes, with references, the diseases it considers relevant on a disease-by-disease basis, with a summary of the information given. However, in my opinion these summaries do not attempt to estimate the probability of importation of infectional disease. They therefore do not meet my minimum requirements for a risk assessment.

60. The individual diseases are also considered in the Final Report in Risk Analysis Factors, Section 1.4.2, page 37. This format seems unnecessarily repetitive and confusing - well I was confused anyway - re-iterating much of the same information that was given in section 2 but this time unreferenced. For 19 of the 25 organisms listed, the conclusion after considering the disease and some potential safeguards is worded along the following lines: "Because of gaps in the information base, there remains some uncertainty about how effective this (or these) treatments would be in practice." Again, this does not meet my minimum requirements for a risk assessment (see my original answers: that in my opinion is not enough to demonstrate only the possibility of an unwanted outcome).

61. In my opinion, therefore, the Final Report has not assessed the risks on a disease-by-disease basis, although it has categorized information on a disease-by-disease basis. Just to illustrate the difference between the disease-by-disease sections in the Draft (May 1995) and the Final Report in December 1996, I will just compare the sections on *Renibacterium salmoninarum* . The Consideration (Section 4.2.8, page 75) in the Draft concludes that: ".... it is very unlikely that titres of bacteria present would be sufficient to cause a disease outbreak". I cannot find any comparable conclusions in the Final Report Summary (Section 2.4.9, page 162) nor in the Risk Analysis Factors Section on *Renibacterium salmoninarum* (Section 1.4.2, pages 41-42) either agreeing or disagreeing with that conclusion. I cannot actually find a conclusion based on the information at all, not in the obvious places to look.

62. However, just to highlight the subjectivity and the problem with a qualitative assessment, I would like to just make another little point which compares two parts - the Draft and the Final Report. There is an interesting and important difference in the wording on environmental survival of the particular bacterium Renibacterium salmoninarum. The Draft Consideration states that: "Renibacterium salmoninarum does not survive well in the environment..." whereas the Final Report Summary states that: "The organism (Renibacterium salmoninarum) has potential to survive in the environment for significant periods." Checking the data and the reference given, these conclusions in both cases appear to be derived from the same reference: Austin and Rayment (1985), Journal of Fish Diseases Volume 8, pages 505-509. I think this illustrates as well as anything, the potential problems with, and potentially subjective nature of a qualitative risk assessment. The bottom line there is: if you do a qualitative assessment and you cannot get to an agreement, I think you are then forced to proceed down the route of attempting a quantitative assessment.

63. Question 5. This question appears to be asking whether, in an import risk analysis, there is a requirement to assess risks using each of the different potential risk management option being considered.

Risk management options generally involve the putting in place of risk reduction measures, otherwise called safeguards. The baseline risk assessment would be one with no safeguards, and it is sometimes appropriate to assess this risk. Often however, some safeguards are integral to the initial risk assessment as they are either already in place (for example, existing legally required testing regimes), or would be incorporated automatically into the risk pathway in question (for example, the safeguard of cooking, if estimating a risk from a cooked product only).

64. In an import risk analysis, if the assessed baseline risk, or the risk with current regulatory or "usual" safeguards in place was considered acceptable to the importing country, there would be no requirement or need to assess any further scenario. Only if this baseline or initial risk is unacceptable would one need to go further. If, in such a case, there are additional safeguards identified which are considered practicable to employ, then in my opinion, it would be necessary for the importing country to assess the risks with the most stringent practical combination of these in place, and demonstrate that the risk were still unacceptable, in order to refuse imports. Whether it is necessary to assess intermediate combinations of safeguards separately depends on the precise problem being addressed.

65. For example, suppose import-risks of fresh whole unchilled unprocessed uncooked carcases of animal X into country Y are assessed and the result considered to represent an unacceptable risk. Then it may be that the removal of offals would be adequate to lower the risk to an acceptable level. But if offal removal is *always*, and here I mean always undertaken, for example, in conjunction with deboning and smoking then there is no point in assessing the effect of offal removal in isolation (unless you are actually testing out a risk with a new product). An assessment with the three processes included would be the appropriate one here, but, if more than one completely separate sets of safeguard options are available, practicable and mutually exclusive then in my opinion an assessment of all those sets of options is necessary in order to demonstrate that there is no method of reducing import risks to an acceptable level.

66. Question 6 was not actually addressed to me but I will just comment on the wording of the question. In my opinion the OIE has advised that certain risk assessment techniques are used, however, these techniques were developed by others rather than the OIE developing the techniques itself, they are more concerned with publishing and collating those techniques. That is all I have to say at the moment. Thank you.

Chairman

67. Thank you very much. I think before I invite the parties to participate, perhaps it would be useful if I could just invite the experts again to, well, let me ask them if they wish to respond or follow-up on anything that has been said so far. There were one or two specific points that were put to each other, for example, Dr. Rodgers on "negligibility", which has already been responded to by Dr. Wooldridge, but I think it was also addressed to Dr. Burmaster, so I do not know whether any of you want to say anything more to develop any points or to respond in any way at this stage. Dr. Burmaster.

Dr. Burmaster

68. I have no further comments now.

Chairman

69. Right, then in that case lets go on to the parties and, as I said earlier, we will start first with Canada and I would ask that in putting your questions or comments that you do identify the speaker at the beginning. Canada, you have the floor.

Canada (Ms. Valery Hughes)

70. Thank you Mr. Chairman, my name is Valery Hughes and I am the General Counsel of the Trade Law Division of the Department of Foreign Affairs in International Trade. If I may just start by expressing on behalf of my delegation and the Government of Canada, my thanks to the experts for agreeing to

participate in this process and for all the work that they have done so far. We very much appreciate their taking time out of their other duties and responsibilities to be with us here today. We have had an opportunity to comment on the responses provided by the experts to the questions put to them by the Panel and therefore, much of what Canada has to say has already been said and we need not repeat it here. I wonder, Mr. Chairman, if you might give, perhaps, me five minutes with my delegation just to confer about what we have just heard so that I can determine whether or not we have other things to mention at this time.

Chairman

71. OK, well let us just have a short break at this stage, we will reconvene here in ten minutes time, so those who want to go down and have a coffee can do so.

[Break]

Chairman

72. Well lets resume now and I would give the floor to Canada for questions and comments to the experts, Canada.

Canada (Ms. Valery Hughes)

73. Thank you Mr. Chairman, I at this time would like to thank the experts for the additional comments and information they provided to us this morning and very useful and helpful, [microphone problem]. As I was saying, if I could thank the experts for their further interventions this morning and the clarifications that they provided, they have been most helpful to us. I do not have any further questions to put to the experts at this time although I would like to reserve the right to do so later if, in the course of the day, other matters are raised that we have questions about. I do have a brief question for you Mr. Chairman, if I may in terms of process and the transcript. I was wondering if that would be made available to the parties today, this evening, tomorrow or ever.

Chairman

74. I am afraid the production of the transcript can be, depending on how long the meeting goes, it can be quite a long process, all we can say is that they will issue it as soon as they have completed the task. If there is a lot of material it can really take a matter of weeks. So I am sorry about that but it is just a fact of life. But we will get it out as soon as possible and it will be verbatim so there should not need to be any question of commenting on it or confirming anything that you have said here in writing.

75. Well in that case, perhaps I could turn to Australia and ask if you have any questions or comments for the experts, you have the floor.

Australia (Mr. Ric Wells)

76. Thank you Mr. Chairman, I am Rick Wells, the Deputy Permanent Representative at the Australian Mission in Geneva. Mr. Chairman, I would like your guidance, we do have an overview statement with regard to issues that have come up in this experts' discussion and we would like to make that statement at some point.

Chairman

77. Well, as long as it is related to the issues under discussion here with the experts then by all means it comes under the rubric of comments and if it contains questions, fine, but if it does not we will still give the experts the opportunity to respond to anything you say in it, so please continue.

Australia (Mr. Ric Wells)

78. Thank you Mr. Chairman. First of all, Australia does not propose to go into WTO legal issues at this point and our comments are without prejudice to our legal position on certain questions, responses and evidence. First of all, we would like to thank the experts for their participation in these hearings and for the time and effort that they have taken in responding to the Panel's questions.

79. The basic science examined and evaluated in the Final Report has not been challenged by the experts or by Canada, nor has any new evidence been provided to Australia that would warrant a revision of its assessment and risks. However, I would like to note, Mr. Chairman, that the experts themselves have underlined at the point that the science and the methodology are dynamic and evolving, a point which of course we have made in our submissions. I would note however, that the one thing that is not changing, is Australia's appropriate level of protection. Australia has adopted a structured approach to the development of quarantine policies, including the assessment and management of risk. The third component of risk analysis, risk communication, is a very important and integral part of Australian Import Risk Analysis. This is often lead to a series of consultations with consequent revision of Draft documents and reassessment of the risks to ensure that the decision is consistent with Australia's appropriate level of protection.

80. I would like to emphasize here that the Final Report, as we have said before, includes all considerations covered in the 1995 Draft Report and all of the scientific papers that are referenced in the Draft Report. I would note too, that consequences are an integral part of Risk Analysis as much as Risk Evaluation. The very favourable health status of animals, in particular aquatic animals in Australia is generally higher then in many other countries, underpins in a very significant way the cost efficiency of Australian primary industries and the wide acceptability of products, both in Australia and internationally. Consequently, successive Australian Governments have adopted a very conservative approach to Risk Management with the objective of preserving the advantages derived from avoiding production loss due to these diseases to help maintain export markets and to protect the environment.

81. In practice, Australia is willing to accept only a low likelihood of the entry establishment or spread of diseases of quarantine concern, if the consequences from the entry of a pest or disease are expected to be significant. When through the lack of important epidemiological information there could be no reasonable assurance that disease will not enter, establish or spread, then due caution is used throughout the risk assessment and appropriately conservative risk management measures are taken.

82. Australia has undertaken a comprehensive risk analysis, including a risk assessment that, in its judgement, used a methodology appropriate to the circumstances. The risk assessment factors identified in the SPS Agreement and by the OIE's International Aquatic Animal Health Code, were all considered in the Final Report. The International Aquatic Animal Health Code is under continuing development and is subject to ongoing refinement. There are important issues that remain to be resolved, including the criteria by which diseases are listed. The code provides voluntary minimum guidelines that should be applied in international trade by importing and exporting countries.

83. The most immediately apparent feature of the Final Report is the large number of disease agents potentially present in Canadian Pacific salmon that have not been found in Australia. For these agents, there are many gaps in the information base, including the infectious dose and root of infection, prevalence in the source populations, numbers found in the various tissues of the host and the agent's ability when subject to various physio-chemical treatments. All of these factors could have a significant impact on the level of risk.

84. In the following, Australia would like to cover three main issues, namely: Risk Analysis, International Standards, and Fish Diseases. It is clear from the expert responses to the question of what constitutes an appropriate risk analysis that there is a variety of acceptable analyses, ranging from the purely quantitative as advocated by Dr. Burmaster, to the more qualitative approach of Doctors Wooldridge and Rodgers. The Australian Final Report is a risk analysis falling within the latter range of descriptions, one that has taken into account the guidelines recommended by the OIE. It is important to

note that the SPS Agreement does not prescribe risk assessment methodology but rather requires that whatever approach is taken it should be appropriate to the circumstances. The variety of expert comment on this issue testifies to the highly subjective nature of what is appropriate in terms of the risk assessment, and the impact that the particular circumstances can have on the judgement to be made, and we would note that the experts appear to acknowledge that there is no obligation to undertake a quantitative risk analysis. Paramount in deciding on the type of risk assessment most appropriate to the circumstances, is an examination and evaluation of the available data. There may be legitimate differences of views between experts as to whether a quantitative or qualitative approach is preferable depending on individual perspective on issues, such as the value of applying qualitative methods where little empirical information is available. The judgement by New Zealand, for example, that it was appropriate in its circumstances to perform a quantitative risk assessment on salmon imports has no direct relevance to Australia's situation. For these same reasons one cannot use outcomes derived from other countries as an indicator of how Australia should have undertaken a risk assessment on Canadian salmon.

85. In its Final Report, Australia took full account of all available knowledge and determined that there was insufficient data to undertake a quantitative analysis, particularly in view of the conservative approach of Australian quarantine policy and the high level of uncertainty involved. The risk assessment conducted by Australia was both comprehensive and intensive. It was the most thorough risk assessment feasible in the circumstances. By world standards, as judged by the risk assessments published by the other countries, Australia's risk assessment is exceptionally thorough, rigorous and transparent. It considered all the relevant scientific information and the gaps and found the probability of pathogene establishment to be low. However, given the uncertainty inherent in this assessment, for example, because of the limited amount of data on infectious dose, prevalence and rate of transmission, and the very severe potential consequences, the report concluded that the risk posed was inconsistent with Australia's appropriate level of protection. I would note here that the experts appear to acknowledge that it is up to Australia to take a decision on the acceptability of risk, and I would repeat again that Australia did take that decision based on its appropriate level of protection.

86. Moving to international standards, given that the IAAHC has been identified as that most approaching international model, we welcome the participation of a member of the Fish Diseases Commission, Dr. Winton in these hearings, and the insight into the workings of the FDC that he brings to these discussions. During these proceedings, Australia has raised some concerns about the lack of ability to determine OIE-FDC opinion or intent with regard to the Code's guideline, as no minutes are kept of meetings, and the balance of global representation in the Fish Diseases Commission, particularly its impact on disease listing. Australia has detailed in its responses to questions, in page 22 of the October 1997 rebuttal, questions the process by which the current OIE notifiable and other significant diseases were selected. Australia would also emphasise that the IAAHC is in its developmental stage and is subject to ongoing review. Further it provides only minimum voluntary guidelines. In other words the IAAHC is a work in progress not a finished document. I would note here that Dr. Winton has acknowledged the usefulness of input that is now being provided on conditions in Australia and New Zealand.

87. This view that I have just given is supported by the current Director General of the OIE and I quote: "The OIE Aquatic Code and Manual are by no means carved on tablets of stone but are fully expect to be revised and refined on a regular basis as countries follow and gain experience of the guidelines", - end of quote which is drawn from the preface to the Scientific and Technical Review of the OIE, 15th of June 1996, page 378.

88. Australia has also raised concerns about the way the OIE implements the definitions used for the categorization of diseases and the resulting exclusion of diseases that may be of very significant concern to some countries. For example, although diseases notifiable to the OIE is a list of transmissible diseases which are considered to be of socio-economic and/or public health importance within countries, and which are significant in international trade of aquatic animals and aquatic animal products, nevertheless a disease is not listed if it has a broad geographical range. Furunculosis is one of the most significant diseases of salmonids, particularly Atlantic salmon, however, it is not listed by the OIE, presumably because it is endemic in most salmonid producing countries. In contrast, terrestrial diseases which have a broad geographic range and which have significant impact are listed in the OIE Animal Health Code.

89. The SPS Agreement allows a WTO Member to decide whether the OIE minimum recommendations can be an adequate basis for achieving its appropriate level of protection. It is not the role of any international organization to determine the appropriate level of protection for a sovereign country. The minimum voluntary guidelines provided by the OIE are one option that importing countries should consider in the addressing the risk of disease entry. Whether these guidelines are sufficient in themselves to make the countries appropriate level of protection is for the importing country to ascertain through a risk analysis.

90. I will move now to "diseases". Evisceration alone would not meet Australia's appropriate level of protection. Other factors will impact on level of risk, including the fact that disease agent may be found in flesh and blood. A more detailed evaluation of this issue is presented in Australia's October 1997 response to question 13 which identified muscle, remnant kidney tissue, bone, guilds, skin and appendages, head with its specialised organs and blood, especially in remnants of major blood vessels, highly vascularized areas and capillary beds as the main tissues potentially harbouring disease agents after evisceration. The FDC has taken an apparent stance without any form of risk assessment that evisceration is an adequate treatment of fin fish to reduce the presence of any pathogen to acceptable levels.

91. In contrast to terrestrial animals, there are no definitive proven instances of the spread of fish diseases via product for human consumption. However, as previously stressed in Australia's first submission, this must be seen in the context of the prevailing situation in most of world, where many or all of the diseases of concern occur endemically so that there is little chance of proving the source of outbreaks of salmonid diseases. Indeed, once a disease becomes established, the high costs in terms of scientific research to determine the source and pathway of its entry, may be a lower priority as compared to alternative use of government budgets for disease management. Diseases of salmonids have continued to spread throughout the northern hemisphere with significant production losses and economic consequences despite the OIE guidelines that were designed to reduce the risk of disease spread. It is Australia's contention that in time there will be definitive proof of the spread of aquatic animal diseases via product for human consumption. Thank you Mr. Chairman. I would like however to foreshadow that we will have some additional questions with respect to the experts responses.

Chairman

92. Thank you very much, do you have that statement you have just given, in writing. Whilst it is not necessary for the record, it might be helpful to the experts in trying to respond to have the text to refer to because there was so much in it. If so, perhaps we could have it copied.

Australia (Mr. Ric Wells)

93. We will be able to provide a final version of this shortly, Mr. Chairman.

Chairman

94. I think perhaps it would be helpful to have that before we ask the experts to attempt to respond.

Australia (Mr. Ric Wells)

95. We can provide an unedited version now.

Chairman

96. Fine, perhaps the Secretariat could arrange some quick copying. I assume the experts would prefer to wait until they have got the document before responding. If you are ready to say something right away, then we can go right into it.

Dr. Winton

97. I am not going to comment on the areas of risk assessment but there are two areas that I think Mr. Wells has raised that do go to the OIE Fish Diseases Commission's areas of interest. The OIE Fish Diseases Commission is certainly a work in progress and we rely on a number of experts around the world and also from input of the member countries: Australia, New Zealand, Canada, Sweden and several other countries have been very diligent in providing comments on both, the Code and the manual to the Fish Diseases Commission. These are discussed at the annual meetings of the Fish Diseases Commission and many of these recommendations are in fact adopted. Many of them are matters of technical precision, changes in language that we find very helpful.

98. Occasionally there are matters where even countries disagree, one country may wish to add a disease, another can make an argument to remove a disease and in this case we try to use scientific weight. But I even brought with me an example of Australian comments that were discussed at the last version and largely we have found these very helpful and the arguments well constructed. So we do appreciate the comments and the great amount of effort that Australia, Canada and other countries have put into this process through the OIE delegate.

99. I also feel that the OIE's list of transmissible diseases, while it varies somewhat from the terrestrial diseases in its focus, is a minimum agreeable standard and as the OIE has said that bilateral negotiations or even the process we are here today, may be required for those situations not covered by the OIE. But that in general the OIE Fish Diseases Commission has used both the lack of documented evidence of transmission by eviscerated products, some personal experience and in fact some unpublished studies to regard the use of evisceration as a method by which risks could be reduced to levels that took it out of the generally agreed upon category such as the Notifiable Diseases in live fish.

100. Now, I do not think anyone can imagine that there are not cases of possibility with transmission of fish or other animal diseases in a variety of situations. But the Fish Diseases Commission at least, in the absence of scientific evidence to the contrary, has viewed evisceration as a way to approach this or to actually remove it from the purview of the OIE's process. There are certainly cases where pathogens could be expected to be in filets or eviscerated product. I do not disagree that certain pathogens could be expected to be found in these, but, given the total sum of risks involved, i.e., is it transmitted with the product? Does it find its way to a susceptible host? etc. The total risk may in fact ultimately be exceedingly low, and we have many examples where fish diseases have been transmitted with the movement of live fish or even gametes, and a few cases where it has been transmitted with uneviscerated fish, particularly those used in aquaculture. Two examples that Dr. Rodgers raised are, I think, particularly relevant, where marine fish species are now seen as a major risk for movement of fish diseases when used in feeding aquaculture species. Australia is certainly familiar with the Pilchard epizootic that occurred in Australia and, while I do not think scientifically it has been proven and Dr. Barry Munday and others can comment perhaps more effectively then I can, there seems to be at least some supposition that that agent may have been introduced by the use of raw marine fish from the southern hemisphere, in South America.

101. Similarly, viral haemorrhagic septicaemia was introduce into the United Kingdom where it was formerly free by extensive sample efforts - probably also by the use of marine fish. So there are many cases where uneviscerated fish, particularly those fed directly to a susceptible species and where fish and gametes has transmitted fish diseases. But in the absence of such information for the eviscerated products, the Fish Diseases Commission has simply not chosen to address those issues. I do not mean to imply that the Fish Diseases Commission thinks that there is a zero risk option in evisceration, there is not a zero risk option perhaps in ballast water, certainly not in live ornamental fish and certainly not in marine fish that are uneviscerated. Relatively, the Fish Diseases Commission has assumed that that was a quite low if not zero level of risk. Thank you.

Chairman

102. Thank you very much, perhaps I could ask Dr. Wooldridge if she would like to respond to Australia.

Dr. Wooldridge

103. OK, I have got one or two areas to talk about which I think all fall within the broad area of risk assessment and risk analysis methodology. I noted the comment that the type of risk assessment most appropriate depends on an examination of the data. I would suggest that actually, well, in my opinion that is not the appropriate way to view it. I would suggest that one normally undertakes the qualitative risk assessment first and then, if necessary, follows up with an attempt to undertake a quantitative risk assessment, and this does not depend upon an examination at the initial stage of the data to decide which type of assessment one wishes to undertake. I think a qualitative assessment gathers the information and categorizes it and orders it and comes up with a qualitative assessment. Leaving aside the meanings of the words, this may be things like high, low, negligible - and if everybody agrees that the risk is too high from this basis to be acceptable, we do not have a problem; if everybody agrees that the risk is negligible, we do not have a problem, and it does not matter what those words mean at that stage.

104. When you have a dispute, I would maintain again - there may be other occasions - but particularly when you have a dispute, I would maintain that the most appropriate way to then follow it up to try and get further on the matter is a quantitative assessment. I would here like to reiterate the point I made earlier in my written evidence that the basis of a quantitative risk assessment is the putting together of a model into which you feed data and the whether or not you have the data, you can still put together a model and put dummy-data to actually clarify the pathways by which you think your identified hazard may become the unwanted outcome that you are attempting to assess. I think the big value of this is that it does clarify the pathways required and the data that you need, and if you say "I do not think I have got the data to do a quantitative risk assessment" without actually attempting to make the model required for that quantitative risk assessment, I do not believe you can categorically state you do not have that data. That is my theoretical point. From a practical view point I would say that when you do try and put together a quantitative risk assessment you almost always do find that you have got a lot more data of appropriate type than you initially anticipated that you would have. So I would say that you cannot tell whether you have got the data to do a quantitative risk assessment until you try and do one.

105. I think, following on from that I would like to say I am afraid I did not find the Final Report transparent. I think there is a quote or a comment that the final version was transparent. I personally found it far less transparent than the draft and difficult to find the information for which I was looking, sometimes I found it, sometimes I did not. It did not appear to me to be set out in a way which made it easy to find the information and to differentiate between what is the assessed risk and the acceptable risk.

106. Having said that, I would like to reiterate and I agree with Australia's contention here that it is up to the country or a local area or the particular place in question to decide what is an acceptable risk for them, and therefore whatever came out of Australia's Draft or Final Report as far as the assessed risk is concerned and whether I believe that was done well or badly is immaterial in this instance, it is up to them to say that is an acceptable or not acceptable risk. However, I think international guidelines would suggest that if they come to the conclusion it is not acceptable, they have to be able to justify it at a meeting such as this.

107. A word about diseases themselves, not specific diseases but which diseases are appropriate to include in a risk assessment and how this interacts with Notifiable Diseases and standard lists of diseases and so forth. We had many discussions on which information it was valid to include in an international risk assessment, when we were redrafting the OIE Risk Analysis Code Guidelines. There were opinions that the only diseases which could be included from a given source were those which had been notified and there were opinions that said "no, you need to be able to include any disease for which you have reason to suspect, or knowledge to backup, that it might be in the product which you are considering". That was my opinion and it was actually the final opinion of the working party, that those diseases which one may legitimately look at are any that one has evidence could be in the product, and that might not simply be the information notified to the OIE, but it might be from a literature search or personal reports or communications. The rational for this was that one wishes when one is doing an import risk analysis and risk assessment to have the best, the most appropriate, the fullest data available and that is not necessarily

only the data that has officially notified to OIE or any other body. I think those are my only comments at the moment. Thank you.

Chairman

108. Thank you very much. Turning to the other table, can I ask Dr. Burmaster? You have the Floor.

Dr. Burmaster

109. Well I have a couple comments in response to this overview statement from Australia. Risk assessments, at least the way I use the word, are always anticipatory of some future event. So by definition, if some group of people are thinking of doing, changing a policy or taking a new action in the future, by definition we *never* have enough data to describe it. A risk assessment is always lacking some data which someone, somewhere thinks are important. It is part of the process, we are looking ahead, and by definition we are missing some part of it. Nonetheless, I would agree with Dr. Wooldridge that by putting together a model has very beneficial results. It sharpens the thinking. By this I mean a quantitative model, a mathematical model, whereby we can put in numbers or put in distributions and make calculations about what if, what if this were true? what if that were true? what if we did this? what evidence do we have? But we will never have - I am not aware of any situation where risk assessment has ever been conducted in any field, at any time, for any purpose, where they had perfect data. The concept of perfect data does not exist in risk assessment or, for that matter, may not exist in all of science.

110. Nevertheless, there are ways working with the model to use a combination of data and a combination of expert opinion and expert evidence and evidence from other fields to come up with calculations which somehow give a numerical value to the proposed action. It can also highlight where data is missing, where to go looking for data. That would then show where the data are most missing and could most beneficially help (this is called the value of information approach). Now this is still in risk assessment, this is still trying to ascertain what risks may occur in the future. Then comes a separate step called risk management, is this risk that we have calculated acceptable or not? I strongly separate risk assessment from risk management. Let me stop here.

Chairman

111. Thank you very much. Can I ask if Dr. Rodgers would like to respond to Australia? You have the floor.

Dr. Rodgers

112. Thank you Mr. Chairman. One of the beauties of coming last is that you do not have much to say providing the other experts have said it for you and in this case to a certain extent that it is true. So I will be brief. At the last European Association of Fish Pathology International Biannual Meeting, in Edinburgh, in September of last year, we organized a workshop on risk assessment for aquatic animal health. In a room of 120 seats there was standing room only. It was freely available meeting for anyone that was present at the main conference. We addressed many of the issues which have been raised by both parties in their submissions. What came out of the meeting was not only a sense of relief because somebody had actually got people together to talk about this subject, but that there was a lack of data in certain important areas in aquatic animal health for use in either qualitative or quantitative risk assessment. These areas are particularly related to species susceptibility, diagnostic techniques, survival parameters of the pathogens themselves in the fish, particularly after harvest, and pathogen inactivation.

113. Now I would think that there is a real need for risk assessment in aquatic animal health but this is already leading to a parallel need for basic epidemiological studies to be carried out to support the data gaps, if you like. I personally have not known this situation before as a scientist because, what normally happens in this sort of situation, is you generate data through research projects which then lead to a need for something else, like risk assessment. This has been driven the other way around, it is coming down from the top and it is being led by agreements such as the SPS Agreement, in my opinion, which says you

must use this technique. It is new, it is evolving okay, but at the end of the day it is pointing out where the data gaps are occurring and that is something which David Burmaster has just eluded to. I think that also one of the most important things at the moment for risk assessment is that it can drive research projects because it does show you where the missing information is. But at the same time sometimes we do seem to be standing on thin ice because we are looking for information, some of which is there, but most of the time it is not there. Where the information is not there, there is a need for expert opinion. I think this has not yet been addressed sufficiently in aquatic animal health. Nobody has actually got experts together other than in this sort of forum, where they can actually give their opinion about missing data. In risk assessment and statistical terms this is acceptable for supporting risk analysis. The beauty of the technique is that the experts do not need to agree either, in fact it is probably better if they do not agree, because you end up then with a range of probability, a range of distribution, a probability distribution - Dr. X would say "there is a one in a million chance of that happening" and Dr. Y will say "no it could happen tomorrow". That is useful and I do not believe that it has yet been done for aquatic animal health. I have no further comments to make on that.

Chairman

114. Thank you very much. Can I ask ... any further questions or comments for the experts? Australia.

Australia (Mr. Ric Wells)

115. Thank you Mr. Chairman. Yes we do have some questions for the experts, I wonder however, whether we could have the indulgence of five minutes among ourselves just before we ask those questions?

Chairman

116. We will have five minutes in that case.

[Break]

Chairman

117. If we can now resume, perhaps I can put the question to Australia again if they have any further questions or comments for the experts please feel free to give them now. Australia you have the floor, Mr. Wells.

Australia (Mr. Ric Wells)

118. Mr. Chairman, I will ask Dr. Gardner Murray, the Australian chief veterinary officer to ask questions. Thank you.

Australia (Mr. Gardner Murray)

119. Thank you Mr. Chairman, I am Gardner Murray, Australia, despite the Scottish accent. We have a number of questions. I suppose the first question I would like to pose relates to consequences. I think only one of the experts talked about consequences this morning, the potential consequences of irreversibility of disease, should enter Australia. My question is this: how can one best resolve the issue of the low probability of establishment of a disease with the high socio-economic consequences that could result should such a disease enter a country? Because this is the point that is made in the Australian submission, low probability but very high consequence. Thank you.

Chairman

120. Thank you. Is that addressed to all the experts or to anyone in particular? Dr. Burmaster.

Dr. Burmaster

121. Well, perhaps I can shed some light on that, certainly that is a key issue in this dispute between the two countries, but it is a common feature of many, many, many risk assessments. For example, people do risk assessments of large earthquakes in Los Angeles, California, in the United States. Now if a low probability earthquake occurs in Los Angeles, California, there could be hundreds or thousands of deaths along with property damage valued in the hundreds of millions of dollars or more. So this is not the first time, I do not want to be deflected into thinking that this is the first time that anyone, anywhere has ever thought about low probability high consequence events. It is a very standard question that occurs many times in many risk assessments and I will stop there for the moment.

Chairman

122. Thank you. Other responses? Dr. Rodgers.

Dr. Rodgers

123. Yes, the only thing I would say in answer to that is that you can reduce the low probability to an even lower risk, if you like, by addressing certain risk reduction factors, as I mentioned this morning. Providing those risk reduction factors were agreed to by both parties, I do not see that there would be a problem. Obviously you do need to consider the high consequences of disease introduction although even that may not reduce the level of risk to an acceptable level for Australia in this case.

Chairman

124. Dr. Burmaster.

Dr. Burmaster

125. Yes, I guess I can go back to it now and say that it is precisely in the situations of low probability and high consequences where numbers help. If we thought that an even might recur in hydrology, with floods and so on, people talk about storms of a certain magnitude, and they talk about a storm that may recur every hundred year, a storm so large that a storm of comparable size might occur only once every hundred year on average, or once every five hundred years, or once every ten thousand years, different sizes of floods. It is important to begin to talk about those numerically, rather than just saying "well it is a big flood". Different people have completely different interpretations of what "big" means, there is no common definition. I think if you posed to people in this room "what is a low probability?" we would have no agreement here in this room, even amongst the Australian delegation, or just amongst the Canadian delegation. If I describe something as a low and each of you wrote down on a piece of paper what you think that might be, there would be orders of magnitude, differences of opinion here. I am using one word, I am saying "low probability", yet amongst the audience here today, there would be orders of magnitude, differences of opinion as to what that word meant in that context on the spoken day. So without numbers we are engaged in an exercise that cannot converge. The English language was not designed to handle this, but mathematics was designed to handle this kind of question. It gives us the tools that we need to try to resolve this kind of dispute and to find out what we know and to find out what we do not know. What we know is important, what we do not know is important. Both of those have to be brought up in a way where we can talk about them and understand what each other means. Thank you.

Chairman

126. Thank you very much. Dr. Wooldridge.

Dr. Wooldridge

127. Yes, I think I am more or less concurring with what Dave Burmaster says here but I will just go through it and put it the way I see it. I think what we need to do is decide first what we are talking about in

terms of consequences and work through similarly to hazard identification listing each of the consequences about which we are worried. These can be simple consequences or very complex consequences. For example, we are talking about the probability of the import of disease, and that is perhaps the simplest consequence that we can envisage in this case. So importing disease is a consequence. We then might think about another consequence perhaps, whether one consequence is an epidemic of that disease. Now the import of disease may or may not lead to an epidemic of that disease. So there are various different consequences resultant upon the previous consequence, some of which may happen, some of which may not, and if you are talking about a quantitative model you can actually model that as the next part in your model pathway, so you can work out the probability of the import of disease, then you can work out the probability of an epidemic of that disease in a given species or in all species or whatever you are interested in. You may also have on your list of consequences that you are worried about and that you have categorized, the loss of a certain amount of economic good in some way. I am not an economist and I do not plan to try and describe this in any more detail - I have just written down loss of X pounds of money due to this epidemic occurring. You can in fact add that onto your model and work out the probability of that given loss, albeit all these probabilities will probably have very wide uncertainty limits on them.

128. So quantitatively, with each of your high impact consequences, you can work out your probability of it happening. You have assessed that risk, you have assessed the loss of that amount of money. What you then got, assuming everybody agrees with the methodology and that is the probability of loss of that amount of money or the probability of that epidemic occurring or whatever - you have then got a risk management decision, "is that acceptable?" This is quite different from your risk assessment. You have actually included your high impact consequences in your risk assessment by calculating this probability of each happening. So then, are we prepared to accept this probability of this epidemic happening? Are we prepared to accept these particular series of consequences? That is very difficult to make a decision on but one potential way is actually to do something similar to a risk assessment, but a cost benefit analysis. That can also be done quantitatively if you are actually in a position where you have something which has a low probability of happening, you can actually look at the benefits that might accrue by letting the process go ahead and then compare the two - as I say, a cost benefit analysis, which can be done in a similar methodological way to a risk assessment in that you can put uncertainties into your benefits as well as your potential for disease importation. So that is perhaps the most straightforward way I can see of actually judging this particular kind of problem. But I accept it is a difficult problem and of course different people from different areas with different backgrounds and different perceptions, and different cultures will view different risks in a different way with regard to their acceptability all over the world. So as I say, I would recommend something along the lines of a cost benefit analysis, which again is lengthy and difficult and time consuming but there we are.

Chairman

129. Thank you very much. Dr. Winton?

Dr. Winton

130. Just maybe a brief comment, Dr. Murray is certainly correct in that the consequences of certain introductions of certain diseases can be quite high in some cases but certainly not all cases. The range can be from nearly not effect or to a manageable level. For example when VHS virus was introduced by, presumably, uneviscerated marine fish into turbot culture in the UK, United Kingdom lost its VHS free status, but that disease was able to be quarantined and was eradicated and the UK has now regained its status as a VHS free zone. So, while there was potentially a very large impact, that impact was contained and managed. Certainly Australia has seen in wild fish, the impact of an introduction for example in the Pilchard mortality which I think by most agreement is probably the largest fish kill ever recorded on the planet occurred in a wild fish. Once a disease is introduced into wild stock it becomes much more difficult to eradicate. In the case of whirling disease in the United States, is an example, where introduced from Europe, this disease has proven virtually impossible to eradicate from large areas due to its presence in wild fish.

131. The consequences can also range from biological which may be losses of natural stocks of fish to economic, which are generally those in aquaculture. So I certainly support Dr. Wooldridge's contention that a risk assessment can also include, for example, those range of consequences and perhaps try to quantify those.

132. Earlier, Mr. Wells talked about Furunculosis as an example of a disease that is not on the OIE notifiable list presumably because it is broad spread. It is also because that disease is manageable in context of aquaculture now through the use of therapeutents or vaccines to an extent that makes it of less concern to the aquaculture industry. Australia also has a strain of Furunculosis that is certainly not virulent in its own right, and so Furunculosis is certainly an example of a disease which might be more concern in certain areas or less in others, but I do not think that its absence in Australia, and its presence in other parts of the world, argues that it could be used for example as a special case. I think there are a lot of cases of diseases that are either present in other areas in the world, or even strains of diseases which are already present in Australia that might be significant in some ways. So both the range of probability of import go from nearly zero to very high, but the consequences also can go from very minor to relatively high depending on where it is introduced and what pathogen into what species of fish. It is virtually impossible for the OIE Fish Diseases Commission or perhaps any group of experts to foresee all of these various permutations. That is where I think the strength of these risk assessments comes in, in that you can then begin to then estimate those probabilities and those consequences in a more quantitative manner that can be discussed more clearly. Thank you.

Chairman

133. Thank you. Well that is the responses to the Australian question. It is now five minutes to one and this is probably a good moment to break for lunch. But before I actually adjourn, can I ask if there are further questions coming from the parties? Certainly from Australia, Canada too perhaps.

Canada (Ms. Valery Hughes)

134. Not at this time.

Chairman

135. So there will be further questions coming from Australia this afternoon. Well lets resume at three o'clock in this room, we have this room at - Mr. Wells.

Australia (Dr. Gardner Murray)

136. Mr. Chairman, Gardner Murray, I do not have a question at this point but I would just like to make an observation on one of Dr. Winton's comments. That was in relation to Pilchard mortalities. It is our view and also the view of New Zealand that in fact the causual organism Herpesvirus is endemic to Oceania, and we could find no relationship between the importation of feed stuff and the event, in particular, as it started first in New Zealand. But that is an opinion that we have and others have different views of course. Thank you.

Chairman

137. Dr. Winton.

Dr. Winton

138. Yes, I appreciate that clarification and I think earlier I had mentioned that while scientifically Koch's Postulates had not been fulfilled and I do not think that epizootic is clearly understood, I appreciate that clarification and perhaps it is not a very good example of an imported disease in that case if that is in fact the case. I do not know, is there an explanation for the sudden appearance of such a large loss, is it an environmental issue in addition then? What is the other explanation?

Australia (Dr. Gardner Murray)

139. The explanation, and they come in large part from New Zealand as well as Australia, is that the virus in question, Herpesvirus occurs in Pilchards but when stressed disease can manifest. The stressors in this case appear to have been a sudden drop in temperature, Pilchards are very sensitive to sudden temperature drops, plus probable physiological changes, hormonal changes at that time of the year. That is the explanation of stressors. Thank you.

Chairman

140. Can I just clarify, is that the only remaining question from Australia or are there going to be others? There are going to be others. So lets resume at three o'clock in this room and we will take the further questions at that time. Before we leave the room, the Panel does have questions which will be putting in later to the experts. We will circulate those in writing right now, so before you depart, if you would like to pick up a copy of that. It will be available in about five minutes time, we are just going to finalize the questions.

Chairman

141. Let me start by inviting Australia to continue. Australia you have the floor.

Australia (Dr. Gardner Murray)

142. Thank you Mr. Chairman, Gardner Murray. Now this first question is to those experts who care to answer: To the best of your knowledge, is it the exception or the norm for countries to base their import policies on purely quantitative risk assessments?

Chairman

143. Dr. Wooldridge.

Dr. Wooldridge

144. I think at the moment it is probably still the exception but I think there are quite a lot of us who think that it is probably the way forward that things are going to go.

Chairman

145. Any other, Dr. Burmaster.

Dr. Burmaster

146. Well I guess I do not know the worldwide answer, but it certainly is the way for the future and this is how these kinds of disputes and disagreements will be settled, I think starting in the last year of two and proceeding into the future.

Dr. Rodgers

147. If I can only say that I agree with Marion, since I do not think there are too many examples of any legislation in aquatic animal health being based on a quantitative risk assessment exercise or any risk assessment exercise. I am thinking in particular of the EU directives which now govern the movements of fish into and out of the Community and I think that was done simply by negotiation, based on expertise rather than a fully functioning risk assessment exercise.

Chairman

148. Thank you. Next question.

Australia (Dr. Gardner Murray)

149. Thank you Mr. Chairman. This again deals with quantitative risk assessment: Assuming one has conducted a quantitative risk assessment, is it not then still a matter of judgement as to how this relates to a country's acceptable level of protection?

Chairman

150. Dr. Wooldridge.

Dr. Wooldridge

151. Yes.

Chairman

152. Dr. Burmaster.

Dr. Burmaster

153. Well, I will say yes also, with the 'but'. I guess I will take my examples from another area where risk assessment is performed, and this might be with pesticides residues in foods - not the topic of discussion here. The notion of risk assessment is partly comparative in nature: you want to compare the risks of one activity compared to a different activity, and if a risk assessment finds, or as the fields develop and it is found, that there is great differentials in two different activities that result in two different levels of risk, that is an insight, that is what we are thinking about and trying to understand how that differential arose - is it really intended? Do people wish to maintain that differential policy? Or is there some desire upon viewing this differential to change policies and practices to bring the two risks to be more commensurate - by either raising one risk or lowering another risk? So the purpose of risk assessment is partly specific and partly general.

Chairman

154. Thank you. I think that is the response unless anybody wants to say anything more to that. Thank you.

Australia (Dr. Gardner Murray)

155. As far as Australia is concerned, we contend we have conducted a probability risk assessment. But having said that, how can one distinguish between a low probability and a possibility? Is not assessing risk as low or small a statement of probability?

Chairman

156. Dr. Burmaster.

Dr. Burmaster

157. Well it is a statement in the English language to say that something is a small probability. But again I would go back to the example I raised this morning, if we were to conduct a quiz in this room, and I said: I am thinking of a certain activity that has associated with a low probability; and then I asked each of you to write down on a card what you do you think Dr. Burmaster might be thinking of? What could

possibly constitute a low probability? I think we would get back answers ranging over several orders of magnitude, such that in my view, let me just continue on that thing, I think that therefore the phrase, low probability is essentially meaningless, it has no meaning. It has no consistently agreed upon meaning even in this room, even in a ten minute interval. By the time you step outside of this room, and by the time you step into different times and locals and different places and speak with different people, many of whom may not have any education beyond high school, and so on, that the word "low probability" becomes a meaningless phrase. It is an absolutely meaningless phrase. So if we wish to proceed, if you wish to do something that is rational, if that is your goal, if your goal is to do something rational - maybe it is not - but if your goal is to do something rational, I think you have to attach numbers or ranges of numbers or probability distributions in order to make any kind of sensible discussion.

Chairman

158. Thank you. Dr. Wooldridge.

Dr. Wooldridge

159. I think I more or less agree with Dr. Burmaster. It is a problem and I think partly it is a pragmatic problem in that if you, theoretically I think, if you are talking about the pathway for a given disease to get into a particular country, you can always sort out a pathway which makes that possible. You can always make the most unlikely, and therefore improbable assumptions, about a given part of that pathway to say something is *possible*. But from the point of view of actually doing a risk assessment on whether something really will get in, and if you have come up with the answer that you say it is a low probability, obviously, you are also saying it is a possibility. If you say something is a possibility, you are not necessarily saying it is a low probability, you could also be saying it is high probability or any other probability. I mean, if you look up the words in the English language, they are different in meaning, but from the point of view of really being helpful to distinguish in terms of a risk analysis or risk assessment, I think it is a pragmatic thing; if you have come to the conclusion that you have something that you are calling a low probability, and you need to go on from there, I think the only way you can advance, if somebody is not happy with that, and is not prepared to accept that as is, is to try and make it into a quantitative assessment. So in the end, what one is saying I feel, in my own opinion, if you left in that position that you have a dispute over what "low probability" or "negligible probability" actually means, you have got to go down the quantitative road, that is my opinion.

Chairman

160. Dr. Burmaster.

Dr. Burmaster

161. If I could pick up on further elaboration of the problems with not just the English language, this language is not unique, the semantic problems are not unique to English, I would imagine that they occur in French and in Spanish and in many other languages as well - the problem is even more profound. The problem, - one of the things scientists like to be able to do, the first most elementary scientific activity in risk assessment is trying to rank two things, you have two alternatives, and you are simply trying to say which is more likely to occur, and which is less likely to occur. You just want to be able to take two things and compare them without attaching an absolute magnitude to their occurrence, you are simply trying to rank and say "this one I think is more likely", "I think it is more likely today that the sun will set". I do, I believe it is more likely today that the sun will set, that than we are going to be struck with an earthquake in the next ten minutes and we are all going to spend the afternoon in the lake. Now, both of those are possibilities. It is possible today that the sun could set, that is a possibility. It is also possible that we could have an earthquake in the next ten minutes and we could all be swimming for our lives out of the lake, those are both possibilities. I happen to believe that it is more likely - the ranking - it is more likely the sun is going to set and less likely that we are going to swim out of the lake together. But that is my own personal ranking, some of you may have different rankings on those two possibilities. The problem with English is that if I say, event A (skip those two examples), if I say one activity I personally rank is "a

low probability" and another situation I rank is "unlikely". You do not have any way to compare those. You do not know which I am thinking of is the greater probability and which is the lesser. The semantic problems are severe. The only way out, I maintain, of this semantic debacle is to start to attach numbers or probabilities or probability distributions to those things. Then we can have a consistent conversation. If we cannot have a consistent conversation, we are just running in circles.

Chairman

162. Thank you. Dr. Rodgers.

Dr. Rodgers

163. Thank you Dr. Wooldridge and Dr. Burmaster because really effectively you have just answered question 2, which is exactly what I wanted to say, but they have done it for me. You can get confused with terminology, since there is always a possibility of something happening, but if you can attach a probability to it, it is more understandable. I did not mean to confuse the Panel in any way in my written answers. What I would say only, I would add, is that even with a probability distribution, or an estimation, you still have to backtrack and attach a textual phrase, if you like, to qualify that statement for the non-experts. Because at the end of the day, a zero point thirteen noughts one probability, is something which most people cannot understand - it is just not something they can tangibly get hold of. So you still have to use phraseology such a "negligible risk" or "low" or "high" or whatever the terminology. That was all I had to say.

Chairman

164. Thank you. So you have helped to shorten our subsequent process. Any further questions from Australia.

Australia (Dr. Gardner Murray)

165. Yes. What we were just discussing, and I apologize, what we should follow-up on some of the answers given. I suppose there are many lines we could take. The fact that using, for example the term "low probability" is meaningless - in fact most countries in the world deal in these kind of terms, really. It does not all look very well, in some ways, for practices in place. But a question I would like to ask, and this is dealing with acceptable risk of quarantines, or acceptable level of protection, and I think I know the answers, but, - is it the exception or the norm to express acceptable risk and quantitative terms?

Chairman

166. Dr. Burmaster.

Dr. Burmaster

167. In my experience, practising risk assessment in the United States as I do, I have not seen, - How do I express this? I have only seen quantitative risk assessments done. So I was quite surprised when I first was asked to join this Panel and read through the background materials. I was really taken by surprise that the, in my view, that the materials prepared had all been qualitative. That struck me as highly unusual.

Chairman

168. Dr. Wooldridge.

Dr. Wooldridge

169. The answer is, I think is, sort of again I would agree with Dr. Burmaster, - in some fields I think it usual to actually look at the quantitative risk and decide whether that is acceptable or not. Some of those are not fields with which I am particularly familiar, but I mean, for the agricultural import exports, veterinary kind of field, which I am more familiar, I think up until now or up until very recently, an acceptable risk has much more often been by negotiation on words than actually mathematical numbers and an agreement on those. Again I would go back to a comment I made earlier, that I think things are beginning to change, and I think it would make for clearer basis for negotiation and challenge and/or agreement or disagreement if one did have a numerical value to work around. Because you could get your numerical value, you could agree or disagree that the method had been done correctly, and if you disagreed, one could go back and look at the individual parts of the model and agree it. Then we would all be talking about the same thing: "yes we agree this is the assessed risk", "we do not actually find that acceptable" or "we agree it is the assessed risk, we do find that acceptable". I think that would make a part of the negotiation process much easier. But it would not give you an answer as to whether it was acceptable or not, as we have said before.

Chairman

170. Thank you. Australia.

Australia (Dr. Gardner Murray)

171. Thank you. This is again a question to any expert who may care to answer: Transmission of disease through product for human consumption is well known for many terrestrial animal diseases. Do you think that there is a scientific reason to assume that this could not occur in aquatic animals?

Chairman

172. Dr. Rodgers.

Dr. Rodgers

173. You are talking about a human disease or an animal disease? An animal disease. Because certainly Cholera is one disease which is possible to be transmitted from fish to humans, but I am not familiar with the terrestrial side. Sorry I was thinking out loud.

Chairman

174. Dr. Wooldridge, would you like to carry on from that.

Dr. Wooldridge

175. A quick comment. I think, in terms of risk assessment, when one is actually starting out on this process, in part of this hazard identification step of this, you need to consider whether these are possibly transmitted diseases through the product for human consumption. As I said before, I think you can put together a number of pathways that show the possibility of that happening. Whether there is any scientific evidence to say whether that would or would not happen, would depend partly on the available state of evidence, but also if it had been shown to have happened in a particular instance, there you have got your evidence. If not, then if you actually did follow your pathways through and had done a quantitative assessment, again you would come up with a probability of that happening, albeit that if your data was not very full, it would be a probability with very wide uncertainties.

Chairman

176. Thank you. Dr. Burmaster.

Dr. Burmaster

177. I guess, at the most general level I work in a profession where - this sounds like a contradiction in terms - but there is no such thing as a zero probability. There is always a risk of something. There is always some - even for rare events - there is some small, finite probability greater than zero, that the undesirable consequence might occur. For example, in under the laws of statistical physics (this example has been around for fifty years and it is in many textbooks), there is a small chance that all of us in this room are going to suffocate to death in the next minute. How could this occur? How can we start to discuss it? Well, through the statistical mechanics of the air molecules and the oxygen and nitrogen molecules that are in this room right now, there is a small chance greater than zero that all of those molecules are going to end up in that corner of the room sometime in the next minute and stay there for a long enough time, just a normal fluctuation, that we will all die. Is there a zero probability of that? No. Well, how big is the probability? It is kind of small, it is probably so small that we would have a hard time in calculating it. But it is not zero. So back to this question: "is there a chance that some disease might be introduced from country Number One into country Number Two?" Can we rule it out and say that there is a zero probability? No. We can never say there is a zero probability. But it might be small, it might be large, we have to do the numbers to find out.

Chairman

178. Dr. Winton.

Dr. Winton

179. Probability and numbers aside, and I have specifically tried to stay away from this, and if you saw my scores in mathematics as a graduate student you would understand why. From a more fish disease perspective, the answer and it is largely opinion, is that probability is relative to other sources of introduction of fish diseases in the case aquatic diseases, is relatively low with human products. You are correct that in the case of [hams ?] for example and Foot and Mouth Disease, and other products, African Swine Fever - there have been estimates that those contain risk; that products for human consumption do carry risks of animal diseases. But there is such a large body of scientific evidence associating movements of live fish and eggs with diseases, and the *absence* of scientific data associating any other products for human consumption that the preponderance of data seem to be that the risk is quite low. In addition, as I said in my comments, there are some unpublished studies of people who have actively looked for diseases in products destined for human consumption and been unable to find them, at least using standard methods. I do not think anyone would say it cannot happen, but at least I think it is my view, that probability is quite low relative to perhaps other sources of risk - those might be ships or tourists or other import products, all of which are not a zero risk option. Until proven otherwise, I think, the risk is estimated to be quite low.

Chairman

180. Australia.

Australia (Dr. Gardner Murray)

181. Thank you. I think the answers to that question more or less indicate that in fact salmonid product could contain exotic agents, in terms of product. On relative terms, as Dr. Winton said, well, gametes and all the rest pose greater risk, but, nevertheless, it can happen. But just to follow on from that, Mr. Chairman, I have got a fairly long kind of list of questions here, and, please accept my apologies, but it kind of deals a bit with the absence of evidence issue that you raised. What does a country do if there is no evidence? Does it wait until the problem happens - and then says "Oh, Hallelujah, we have got evidence

now!", or does it take action, the Australia approach? I apologize if I am long and convoluted today, if I could get some sort of answers I would appreciate it. Given the high cost of investigating disease outbreaks, in cases where the cause is not immediately apparent, determining the cause of an outbreak may be a low priority compared to implementing disease control measures. In countries where many or all of the diseases of concern occur endemically, it is likely that the cause of all new outbreaks of any of these endemic diseases would be investigated with sufficient thoroughness to determine the origin. Could outbreaks of endemic disease cause by products imported for human consumption occur and not be recognized? Could outbreaks of endemic diseases caused by newly introduced strains occur and not be recognized?

Chairman

182. Dr. Winton.

Dr. Winton

183. Certainly it is possible that it would be difficult or impossible to see very low level of introductions in the background of a number of cases. Your are correct, some of these are expensive to investigate. In a few cases, some investigations have been undertaken and our laboratories, using some molecular tools now to begin to trace some of the epidemiology of some outbreaks. This kind of approach I think will help in this regard, but yes, I do not think anyone would say, "no, of all of the cases of Furunculosis in North America, could some of those actually have come by imported Atlantic salmon from Norway and not be an endemic disease problem?" We would not know that. So your assumption is correct. However, unusual outbreaks, for example, when viral haemorrhagic septicaemia was first found in North America, tremendous amount of effort went into that. In our laboratory, we investigated those strains at the molecular level, we have since developed ways to identify those strains uniquely, and we now have a surveillance mechanism in place to be able to differentiate between a European strain and a North American. So at least for this particular disease and in this particular case, such work was done and we know that all of the isolation of VHS in North America, every single one has been typed in our laboratory and they are all of North American origin. So, in some cases we know that. But in the background of large numbers of cases, no, we would not - or for lower priority conditions.

Chairman

184. Thank you very much. Dr. Wooldridge.

Dr. Wooldridge

185. Just another very quick comment about a completely different disease. I can say from personal experience of attempting to differentiate between the various different sources of a particular disease with similar clinical and pathological manifestations, that actually, even when you know what different sources you are looking for, it can be actually very difficult to decide whether you have got a different disease from a different source or whether it is another endemic outbreak. Nothing to do with fish, in that particular practical instance I am talking about.

Chairman

186. Thank you. Dr. Rodgers.

Dr. Rodgers

187. I would just like to echo what Jim Winton said. I would just like to add also that it is very much easier to characterise and identify disease causal agent in a clinical outbreak than it would be in, for instance, a routine monitoring programme. When you are doing routine monitoring, unless you are selecting fish, in this case which are diseased looking or sick or dying, to actually weight your sample towards finding something, then you are really looking at the limits of your detection tests, which is

something I have mentioned this morning. Routine monitoring nearly always brings you around to a negative result, if you like, but based on the limits of the detection tests.

Chairman

188. Thank you very much. Dr. Winton.

Dr. Winton

189. Maybe one additional comment too, that in the face of this is a compounding factor as well. At some point today I wanted to mention this and this is as good a time as any. That is as detection methods improve there always appear now to be cases that you have missed before or low level sub-clinical carriers and disease agents, not all of those of course are introductions but they are first-findings. I think in many times we have difficulty even distinguishing between what is in fact an introduction and what is in fact a discovery because of improved methods in diagnostic methodology. Many times the first case of a disease in a country is assumed at first to be an import until proven otherwise. But I think that we have some experience now suggesting that many of these are simply better detection methods and more observation. In the case of Canada and Australia, the distributions of all of the diseases that have even been mentioned, I do not think are know with certainty at this particular instance. That will become more clear over the next decade of centuries.

Chairman

190. Thank you. While you have got the floor, Dr. Winton, I wonder if could just help the Panel by explaining what the term "gametes" means. We have heard it used a couple of times but we are not very clear on what it is.

Dr. Winton

191. Gametes, are the sperm or eggs and they are often imported separately to fertilize eggs in a country or to use just the eggs or just the sperm as opposed to eggs or fertilized eggs, which is the other term. Gametes would simply be the seed stock. Many pathogens, particularly viral pathogens and a couple of bacteria can be transmitted with gametes themselves as they can with fertilized eggs or live fish.

Chairman

192. Thank you for that clarification. Dr. Rodgers.

Dr. Rodgers

193. Yes, I would just like to make one comment, not on gametes, but following on from disease identification and characterization. I do not know, perhaps Jim can correct me if I am wrong, but I do not know of any national legislation anywhere that would, on the finding of a disease causal agent, unless that disease causal agent was isolated and fulfilled Koch's Postulates you would not act, for instance, on a molecular technique which pointed to the fact that you had detected VHS but that you could not isolate it in culture. I think most monitoring programmes and most national legislation is based on the understanding that to take action you must actually isolate the organism itself.

Chairman

194. Dr. Winton.

Dr. Winton

195. I think that is generally true and I think that is going to run into some problems as some of the molecular techniques are more wildly adopted because we now have techniques that, as you say, can find

evidence of agents in the absence of the infectious dose or even sometimes viable agents themselves, just genomes or killed organisms. So this is going to be a problem but not just obviously in fish.

Chairman

196. Australia.

Australia (Dr. Gardner Murray)

197. Just on that last comment. There are occasions and circumstances in Australia where we might take action without insolating the organism, particularly in emergency situations.

Chairman

198. Before you go on to another subject, would Canada like to come in on that point?

Canada (Ms. Valery Hughes)

199. I am certainly not going to comment on the science. I wonder if I just might seek a clarification as the questions are piling up and as they seem to be getting longer it is more and more difficult for us to follow them and I wondered if we could have a copy of those questions. It would certainly facilitate things for us.

Australia (Dr. Gardner Murray)

200. Yes, well the good news is there are only two questions to go. I suppose the bad news is that they are both fairly long, so I apologize. We had to make a number of modifications to these questions over lunch which is why did not have a chance to type them up and give them to you. I apologize.

201. The second last question is to Dr. Winton, and I think you have covered it a bit this morning, but I would just like a bit more clarification. Dr. Winton, you have stated that the Fish Diseases Commission was unanimous in its belief that evisceration is an effective measure to reduce greatly the risk of transmission of notifiable diseases. What are your views on the efficacy of evisceration as a measure with respect to the other significant diseases such as epizootic ulcerative syndrome and viral encephalopathy and retinopathy. Does this apply in the case of fish harvested from emergency slaughter, that is evisceration? Or would evisceration of Canadian salmon result in an equal degree of reduction of infectivity for all of the pathogens identified in the Final Report?

Chairman

202. Dr. Winton.

Dr. Winton

203. Well that is a difficult question. I think first of all, I should say that it is not entirely correct to say that the Fish Diseases Commission felt that evisceration would, *per se*, reduce Notifiable Diseases and was therefore somehow thought to be a measure that was recommended. To a large extent, and I think that it is important to clarify, the Fish Diseases Commission was unanimous in its feeling that eviscerated products, by themselves, represented a low enough risk that they were not really within the purview of the Fish Diseases Commission to consider. We were more concerned with the aquaculture products, and particularly live fish and eggs moving international shipment. As several countries have done, there was a presumption that if the product was eviscerated, whether it came from a wild source or even from an aquaculture facility - even from an aquaculture facility at which a disease outbreak was occurring - that evisceration removed that product from the purview of the OIE recommendations. So we do not necessarily have an opinion, *per se*, about evisceration other than the fact that it seemed to reduce the risk significantly such that it was no longer of interest to us at that particular point. If the scientific evidence is

such that eviscerated products are a risk, then perhaps, we would reverse that opinion. We have considered for example, uneviscerated bait fish and whether or not we should include these as a source of discussion, but we currently do not discuss them either.

204. In addition to saying that evisceration of fish was thought to reduce notifiable diseases, you are correct that evisceration would probably be more effective for some diseases than others. More stable agents, and particularly agents that might be found in the flesh of the animal, as opposed to viscera, might well be expected to survive longer in such product and therefore perhaps be of slightly higher risk. We are not able to carry out such an analysis because we do not have the survival curves of all of the potential pathogens in such products. But I think it is safe to say that for both the Notifiable and the Other Diseases, we assume that evisceration significantly reduced the risk to a level that we no longer were concerned about.

Chairman

205. Thank you. Dr. Murray.

Australia (Dr. Gardner Murray)

206. One final question to Dr. Winton. Dr. Winton, is it anomalous that a disease occurring in the Southern Hemisphere, EHN, is made notifiable, but one occurring exclusively in the Northern Hemisphere, for example ISA, is not - especially when the later is much more devastating then the former? What implication does this have for the application of the Code?

Chairman

207. Dr. Winton.

Dr. Winton

208. Well, you raise a point that has behind it a suggestion that somehow Australia is being treated unfairly in the case of EHN versus ISA. Diseases are so called listed diseases by the Fish Diseases Commission not only on the basis of their geographic distribution. In the case of ISA it is now know to be confined to Norway and to Canada. EHN, initially, was believed to be only in Australia. But the second thing and third things that we consider are how treatable they are. In this case neither one is treatable being viral. The last thing is how robust are the diagnostic and certification methods. In the case of EHN, good, robust cell culture detection in serological identification were in place, such that you could in fact certify a population of fish as free of EHN virus such that it could be moved. That was not the case of ISA for which, until the last month or so, no standard diagnostic method had been available, except clinical signs. It was impossible, literally, to certify a population as free of ISA.

209. Now the Fish Diseases Commission may well, based on the findings of ISA in Canada and the now improved diagnostic methods, including a cell line which will replicate the virus and a molecular method - may well choose to add ISA. The second point is that EHN is now seen as part of a much larger pool of iridoviruses of fish. Our biggest problem on the Fish Diseases Commission in the next year is how to define this group. I can almost guarantee you that this group will expand from being simply an iridovirus in Australia, primarily of Redfin Perch to a pool of viruses, and the noda virus in the marine environment are going to represent the same difficulty. It is a pool of strains of very closely related viruses which can have devastating effects for which there is a limited geographic distribution but a fairly wide species distribution. We are going to have some troubles trying to decide how to define this new thing. I have asked for example, Dr. Ron Hedrick (on the Fish Disease Commission) to help us define these iridoviruses of fish. It is as you said, a work in progress and we will make some adjustments accordingly. But I would say, and you only have to believe me on this, I guess, but there is no bias against the situation in Australia regards to ISA versus EHN virus.

Chairman

210. Just for the benefit of the Panel, I wonder if you could just clarify what EHN and ISA are.

Dr. Winton

211. Ok, is an iridoviral disease, initially found in Redfin Perch and we have experts here that can tell us a lot more about it than I can. It was formally thought to be confined to mainland Australia, and it now appears related to a series of viruses from Sheatfish and Catfish in Europe and the United States, that are very difficult to differentiate from each other, and are somewhat related to a frog virus and amphibian virus, and this particular disease, so called Epizootic Haemorrhagic Necrosis was first described in Australia. ISA, *Infectious salmonid anaemia* was first described in Norway, and that is now know to be caused by an orthomyxovirus.

Chairman

212. Thank you very much, sorry for that diversion. Another question?

Australia (Dr. Gardner Murray)

213. No, I have - we have kind of finished. I would like to, in finishing, thank the experts very much for the effort they have put into this exercise and answering my questions so frankly and honestly. Thank you very much.

Chairman

214. Thank you very much. Can I take it that we have come to the end of the parties questions? Does Canada have anything to add at this stage? You have the floor.

Canada (Ms. Valery Hughes)

215. Thank you Mr. Chairman, I wonder - I realise that the day is getting long - but I wonder if you might give me five minutes just to check with the experts that I brought with me because there is of course a lot of information that has been raised since we have returned?

Chairman

216. Ok, five minutes.

Canada (Ms. Valery Hughes)

217. Thank you.

[Break]

Chairman

218. Well thank you for observing five minutes more or less exactly. You have the floor Canada.

Canada (Ms. Valery Hughes)

219. Thank you Mr. Chairman, and thank you for giving us that time. We have no questions at this time.

Chairman

220. Right, well in that case that seems to bring us to the end of that stage of the meeting. Perhaps we could now turn to the questions from the Panel[*] that were tabled just before lunch. I am going to ask the experts if they would address these questions. I will give the experts the floor one-by-one and ask them to run through the whole list. I think in the light of the discussion we have had this afternoon, that some of them actually fall away and do not need to be addressed further; I am thinking particularly of 1, 2 and 6, which I think we have covered. But by all means feel free to add something if you want to, but I think we have dealt with those this afternoon. We would like to change the order to bring number 17 up to number 1, if you would. Also, I have something to add to question 15. We have had some discussion on evisceration and we want to put a rather specific addition to that question which is as follows: What is the effectiveness of evisceration in reducing risk from *Renibacterium salmoninarum*, IHNV, Salmon leukaemia virus, and *Henneguya salminicola*, that is just for those four diseases - so that is an addition to question 15. If that is clear perhaps I could start by offering the floor in alphabetical order. Perhaps start with Dr. Burmaster, if you would be kind enough to address the questions.

[Dr. Rodgers took the floor first]

Dr. Rodgers

221. Could you clarify whether you want to run through them as they are or do you want each expert to go through all of the questions one by one.

Chairman

222. Well, I will offer floor to each expert and ask each one to run through them and address those questions which you feel you can, - no, perhaps that is - Let us take them question-by-question. Yes, sorry, I am confusing the issue. Let us take them question-by-question and let us start with question 1 which is now 17, renumbered 1 and on the sheet 1, 2 and 6 have disappeared.

Dr. Burmaster

223. I am, question 17 now renumbered to become Number 1. I do not fully understand the question, so it might be better if we went in reverse alphabetical order for a moment. I am sorry.

Dr. Wooldridge

224. I have to say I think I know what the question means but I am not quite sure either. So I wonder if it is possible to clarify the question at all.

The Secretariat (Mr. Joost Pauwelyn)

225. Well the question relates to the third requirements invoked by Canada; the idea that you should assess the SPS measures you, upfront, want to consider. So if you think this is a requirement, do you think it is enough to just assess each option separately? Or do you have to - once you have made such an assessment - do you have to compare the different options? Do you have to compare and examine the relative risks related to each of these options? And, in the end do you have to justify the option you finally choose, as to whether this option reduces your risk appropriately?

Dr. Wooldridge

226. Starting somewhere in the middle of that question first - if you actually undertake a quantitative risk assessment for each of the options under consideration, your answers will automatically give you a comparison of the different options. Therefore, if you have undertaken a quantitative assessment, I think

[*] See Attachment of Annex 2.

the question is redundant, or at least the central part of the question is redundant. I suspect, with regard to giving a rational explanation as to why you have chosen those measures, if they are measures that are acceptable to whoever else is involved in the question under consideration, you will not need to give a rational explanation because they will be accepted without any explanation. If they are not accepted then you would have to give rational explanation if you wished to persuade somebody to accept them. So again I cannot quite see that there is a question there, the answer is almost automatic. If there are - and I think I have sort of answered this morning when I answered the questions that were put additionally to the original questions - but, if there are several different options that one can undertake, then if you are going to say that the risks are unacceptable in importing a particular product, then you do have to have looked at the most stringent feasible combination of safeguards and concluded that the risk is still unacceptable in order to adequately demonstrate your position in denying imports. Is that clear? Have I answered the question? Well I have done my best at answering the question, anyway.

Chairman

227. That is helpful, thank you. Dr. Burmaster do you want to say something on this subject.

Dr. Burmaster

228. Well having heard that answer, I have nothing to add.

Chairman

229. Thank you. Can I just clarify whether - right, yes. Well, I think unless anybody else want to address that question perhaps we can go on to the one that is numbered 3. Now this is primarily for Dr. Rodgers, but it also relates to something that has come from Canada so perhaps we can start with Dr. Rodgers.

Dr. Rodgers

230. Yes, thank you Mr. Chairman. I did not mean to confuse anybody with my non-inclusion of the citations from the public literature. I was, for the sake of completeness, trying to answer the question which says "which disease agents" it does not actually say "which disease agents from the Australian list", it just says "which disease agents", so I was trying to be complete. I will agree that flexibacteriosis is probably ubiquitous as is *Kudoa*, and is probably not of concern. However, there are references in the scientific literature to *Kudoa* appearing in Canadian salmon, whether the Canadians are aware of it or not I do not know. There is for instance a reference by Kabata and Whitaker in 1989 which says that all species of returning adult salmon in British Columbia, Pacific salmonids, except Chum salmon and Sockeye salmon had *Kudoa*, isolated from cardiac muscle and I believe it was also reported at a *Kudoa* workshop in Nanaimo in 1994. But, as I say, *Kudoa* is ubiquitous and I would agree if is probably of no concern now, specifically as it has been taken off the list by Australia. As far as the other one is concerned - *Parvicapsula*, there is a report in 1992 by Kent which says that wild Sockeye salmon, did have an isolation of *Parvicapsula* and they occurred off the coast of British Columbia which I assume was in shore, I do not know, - I assume in Canadian waters. There is a very recent publication by Kent *et al* in 1997 which says that adult Sockeye salmon recently returned to the Weaver Creek from the Pacific Ocean, have had what has been identified as a new species of *Parvicapsula*, isolated from them. So there are references, as far as I am concerned as a scientist, in the literature to both these species - both these disease causal agents rather. But I would agree that they are not of overriding concern for us today. Does that answer the question? I thought there was another aspect to it. Oh, PKD. PKD I believe has not been found in adult Pacific salmon, it does occur in juveniles and with previous exposure to PKD as a juvenile, most adult salmon would become resistant anyway to subsequent exposure. But I believe it has not been reported from adult salmon. That is true.

Chairman

231. Thank you very much. I do not know whether Canada wants to come in on that at all. Yes, Canada.

Canada (Ms. Valery Hughes)

232. Mr. Chairman, I would just remind the Panel that Canada has commented on this previously in the comments filed on December 18th, and we stand by the response provided to question 2, on October the 7th. I think that Dr. Rodgers has confirmed that point. Thank you.

Chairman

233. Thank you very much. Perhaps we could now go on to question 4, I do not know whether Dr. Rodgers, you would just like to carry on with that one.

Dr. Rodgers

234. Thank you Mr. Chairman. There is a distinction here between dead fish and eviscerated fish, I assume they are one and the same. Because a dead fish which is not eviscerated - well, in fact, a dead fish which has been eviscerated also has autolytic processes which would render some disease agents inactive simply because of the autolytic enzymes which are present as an actual process of decay. Any fish which entered the evisceration process as a carrier fish could still remain with some level of disease agent depending on what that agent was, as we have already heard today, because the evisceration process is not totally efficient at removing all pathogens, particularly those pathogens which occur in the kidney, for instance. The evisceration machine (if the machine is being used) tends to leave some kidney behind in the backbone of the fish and any viral agent, for instance, would remain also in blood - but as to how long for, there are very few studies done on pathogen survival in eviscerated fish, so I could not say at what level they would occur. But as we heard from Jim Winton, evisceration is an effective way of reducing the level, but to what level, and whether that level is acceptable, is another question completely.

Chairman

235. Right, thank you. Dr. Winton.

Dr. Winton

236. One thing is the definitions of carriers and reservoirs. In a general sense, carriers and reservoirs are live species, either the same or in some cases a different species, that serve to maintain those infections. A good example might be Pacific herring which are now known to be an important reservoir and carriers of VHS virus in North America. VHS virus has been introduced into some North American salmonids but primarily from an enzootic pool of these carriers. A dead animal, probably more accurately comes under the definition of a fomites, which is an inanimate object which serves as a potential source of contamination, much as contaminated boots or other items might - the organism does not replicate in such a state and it is really incumbent on the fomite to have been contaminated at some point and then you have a decay curve that goes on depending on the organism, the length of time and the conditions. So a fomites in general, or a dead fish, really is of less concern in a way because it is not replicating the agent in an active state or maintaining it such that it could be expected to have high level at any particular point in time.

Chairman

237. Thank you very much. Unless there is anything else on 4 can we go on to 5. Dr. Rodgers.

Dr. Rodgers

238. Basically, yes. The salmon are quite high up the respective food chain. They would eat scraps of salmon meat. The answer is yes.

Chairman

239. Thank you. Unless anybody else wants to say anything on that. We will skip 6, which we have dealt with, and go strait to 7. Dr. Wooldridge.

Dr. Wooldridge

240. I gather from this question that you were not quite sure what I was trying to say in my answer 2.4.3, is that correct?

Chairman

241. Yes, it is a clarification of that.

Dr. Wooldridge

242. On a theoretical level, the risk assessment that you wish to do depends on the risk that you wish to assess and therefore, on a theoretical level, I have put down in my 2.4.3, two potential questions, and there are many but I have chosen two. The first one being "what is the risk of an exotic disease being introduced with product X", and here you are imagining a situation where somebody wishes to introduce product X and you need to assess *any* risks of *any* diseases potentially in product X. So you need to go through a hazard identification exercise looking at all potential diseases which might be in product X, and in some way assess the risk of each one of those being introduced with that product. However, if your initial question is simply concerning one disease, for some reason, somebody has brought up perhaps the question of *a* particular disease, then you only need to look at that disease because that is the hazard that has been identified as being the requirement that you have been given to do a risk assessment on. So that is the theoretical background as to whether you would do a disease-by-disease or a product-by-product assessment. It very much depends on the question you are trying to answer. But your question number 7

here then goes on to ask "are these two alternative models", well, the final sentence. In a real life situation, if you are actually interested in every possible way in which exotic disease Y, might be introduced, then you would have to consider all the products that could carry exotic disease Y. So you then you would have your disease and your hazard identification will be saying "hazard of this disease in *that* product, this disease in *that* product, this disease in *that* product". So in a practical situation you would then need to broaden it out to look at other products. But the final analysis is that it very much depends on - the way you approach it very much depends on what is the question you are trying to answer. Does that clarify or not?

Chairman

243. Yes, I think that has got to the point, thank you very much. So if there is nothing further on that one, perhaps we can go on to number 8. Dr. Rodgers.

Dr. Rodgers

244. Thank you Mr. Chairman. Basically, I cannot answer question 8 without doing a full quantitative risk analysis. Following what you have heard this morning about terminology, would you like to qualify what you mean by the term very small.

Chairman

245. Negligible.

Dr. Rodgers

246. I think the answer is linked to the sensitivity of your detection method. If you bear that in mind then - yes, you cannot say that the disease will be totally absent if you have not found it, unless you have a background database with time of regular testing, and even then, if you have never found a single fish out of - maybe you have tested thousands - even then, you cannot say the disease is absent. That will give you a probability - thank you, I was just about to say it - a [beta-distribution] which will indicate the level of probability of it being absent. Perhaps Marion would like to elaborate further?

Chairman

247. Thank you. Dr. Wooldridge.

Dr. Wooldridge

248. It think yes - if you do not look for something you will probably not find it. You have a number of different problems here. If a disease has not been found in a category of fish it might simply mean we do not have a test that is able to find it, yet. Or it might mean that we have not actually tested any fish yet, and, so - yes, we are talking about the numbers of fish that one has tested, we are talking about the sensitivity of the test and if you have found no fish in a given number that you have tested then you still have a probability because you may find in the very next fish that you test that you have actually got that disease. You cannot - to say that it is a very small probability, well, again, you are talking about how many you have tested. If you have tested every fish out of two and you have not found it, you are not necessarily talking about a very small probability. If you have tested every fish in ten million and you have not found it, you are probably talking about a very small probability given that you have got a test that will pick it up.

Chairman

249. Thank you. Dr. Burmaster.

Dr. Burmaster

250. I agree with both of the previous statements and I think it is summed up in science as saying that: in science, one can never prove the negative. You can never prove the negative, it just cannot be done in science.

Chairman

251. I am not quite sure how much those answers have already addressed 9 as well but perhaps we could just have a look at that and see whether we have - Dr. Wooldridge.

Dr. Wooldridge

252. I think they have partly addressed 9, but the format of question 9 is slightly different. It is the first sentence: "should this disease nonetheless be considered in a risk assessment of fish from this area?" I think the answer is yes, this disease should be considered in as much as when you do a hazard identification, which should be your first stage, you would start off with thinking about all potential diseases that might be in that particular species of fish and then reduce it down to those - or you might then prioritize - looking next at those diseases which had been found in that species, in that area. So you would consider them, you would not throw them out. What you might then say is, well, if they have not been found, given the things we have already talked about in the previous question, and if something else has been found, then our initial risk assessment, where are perhaps going to get further details and do a quantitative assessment perhaps needs, perhaps, to be prioritized first on the ones that have been found.

253. Given the assumption that you have got equally sensitive tests, and you might not have, and given the assumption that you have tested an equal number of fish for both diseases, which again you might not have, if you have found one disease and not found another, then the probability - or it is likely that you are going to end up with higher risks overall from the one you have found. So if you wish to pursue the quantitative argument and do a quantitative assessment based on the prevalence of the disease you actually have found, and if you find that gives you a risk which is, when you have quantified it out, acceptably low, then it might be considered safe to say (if you agree with the use of the word "safe"), that something with a lower prevalence would have an even lower probability of being imported, therefore that is also acceptable. If you come to the conclusion that the disease which was found, and therefore of probable higher prevalence, has an unacceptably high risk, and there is no safeguard, or mitigating, or disease reduction measures you can put in place and you are left with something that because of this disease you found is unacceptably highly risky, then it does not really matter if the other diseases are there or not because you are not going to have it, because it is too risky for *that* reason. So you consider these things but whether in the last analysis they make a practical difference, depends on the exact circumstances, but you might argue that actually maybe you do not need to worry too much given the proviso, you have tested for it and you have got a sensitive test.

Chairman

254. Thank you. Anything else on that, Dr. Burmaster? No. Unless anyone else wants to add anything on 9 lets go on to 10. I think this was mentioned as an example by one of the experts this morning. I do not know whether you have got anything else to add on the subject of the "Vose Assessment".

Dr. Wooldridge

255. Well in broad terms this would be the kind of way that I would like to see any problem of this sort tackled. I am not talking about the detail of this because I have read through it but I have not actually committed to memory all the details - but in broad terms this is the way I would like to see any dispute of this nature taken forward to the next step. Something along these lines that David Vose has produced. I think it is very relevant.

Chairman

256. Thank you. Dr. Burmaster.

Dr. Burmaster

257. Yes, I agree with Dr. Wooldridge's formulation exactly.

Chairman

258. Thank you. Unless there is anything else on that, lets go on to number 11 which is addressed to Dr. Burmaster.

Dr. Burmaster

259. Well, I continue to agree with my previous answer, which is yes. But I am not sure maybe there is some semantic detail here that I am missing, but let me tell you what I am answering yes to. Let us say there is one bacterium which is responsible for some terrible disease in some stock of fish. And let us say that bacterium could have originated in just two places on the globe. So it might have originated in country A or in country B. Somehow that bacterium got to country C and damaged the fish, it caused fish disease in country C. I think from the fish's perspective, the bacterium is there in country C and it is damaging the population of fish in country C and from the fish's point of view, the fish really do not care whether it came from country A or country B, they are sick fish and they are not liking this experience in any way. I am trying not to be factitious about this, but it is only the humans who really care about where it originates. The humans care a lot about whether it came from A or B because they may want to go back and under some trade treaty or something they may wish to collect monetary damages or something else. But it really the phrase I am sticking here with is "regardless of imported host", and I guessed that is where I stand. Thank you.

Chairman

260. Thank you. Question 12 is addressed to all. Dr. Winton.

Dr. Winton

261. Question 12 is a very difficult question because it might be possible, given enough information around specific disease, to rank these relative risks. In a general sense, fish that have been inspected by a competent inspection set procedure, and which are in a pathogen free water supply, or at least a controlled water supply, represent a rather high level of safety. These are the areas in which the OIE Fish Diseases Commission imagines most trade would occur. In the case of these Canadian fish here, we are talking about ocean-caught Pacific salmon which has its own suite of diseases versus freshwater-caught Pacific salmon, which have a slightly different subset of diseases, versus cultured fish on the Pacific coast which well be inspected but are in an uncontrolled water supply, Atlantic salmon, a different host species. So there could be different subsets - in fact very likely there are different subsets - of pathogens in all of these different groups. So it is difficult to rank them to say that they pose less of a disease risk. If these were wild adult fish that were being moved live, then I think that you might find one set of pathogens. If they are dead fish or eviscerated fish you might see a slightly different set of surviving pathogens. So I think that is a very difficult question to address. But in a general sense, wild ocean-caught Pacific salmon during their ocean phase, would be probably free of several of the disease that might be expected to be either present in freshwater, or present at higher level if the fish were reared in captivity. So that in a general sense, the fresh water fish and the cultured fish, provided they were in an uncontrolled water supply might in fact be somewhat more dangerous product than a wild open ocean fish at that stage of its life. But it really depends a lot on which diseases you are talking about.

Chairman

262. Thank you very much. Dr. Rodgers.

Dr. Rodgers

263. I agree entirely. I would just like to add - if you have a monitoring surveillance programme in place and you are using diagnostic tests which you have faith in, if you then had to rank the expected ranking, if you like, for these groups of fish in increasing risk, it would be the wild ocean-caught at the bottom, the wild fresh water migrating fish in the middle, and the cultured fish at the top (being, as Jim pointed out, the most risky fish). But it may also be that a non-monitored wild population of fish may have normal pathogens which we have not even found anything about yet, we have not even discovered yet which, put into another situation, such as a cultured situation, could cause a lot of damage.

Chairman

264. Thank you. I believe Jeff, you may have a follow-up on that. Yes, perhaps the legal advisor would like to follow up a little bit on that.

The Secretariat (Mr. Jeff Gertler)

265. Thank you Mr. Chairman. This is not directly in this question by I think it something that is of concern to the Panel here. Could you make the same sort of comparison of the relative disease risk of the Canadian salmon, that is wild ocean-caught Pacific salmon, versus risk from live ornamental fish or bait fish.

Chairman

266. Dr. Winton.

Dr. Winton

267. Again, the subsets of pathogens in these different species will be different. Ornamental fish will have their own subset of pathogens. But in a general sense, live fish that are introduced carry probably, in my view, the highest risk of any category. We have documented examples of ornamental fish carrying both Notifiable Diseases of the OIE and non-notifiable other fish diseases in international trade. Second level, might well be those fish used as bait. Again Dr. Rodgers' point is good, we may not have ever sampled them adequately to know, but in an example from the North American coast, for example, number of years ago, everyone assumed that herring were sent around as safe products up and down the coast and used as bait. We now know that Pacific herring, and in fact Atlantic herring in the Baltic and North Sea are probably the major reservoir for viral haemorrhagic septicaemia virus, and probably constitute a much higher risk than a certified population dead salmonids or eviscerated salmonids. So I would put them in the second most risky category. The most safe of the three groups would be uncertified uncontrolled open-ocean salmonids such as I have talked about here.

268. Now there may in fact be even higher levels of safety in a well inspected aquaculture environment where you have, say, a well-water source, the stock has come from a certified disease-free population, it is a single species that has been looked at for years by very good methods. In my view, that might be the safest of all of the possibilities, but of the three you mentioned, I would rank them the live ornamentals the most dangerous, the bait fish second and the open-ocean salmonids third.

Chairman

269. Thank you very much. It might be a sensible precaution Jeff, if you would record that question because I ...

Mr. Gertler

270. Mr. Chairman, - it is just this light that is not working.

Chairman

271. Right, good. That brings us to number 13, which again to any or all experts. Dr. Wooldridge, would you like to start on this one?

Dr. Wooldridge

272. I think this is possibly the most difficult question to date actually. I think, by rolling all the things under consideration into this one sentence, one tends to loose track of what we are actually talking about here. I think one needs to break it down into its constituent parts, because we are talking about uneviscerated bait fish, live fish, eviscerated fish of a different species and we have a number of different things implicit in this sentence which need considering. Most of them have been considered somewhere or another, but I think here we need to be clear about what we are trying to compare. The question is asked, whether you need to do a completely detailed scientific risk assessment for each of these situations, I think.

273. My answer is that you need to take account of all the differences in your risk assessment. You should be able to do that in a quantitative assessment in terms of the models you are using. For example, you can compare directly evisceration and non-evisceration by looking at such things as where the organism localizes in the animal or fish. So you may be able to say that the probability of the organism being in the uneviscerated fish is this, and in the eviscerated fish is that. So then, depending upon which type of fish you are talking about in your risk assessment model, you can put in the probability of whether the organism is present or not. When thinking about whether you are talking about a fish that is intended for human consumption after processing in a particular way or whether it is a live fish that is going into a water-way as bait or whatever, then you are thinking in terms of adjusting your model with a different exposure, and possibly different transmission pathways. So you would need to take account and put in the appropriate pathway for this situation under consideration. When you are talking about different species, you may need to take into account that there might be differences in where an organism may localise or the amount of viable organism that might be present in different species and in different tissues in different species.

274. So my answer is: "Sort of". You can look at all these factors in one risk assessment but it might end up with being - with looking like, or with including, several different models depending on which particular aspect you are looking at. So you may in fact end up as having effectively done a number of different risk assessments in order to compare the differences. So I am not giving a clear yes and I am not giving a clear no to that. Because it really depends, I suppose, to a certain extent, what you call a single risk assessment and how complex you need to get given the data you have got to actually compare the differences.

Chairman

275. Thank you. Would anybody else like to have an answer to that? Claudia, do you want to - ? Please.

Panel (Ms. Claudia Orozco)

276. If I may Chairman. Well thank you for that answer, and not being an expert on risk assessment I am puzzled. Because, somehow, two minutes ago - or trying to clarify an answer for question 12, there was a kind of generalization of what experts seem to understand as different levels of risk of different situations. Now we will try to see if we need a complete risk assessment then we have this full explanation. If we tie this back to question 7, it is not clear to me how far a risk assessment has to go if there is a situation like the one that we are looking at where you have identified several diseases of concern and it seems to be ... several products in types of fish and species of fish that are known to carriers of those

diseases. So, in trying to have a full risk assessment, do you need to incorporate a risk assessment of those other products, because you have identified several diseases of concern? From what you are telling us now it seems that you might need, you can - it is not clear if you can generalize or not that bait fish for example poses a higher risk or not. It seems, from what you are saying, that you might need to have a risk assessment - either complete risk assessment or part of the analysis that you are doing. But then in order to have a complete picture, do you have to expand the scope to your original risk assessment once you have identified several diseases concern and that you know that they are potential carriers out there more than the one product that you have in mind?

Dr. Wooldridge

277. I think this is partly why I said this is probably the most difficult question. I think, all I can really say, and I would like Dave Burmaster's opinion on this as well in a moment, is that it, what you do depends on the particular risk you are trying to assess. That goes back to question 7 and that takes care of varieties of products. If you need to look at the risks - or if you are trying to look at a particular disease X, and it is potentially present in certain products, you would need to do an assessment for each of those products.

278. In this question, what you are trying to do, perhaps, well - if you are trying to actually assess the probability of, say import of a given disease in a given product, and you undertake a quantitative assessment, you actually do not need to worry about the probabilities in a different product if you are only thinking about this one particular product. However, if you are trying to say which is the most risky, then you do need to know something about and possibly do a full assessment for another product. The most likely - if you had full data for your original assessment, you really would not be worried about these other products in that context. But the question, or as the problem comes, when you do not have the data you would perhaps ideally want for your initial risk assessment, and you have to base some parts of that model and the data you put into it, on knowledge from a different source, and you would then say something like, or one might say something like, "well, we have been importing this and" - or, "you have been importing that and it looks riskier so it must be alright". Then if you wish to actually compare them in a proper risk assessment fashion, you would need to actually pick out the bits that were different and show that the one you were saying was riskier, actually *was* riskier in the particular part that you were talking about. For example, if you are trying to compare the eviscerated with the uneviscerated you would want data to show where the organism localized in the fish. If you were trying to compare the *use* of the product, you would want data to compare the exposure pathways for example. I am not aware that actually clarifies things or whether I am making things more confusing. I would like Dave to come in and see if he can put it a different way that perhaps clarifies the issue from a different perspective.

Dr. Burmaster

279. Thank you Mr. Chairman. Let us see, as this question is written (question number 13), the first sentence contains a contention - a very sweeping generalization. It is a very sweeping generalization, and I guess I am sceptical of that generalization as it is written. I do not know enough to prove that it is absolutely true, I could not tell you if it is absolutely true, I cannot tell you it is absolutely false either. I cannot name here a counter-example. One of the things scientists like to do is to find a counter-example of something and say "well here is specific counter-example" and that one counter-example makes the generalization false. So I guess I cannot either support or criticize or condemn, or disagree with the generalizations written. Nonetheless, it may contain sort of the kernel of a truth. I heard one of the previous experts say that there nonetheless maybe a something of a kernel of truth in this, that eviscerated fish - I think, of the list of three that you had earlier - that eviscerated fish was the least risky. Am I correct in that?

Chairman

280. Well I think that is partly where the Panel's confusion has come from because we understood from the earlier discussion that fish put directly into the water course, which are the first two that are mentioned here, the bait fish and the live fish, are likely to be a higher risk than product which is imported solely for

human consumption and is not intended to go in the water course. So is that statement compatible with the answers that we have now heard?

Dr. Winton

281. Yes, for a couple of reasons. One, the fish that go directly in the water course bypass some of the exposure methods that might be imagined, some of which are not so likely that would accompany human consumption products, and, secondly, because some of these fish are known to be carriers of diseases and if they are particularly uncertified or unexamined, could be carrying that disease at a level as high or higher than that of an eviscerated product.

Chairman

282. And you can make that statement without having a scientific risk assessment?

Dr. Winton

283. You can make that statement for certain species of fish in certain areas of the world. I could make that statement with a high level of certainty for Pacific herring in North America. As bait fish those fish contain a significantly and quantifiably higher incidence and prevalence of infection than do Pacific salmon. Thank you.

Chairman

284. Australia, you have a follow-up - ?

Australia (Mr. Gardner Murray)

285. Gardner Murray, Yes, I will just make more of an observation more than anything else. As a sweeping generalization, everyone agrees with these kind of three levels of risk. What Australia is saying is that you have got to do more than that. You have go to do more than sweeping generalizations if you are looking at product which may have a different intended purpose. So therefore, Australia contends that whether ornamental fish, or whether bait fish, we need to do a risk assessment because the source, which are - the country factors, the number of diseases, the intended use, the pathways, the socio-economic consequences, might give you a different equation. So in short, we agree with generalizations, but the specifics are really what we are dealing with.

Chairman

286. Dr. Wooldridge.

Dr. Wooldridge

287. I think actually, that was precisely the point I was trying to get at perhaps when I said that you actually need to be able to have the data for each part where a difference may occur and compare or put into the model those differences. So for example, if you are talking about eviscerated versus uneviscerated you need to have the two parts of information to compare in the model that you are using. If you are talking about a different *use* for fish, for example bait fish as opposed to human consumption, you need to be able specifically to put the data for the different exposure pathways into that model. That is, I think, we are saying something like the same thing there. The question asked whether it would require a complete, detailed scientific risk assessment. The simple answer is, yes - but many parts of that risk assessment, many parts of the model, might already be present in your previous model for one of your other scenarios and that certain parts of that model would need to be altered specifically to take account of each of the differences which are present in the different scenarios which one might be attempting to compare.

Chairman

288. Thank you. I do not want to labour this too much, but if you were going to do a risk assessment in these three areas that are mentioned, would it not be a logical approach to start with what you perceive the highest risk area rather than the one that you perceive to be the lowest risk area. I mean, if you were going to commit resources to a risk assessment at all -

Panel (Mr. Kari Bergholm)

289. My questions goes that, in fact, I think we are here speaking not about risk assessment so much as to hazard identification. You have said that the first stage always must be a hazard identification. We know that the objective of the Australian measure is to protect their domestic salmon stock, that is the aim, the objective of their measure. Then I think the first stage of risk assessment should be hazard identification. What is your opinion as expert, what would pose the most likely hazard, in this case: the eviscerated salmon or the bait fish or the ornamental fish? If you make the hazard identification, where should you then concentrate your risk assessment? Thank you.

Chairman

290. Dr. Wooldridge.

Dr. Wooldridge

291. Yes, the hazard identification is the first step. From there, one would prioritize in whatever seemed the most logical way. I am not, as you know, a fish expert. If I had got the various scenarios suggested in this particular question, I would go and ask a fish expert which was the appropriate order of prioritization to tackle the risk assessment, and that is passing the buck, but that is the best way to do it. There is no point in me, not an expert, deciding which to do. So yes - but, and starting from a completely open beginning, it would be sensible to assess that which you have prioritized initially to have the highest risk first, but, until you have done the risk assessment, you actually cannot be sure you have got that right. So there is a circular argument here, it is a problem, you could get it wrong whatever you do, and you might never know.

Chairman

292. I thank you. Dr. Winton, you have anything to add to that? No. What about Dr. Rodgers, as the fish expert - about hazard identification?

Dr. Rodgers

293. Thank you. I get the distinct impression in this case that we are talking about wild caught Pacific salmon and not ornamental fish, which is why we are here. So the first place where you would start, if that was the premise, would be to do your risk identification, your risk assessment exercise on that group of fish. However, if you were also concerned that there were other potential imports, or existing imports, in another group of fish which had been demonstrated already through the scientific literature to be carriers or to undergo certain clinical disease outbreaks which you confidently believed by monitoring did not exist in your country, then you would almost certainly have to do a risk analysis and a risk assessment on that group as well. So as Marion said, it is a circular argument. If the issue is wild ocean-caught Pacific salmon, there is not much point in starting with ornamental fish, although they may come into the equation.

Chairman

294. But if the issue is measures to protect Australian salmon, then what would your answer be?

Dr. Rodgers

295. That is a political decision. I would have to undertake a scientific risk assessment which would give me an answer as to which was the most risky group and that advice, irrespective of which group that would be, would then be past to my civil service equivalent. I was a civil servant, I was good at saying "Yo". No, you cannot say, without doing the risk analysis, the full risk analysis, which includes risk communication, so -

Chairman

296. I think we have probably had all that we are going to get out of that. Not much point in trying to squeeze the lemon any further. Can we go on to number 14 which is addressed to all? Who would like to start on that one? Yes, Australia, are you still on 13?

Australia (Mr. Gardner Murray)

297. Yes, I was just going to sort of make another observation. One which deals with your logical approach, and second which deals with the issue at hand. The reason we are here is because there has been a request, and so therefore we have conducted a full-blown risk analysis to meet our obligations. On the second issue, that is the logic of the situation, our government has decided that a series of risk assessments need to be carried out on a range of products, and this includes additional staffing, it includes a timetable for those risk assessments. These include ornamental fish, a re-evaluation of our approach on ornamental fish; this includes a re-evaluation of our policy on bait fish. But at the same time, the quarantine service has still got to deal with requests from countries for access so it is an enormous effort. Concurrently you have got to deal with requests from Canada and other countries and do risk assessments while at the same time you have got to look at those areas that you wish to examine because you continually want to protect your fish health status and this is the balancing act that Australia is involved in at the moment.

Chairman

298. Thank you. Right, well, obviously we will no doubt have the opportunity to go into that sort of issue a bit further tomorrow. For now I think perhaps we could pass onto the next question. Which of the experts would like to address number 14? Dr. Burmaster?

Dr. Burmaster

299. Thank you Mr. Chairman. I am unaware of any advances in scientific knowledge that occurred between May of 1995 and 1996 which would justify the changes between those two documents.

Chairman

300. Thank you. I am sorry, could you repeat that answer again please.

Dr. Burmaster

301. Yes, I will repeat it. I am unaware, I am not aware of any advances in scientific knowledge that would justify the changes and conclusions between the May 1995 Draft Report and the 1996 Final Report.

Chairman

302. Dr. Rodgers.

Dr. Rodgers

303. I think all the experts are in agreement.

Chairman

304. Right, well in that case, let us go on to number 15 and this is the one where I had an addition. I suppose you have noted my addition to that, Dr. Winton.

Dr. Winton

305. You have only made the question more difficult but I will attempt to answer it. I think I have already tried to state that evisceration really is seen as a way to reduce the risk, perhaps not just of Notifiable Diseases but of other diseases, but certainly in different levels with respect to the nature of the disease, where the organism might be found and at what levels . For each disease we have some, but perhaps not enough information, to be able to rank them convincingly. Relative to evisceration for *Renibacterium salmoninarum*, IHN virus, salmon leukaemia virus and *Henneguya* it is sort of tough. For example, *Renibacterium salmoninarum*, is generally regarded to be a pathogen exclusively of salmonid fish and, as its name suggests, *Renibacterium* is primarily associated with bacterial kidney disease. It is found in large amounts in the kidney and in other haematopoietic tissues (kidney, spleen) and to that extent would be reduced significantly by evisceration. But foci *Renibacterium salmoninarum* have been found in other places in the fish, maybe less frequently, but behind the eyes is one, occasionally in the muscles. *Renibacterium* is generally vertically transmitted from adult to progeny through the egg, in many cases of Chinook salmon and salmon in the North West, and occasionally by water-borne exposure but the water-borne exposure levels are somewhat lower. But the effectiveness of evisceration for *Renibacterium salmoninarum*, in general, is quite good in that the visceral organs would be the areas in which you would expect to find the highest levels of bacteria. Similarly with IHN virus - this is primarily a virus of the haematopoietic cells - the kidney, the spleen of the fish, and likewise would be found at high levels in the viscera. But examinations of different tissues and organisms, organs of fish, have also revealed levels of IHN virus in the mucus and skin of the surface of the fish and certainly in the blood, so again, evisceration could be judged to provide a substantial, but perhaps not complete level. I am unaware of sufficient data on salmon leukaemia virus to be able to make a judgement but presumably it would be found primarily in the blood cells of the fish and to the extent that evisceration removed the blood which must be 90 some per cent, it could be expected to be somewhat effective there as well. For *Henneguya* I would refer to Dr. Rodgers, a little bit because I am not a parasitologist by training, but *Henneguya* does not survive all that well except on live animals like a lot of parasites. I think it would be tough to judge in my view, and I guess evisceration probably would not make as much difference as it might for the other diseases.

Chairman

306. Thank you. Dr. Rodgers.

Dr. Rodgers

307. I agree, but I am a bacteriologist as well so - No, I agree that it does not survive particularly well outside of the host, and this probably would be an effective method particularly with the washing step included in evisceration.

Chairman

308. Thank you very much. So if there is nothing more on that perhaps we can go onto 16 which is addressed to all. Who would like to start? Dr. Wooldridge.

Dr. Wooldridge

309. We have - and I think I touched upon this in the written answers that I gave you (the extra ones) this morning. With a risk assessment one would normally look at a baseline with either no safeguards in place or the current level of safeguards in place. If that produces an unacceptable risk, then one needs to look at the assessment with various safeguards in place. If you already have quarantine requirements as part of your normal safeguard then I can see no reason why they should not be included in your initial

assessment. If you actually end up by having an assessment result that gives you an acceptably low risk having put in place vast numbers of additional safeguard measures, then, without looking at the intermediate stages, I think that probably is not acceptable. But we do not have that situation here; we have a situation where even putting in place all the safeguard measures, the risk assessment has come out giving an unacceptable level of risk. So the conclusion is to my mind that in order to be acceptable as things stand at the moment to Australia, they would need to be even more safeguards in place which we are not sure what they might be at the moment. So - in *their* terms we have not yet reached the appropriate level of protection. So what I am trying to say is that if we have reached what they consider to be the appropriate level of protection and that perhaps in fact that had been reached at some way prior to putting in all those safeguards, then the appropriate methodology would be to actually go back and look at the problem with fewer safeguards in place. But in their terms we have not reached that point, so that is not, from their point of view, yet an appropriate option. Does that answer the question?

Chairman

310. I think so but I think we may need to provide a bit of clarification. I am going to ask the legal advisor to just say a word or two on that.

The Secretariat (Mr. Jeff Gertler)

311. Thank you Mr. Chairman. Just to point out that the current safeguard as we understood it here what heat treatment and should that be built in? Does that change your - modify your response in any way?

Dr. Wooldridge

312. In as much as heat treatment changes the product, we are then effectively looking at a different scenario so what you are then saying is that - I think logically you should, well, what, - What am I trying to say here? Let me try and get this right. Heat treatment did not even - if the level of protection is acceptable without heat treatment, then any other safeguards, for example, removing offals, de-boning etc., it is acceptable to include them in the methodology. If heat treatment takes you to the stage where you change from unacceptable to acceptable, then you do need to have two different risk assessments, one included and one not, in order to compare the differences and say "this is where we find it acceptable and this is where we find it unacceptable". It would not I think be enough to just do a risk assessment with heat treatment in it, quantitatively, now I am talking about, and say "we need this safeguard". I think it would be necessary to show that without that the risks were unacceptable. Does that clarify the -

Chairman

313. Thank you. Dr. Rodgers.

Dr. Rodgers

314. I would just add that I think what Marion is trying to say is that you can adapt the model, if you like, by putting in and taking out your, in this case risk management measures, your risk reduction factors, to see how it effects the final result. Heat treatment is a potential risk reduction factor, as well as evisceration for instance - but it may be the last one, the most effective, but you would not know until you had incorporated it into the model and seen how it would effect the overall result.

Dr. Wooldridge

315. I think the point of the question, I think, was to try and work out whether simply saying "we need to do that in order to make it acceptable" is good enough. Do we need to actually show that the level below that is unacceptable. I think if you are going to say we need to do that as an extra over and above the normal measures of quarantine or testing that we would take, then you do have to actually do the two

and show the difference. To just go straight in and have a risk assessment that includes heat treatment when heat treatment is not your normal baseline safeguard is not appropriate methodology.

Chairman

316. Thank you. Yes, Jeff.

The Secretariat (Mr. Jeff Gertler)

317. But let us assume, as my understanding of it is to be the case in Australia, that heat treatment is the normal baseline safeguard, is it then appropriate to build it in to your risk assessment or should you still do one with and one without that safeguard?

Dr. Wooldridge

318. Since I think heat treatment effectively changes the product, I mean, if you are looking for muscle meat and you eviscerate and you de-bone, you have not changed the product, you are giving the consumer the product that they think they are getting. If you heat treat that actual muscle you are changing the product, therefore you are effectively importing a different product. Therefore if you are talking about the import of salmon, uncooked, unheat-treated, fresh salmon, then that is not actually a safeguard that you can put in place and still have the same product. So you do need to actually do a risk assessment which does not have that in place to get a level of risk out of that to decide whether that is acceptable or not.

Chairman

319. Thank you. Sorry, go on.

Dr. Burmaster.

320. Okay, thank you Mr. Chairman, that is an interesting answer. It is very difficult to import fresh salmon that had been cooked. I think that is a contradiction in terms. If you are interested in doing a risk assessment on fresh salmon I think you do it on fresh salmon and there is an old adage in computer science I want to bring up, but first let me sort of set the stage. I think that the type of risk assessment that needs to be done in this situation is one that would be done somehow using computers and software to do a simulation. It would have many of the characteristics in the report as prepared by David Vose. This report would be a computer simulation that would consider various risks, various options. Now the adage from computer science, is that the purpose of computation is insight and it seems to me that if there is a contention here in the room about what effect does cooking have, well you could build a computer software to include a toggle switch where you have cooking yes or cooking no and you run the software two different ways, one with the toggle on, you get some results, and one with the toggle off and you get a different set of results and you compare the difference. From that difference you try to figure out what is going on, what is going on in the computer programme and what is going on in the real world. So I guess those are my two thoughts.

Chairman

321. Thank you very much. Does anybody have anything else to add to that? Well, I think that brings us to the end of the list of questions. We have dealt with seventeen. I propose at this stage to invite the experts one by one to make any concluding remarks that they may have, rounding up the discussion and stressing any views and conclusions that they regard as important. Perhaps we can proceed in alphabetical order again. Dr. Burmaster.

Dr. Burmaster

322. Well, at the risk of simply reinforcing what I have stated in my written response, and in my spoken comments here today, I think there is a consistent theme and I may just as well round out the

afternoon by stating it fairly bluntly. To my mind, the documents prepared, both the May, sorry, let me get the dates out here, the two risk assessments, so called, prepared by Australia in 1995 and 1996, do *not* meet what I consider to be the minimal requirements of a risk assessment. So in the last couple of weeks I have posed myself - well, they are long thick documents and there was a great deal of effort put into the preparation of these documents, it was a sincere effort on behalf of Australia to prepare those documents. What could they possibly be? If they are not risk assessments what could those wonderful, those long thick documents be? And I guess I come to the point of view that they are hazard identifications. They are long, and I think thorough, and if I understand Dr. Winton's and Dr. Rodgers's comments, they have really looked at a comprehensive list of the bacterial and viral diseases that could *possibly* be transmitted into fish in Australia. But because there is no quantitation, there are no quantitative arguments, it is for that reason, I believe that these documents prepared by Australia, do not meet my definition of what the minimal requirements for a risk assessment. So I think we have all been reading very thorough hazard identifications and we are yet to read a risk assessment from Australia. Thank you.

Chairman

323. Thank you very much. Dr. Rodgers.

Dr. Rodgers

324. Thank you Mr. Chairman. I really have not got any extra comments and I would not like to sum up the whole day in two minutes. I stand by what I said this morning in my opening 20 minutes. The only point I would like to reiterate from what I said this morning is that I think that everybody is in general agreement that there is a level of risk, and whether that risk is then acceptable or not is the key issue. That level of risk can only be acceptable providing you put in place a risk management procedure which is a risk reduction, a set of risk reduction factors, which are acceptable to both parties. That is the only way you can get some leeway in the situation. But personally I think that looking at the SPS Agreement and the OIE guidelines that it does seem that a country can set its own level of - its own acceptable level of risk, whatever that is. Just coming back to what Marion was talking about now, is that somewhere down the process, somewhere, by building in a set of risk reduction factors, you reach a point where you do find an acceptable level of risk. Now that may be when you have finally put in the last risk reduction factor or it may be in the middle. It is just something which has to be done by risk analysis and also by negotiation if the parties cannot agree on what that acceptable level of risk is.

Chairman

325. Thank you very much. Dr. Winton.

Dr. Winton

326. I only have two comments and I hope they are relatively short. One from the OIE Fish Disease Commission standpoint, in question 6 which we actually ignored, in the last statement is this actually the OIE recommendation, i.e. evisceration or a *de facto* standard. I think I have tried to explain that the OIE Fish Diseases Commission, in the absence of information to the contrary, viewed evisceration as taking that risk to below that would remain in the purview. But to some extent it is also a *de facto* standard in that many salmon-trading countries have viewed evisceration as acceptable for imports, for example regulations in the United States, the entire European Community and in Canada, now allow the importation of eviscerated without inspection regardless of origin. So to some extent, many of the salmon-trading partners have already decided this by themselves and so it is hard to say it is a *de facto* standard but it is not the OIE Fish Disease Commission that is actually pushing this, it is more widely I think understood.

327. Secondly, I think today has pointed out the very great need for additional scientific information. As a researcher I go away from here really with the understanding that we need a lot more information on things like decay curves of pathogens, reservoirs of infection, transmission mechanisms, the basic epidemiology of fish diseases. I think many of these disagreements are partially a reflection of the absence of information, and Australia's coming down in the absence of information with a more conservative

approach; Canada in the absence of the same information with a more trade-orientated approach. But in neither case are all the data available by which to construct the final perfect quantitative risk assessment. For example, as detection methods improve it would not surprise me to find *Renibacterium salmoninarum* in some Chinook salmon in Australia. I cannot predict that for certainty but I would be willing to bet a substantial amount of money on it. The same issue occurred in New Zealand when we developed a new test for *Renibacterium salmoninarum*. We went looking for negative control tissues for our test and we were sent some tissues from New Zealand, and in fact we found low levels of positives, and by exhaustive examination we actually in our laboratory have evidence that very few numbers of those salmon are in fact at that very low sub-clinical level. This is not unexpected given the fact that Chinook salmon were brought to New Zealand from the United States, and that this disease is commonly transmitted with the eggs. So I think that as detection methods and our understanding and our data improve, many of these issues will begin to resolve themselves and I apologize, as a scientist, that we do not have sufficient data that this large exercise has been necessary. I think perhaps had we been better at our jobs a lot of this information would have been available and it would have been easier to make these sorts of decisions. Thank you.

Chairman

328. Thank you very much. Dr. Wooldridge.

Dr. Wooldridge

329. I am not sure that there is a lot left to say really, we seem to have said quite a lot already but I would just like to reiterate, restress two points which are very important from my standpoint and the way I see things. The first one is the absolute necessity of differentiating between the assessed and the acceptable risk and I think at the beginning of the day maybe that was not quite so clear. I think we all know now that there is a difference between the two and they both need to be taken into consideration but in different ways. The other point I would like to make is that I see risk assessment as a sort of a fairly pragmatic process, in a way, in that you start at the simplest level with what I would call a qualitative risk assessment, what Dave Burmaster would call a very thorough hazard identification, and if everybody agrees on the results then that is as far as you need to go, bearing in mind things like these are incredibly costly, time-consuming etc.. However, if there is disagreement then you need to go to the next step, and the next step is probably to undertake, or attempt to undertake a quantitative assessment. And if you do that successfully and everybody agrees, fine. But if you find that you do not agree on the data or the data is not available, then you need to go to the next step and put in place the required epidemiological or bacteriological or other studies or experiments to get the evidence in order that you can complete a quantitative risk assessment. So I think you go as far as you need to go until you can get appropriate agreement on the level of risk by all concerned. And when you have got that - that was the easy bit - you then have the difficult bit sorting out what is acceptable. Because we have all discovered that varies, and I think that is actually much harder to agree on and that is really all I have got to say, thank you.

Chairman

330. Well, thank you very much. I think it only remains for me to thank the experts for their very patient and expert answers to our not always very expertly phrased questions. I think at the end of the day it will be clear that your input has been extremely valuable to the work of the panel and we are very grateful to you for participating in this process today and for the written work that you produced before that. So thank you all very much indeed. We will meet tomorrow morning with the parties at 10 o'clock in Room C, downstairs, and continue our process there but as far as the experts are concerned, thank you. That now concludes our session for today and have a safe journey home. Thank you very much.

ATTACHMENT

Questions Posed during the Joint Meeting with Experts, held on 4 February 1998

1. **To Dr. Winton:** With reference to the Panel's initial Question 3, do you believe that a risk assessment must consider the **probability** of risk or is it sufficient to identify the possibility of risk?

2. **To Dr. Rodgers:** We remain somewhat confused regarding your views on probability versus possibility in terms of risk assessment. In some of your written responses, you appear to equate estimates of probability with quantitative risk assessments and conclusions of possibility with qualitative ones. In another response (to initial Question 1), you indicate that the May 1995 Draft Report uses a qualitative risk assessment methodology to identify probabilities to disease introduction. Could you please clarify your views on the differences in these terms in the context of risk assessment.

3. **To Dr. Rodgers/Canada:** With regard to the identification of possible diseases in Canadian salmon, Dr. Rodgers has identified four disease agents not included in Canada's list (*Kudoa thyrsites*, *Parvicapsula* sp., flexibacteriosis and proliferative kidney disease (PKD). Canada argues that these should not be included in the Panel's consideration because the first two disease agents have not been found in adult, wild ocean-caught Pacific salmon and PKD is not known to occur in any of the five categories of adult salmon. Furthermore, Canada notes that Australia does not include *Kudoa thrysites* or flexibacteriosis on its most recent list of diseases of concern. To what extent does Dr. Rodgers believe these diseases are of sufficient concern to be considered in the evaluation of risks?

4. **To Dr. Rodgers and Dr. Winton:** With regard to concerns about "carrier fish" as "reservoirs" of a disease agent, to what extent is this concern applicable to dead fish (rather than live fish)? to eviscerated fish?

5. **To Dr. Rodgers:** Are salmon scavengers? Will they eat scraps of salmon meat?

6. **To Dr. Winton:** The Final Report refers to the "... current international standards for trade in salmon product for human consumption, that is, OIE recommends that product be eviscerated and that no other risk reduction measures need be taken". Is this actually the OIE recommendation, or a de facto standard?

7. **To Dr. Wooldridge:** Could you please clarify whether you believe that a risk assessment should consider risk on both a disease-by-disease and a product-by-product basis, or one basis or the other? Response to 2.4.3 seems to suggest two alternative approaches - what is the risk of exotic disease Y being introduced by product X? or what is the risk of introducing exotic disease Y, independent of the product. Are these two alternative models or once you decide there is evidence or suspicion that exotic disease Y might be in product Z, do you need to broaden the risk analysis for any other product of which you have evidence that carries disease Y?

8. **To Dr. Rodgers:** To the extent that a particular disease has not been found in a category of fish, can one assume that the probability of its existence is very small?

9. **To any/all of the experts:** If a disease has not been found to exist in fish from specific waters/area, should this disease nonetheless be considered in a risk assessment of fish from this area? If several diseases are included in a risk assessment model because there is suspicion that the product in question may be a carrier, and during the analysis evidence does not show that the disease is known to exist in the product in question, i.e. the first event in the chain of events does not occur, should you narrow the analysis to the diseases confirmed to be in the product in question?

10. **To all of the experts:** solicit comments/reactions to the "Vose Assessment" provided by Canada.

11. **To Dr. Burmaster:** In responding to Question 6 regarding the consequences for disease establishment regardless of the imported host, you indicated that you believed the statement was correct

and that you could not think of a counter-example to this principle. Do you believe that this principle is valid in virtually all circumstances? Do you believe that this principle is valid in regard to the fish diseases of concern as identified by Australia?

12. **To any/all of the experts:** Do you believe that adult, wild, ocean-caught Pacific salmon pose less of a disease risk than the other categories of salmon identified by Canada (i.e., (i) adult, wild **freshwater-caught** Pacific salmon; adult, **Pacific** salmon cultured in seawater on the **Pacific coast**; adult, **Atlantic** salmon cultured in seawater on the **Pacific coast**; and, adult, **Atlantic** salmon cultured in seawater on the **Atlantic coast**)?

13. **To any/all of the experts:** Australia contends that the "generalization that uneviscerated baitfish or live fish pose a greater threat than eviscerated fish of a different species cannot be substantiated without reference to a risk analysis including detailed scientific risk assessment." Do you agree with this contention?

14. **To any/all of the experts:** The Panel previously asked (Question 18) if there were any advances in scientific knowledge that would justify a change in the conclusions from the May 1995 Draft Report to the 1996 Final Report? Are you aware of any such new scientific information?

15. **To Dr. Winton:** Australia characterizes your responses with regard to evisceration to be limited to the FDC list of "notifiable" diseases. Do you believe that evisceration provides the same effective reduction of risks for "non-notifiable" diseases?

16. **To any/all of the experts:** Australia indicates that "Options for pre and post entry quarantine conditions on imported product were built in to all stages of the risk analysis and can not be separated out. This includes .... evaluation of measures for reducing risks and consequences in the context of the appropriate level of protection." Is this an appropriate methodology for consideration of various sanitary options for reducing risks to the acceptable level? Article 5.6 of the SPS Agreement requires that

> "... 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."
>
> A footnote to this provision indicates that:
>
> "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."

17. **To any/all of the experts:** If, in your view, an option-by-option assessment is one of the minimum requirements of a risk assessment, is it enough to "assess" the risks associated with each of the SPS options (i.e. risk reduction measures) a country is considering? Or does one also need to "compare" the risks related to these different options and in the end give a rational explanation, in terms of relative risk, why one option is chosen rather than another?

WORLD TRADE ORGANIZATION

WT/DS18/R/Corr.1*
13 July 1998

(98-2751)

Original: English

AUSTRALIA – MEASURES AFFECTING IMPORTATION OF SALMON

Report of the Panel

Corrigendum

The cross references highlighted in the paragraphs below were inadvertently deleted from the report:

7.6 Following Australia's more detailed objections to take into account evidence submitted by Canada after the 7 October 1997 deadline we imposed, we modified paragraph 8.4 and added paragraph 8.5.

7.7 Canada requested us to review our finding in paragraph 8.20 that steelhead/rainbow trout falls outside our terms of reference because, Canada submitted, the measure subject to the terms of reference applies to all salmonids, not only to salmon. Canada further indicated that some debate exists as to whether steelhead/rainbow trout is a salmon or only a salmonid and that practice in North America considers it to be a salmon. We recall that in paragraph 8.20 we stated that "steelhead/rainbow trout ... is - according to the experts advising the Panel on this issue - not a "salmon" species but only part of the wider "salmonid" family".

8.17 The 1996 Decision is a decision taken by the Director of Quarantine on the basis of the authority delegated to him by QP86A. Following a recommendation of the Chief Veterinary Officer "that the status quo for quarantine policies for uncooked salmon products continue", it explicitly states that the "importation of uncooked, adult, wild, ocean-caught Pacific salmonid product from the Pacific rim of North America should not be permitted on quarantine grounds". It thus confirms the general prohibition in principle imposed by QP86A on the importation of all salmonid products (unless special authorization is granted) for a limited category of salmonid products. It confirms, more particularly, the decision taken by the Chief Quarantine Officers (Animals) Conference, referred to in paragraph 8.15, that "all fresh or frozen salmonid flesh is prohibited".

8.37 On these grounds, we find that, even though both definitions of a "sanitary measure" invoked by Australia might be applicable to the measure in dispute, in the specific circumstances of this case we need to examine this measure as a measure applied "to protect animal ... life or health within [Australia] from risks arising from the entry, establishment or spread of pests, diseases ... or disease-causing organisms" in the sense of paragraph 1(a) of Annex A to the SPS Agreement. Given our earlier considerations in paragraph 8.30, we thus find that the SPS Agreement applies to the measure in dispute.

*English only

./.

The following correction should be made to footnote 284:

Wooldridge answers, p.6, ~~quoted in para. 8~~. and Rodgers answers, p.1 ("As such, the 1995 report is a more useful document, in the sense of an internal risk assessment exercise, since it 'evaluates' the data to conclude that a negligible risk exists, while at the same time recognising that the overall risk of disease introduction cannot be quantified. The final report seems to lend more weight to the unknown elements of the assessment and as such is more cautious, which results in an outcome closer to the 'unacceptable' rather than the 'negligible but acceptable' end of the scale").