CHAPTER SIX

THE METHODOLOGY OF THE IMPORT RISK ANALYSIS AND THE SCIENCE

Introduction

6.1 The basis of quarantine restrictions must be scientifically justifiable. AQIS has stated that its 'studies are based on the most comprehensive series of scientific studies undertaken by a quarantine service on the import of fish products for human consumption'.[1] However, AQIS has been criticised by some stakeholders for the rigour of its scientific analysis and particularly for the conclusions and policy ramifications resulting from its 1999 import risk analysis.

Import Risk Analysis Methodology and WTO Requirements

6.2 In preparing the IRA, AQIS drew upon the principles outlined in the OIE *International Aquatic Animal Health Code* (the Aquatic Code) and the OIE *International Animal Health Code*.

6.3 The difficulty of undertaking risk analyses and the emerging nature of the process has been recognised by the OIE. That organisation conducted an international forum on risk analysis in aquatic animal health in Paris in February this year. The opening statement to the conference emphasised the difficulties inherent in undertaking risk analyses for aquatic animals:

> The aspects of the life-cycles and survival parameters of fish and shellfish pathogens are often poorly understood and consequently complicate the application of risk assessment to even the most thoroughly studied models. There are certain critical areas, such as diagnostic techniques and the environmental impact of pharmaceuticals, for which research is lacking and in which risk assessment can be used to highlight research priorities for these topics. Risk analysis is a tool designed to assist decision-makers.

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1 AQPM 1999/51, 19 July 1999, p 2

There is a pressing need for a supportive forum to help solve the problems encountered when performing existing risk analysis methods.[2]

The 1999 Import Risk Analysis Methodology

6.4 The International Animal Health Code [Appendix VI to the AQIS submission] contains the guidelines and principles for conducting 'transparent, objective and defensible' import risk analyses. These have been developed by the OIE, which identifies the components of risk analysis as being:

a) *Hazard identification*;

b) *Risk assessment*[3] - identifying and assessing the risks and evaluating the consequences - this is the component of risk analysis which may be quantitative or qualitative;

c) *Risk management* - identification, documentation and implementation of measures that can be used to reduce the risks and their consequences; and

d) *Risk communication* - means of communicating the results of the risk assessment to decision makers, regulators, industry and the public.[4]

6.5 The AQIS IRA model is shown in Figure 6.1.

Hazard identification

6.6 The starting point of the IRA is hazard identification. In the IRA, AQIS used the following criteria to identify the disease agents of quarantine concern requiring consideration in the IRA. This is one aspect of an IRA which it is agreed is appropriately undertaken qualitatively.

6.7 AQIS gives detailed consideration in the IRA to a disease agent if it is:

1 infectious; **and**

2 (a) exotic to Australia; **or**

(b) present in Australia but subject to official control; **and**

3 (a) OIE listed, **and/or**

(b) would be expected to cause significant harm in Australia.

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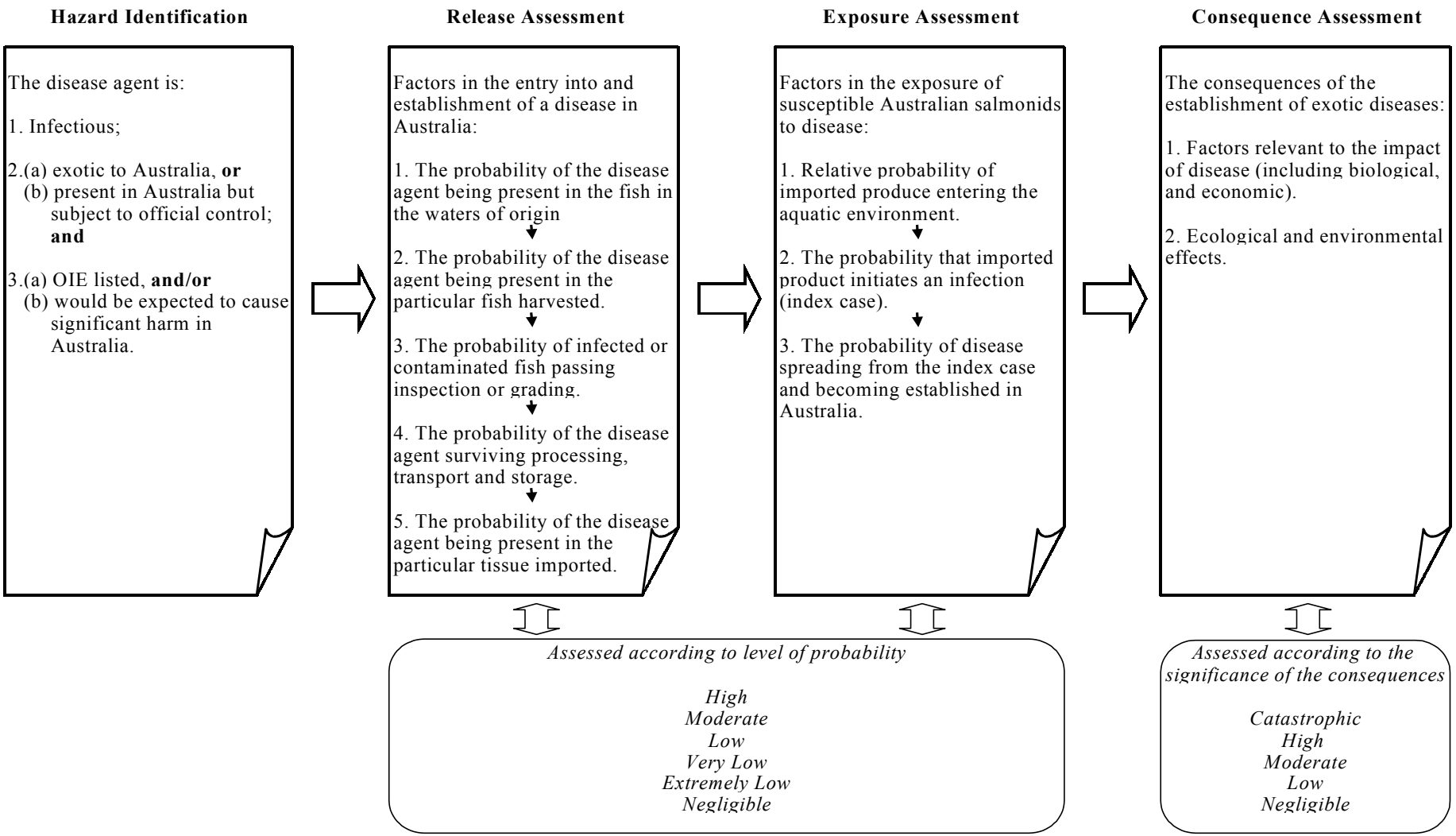
2 Welcome message, OIE conference on risk analysis in aquatic animal health, Paris, 8-10 February 2000

3 The compiled responses from the Panel of Experts set out in the Panel report, noted the confusion within the AQIS documentation on the use of the terms *risk analysis* and *risk assessment*, and the use of the phrase *risk analysis*, when the more restrictive term, *risk assessment,* should have been used. Report of the Panel, p 96. This report uses the term in a restrictive way, ie as an element in the risk analysis process.

4 OIE, *International Animal Health Code*, Article 1.4.1.1

Figure 6.1 - the AQIS IRA model



Prioritisation of Diseases and Disease Agents

6.8 The OIE's Aquatic Code classifies aquatic animal diseases as diseases notifiable to the OIE (transmissible diseases that are important for public health and/or trade reasons); and other significant diseases (diseases that are of current or potential international significance in aquaculture but of less importance than the notifiable diseases, are less widespread, or have less well-defined aetiology).

6.9 There are four diseases of fish listed in the International Aquatic Animal Health Code as 'notifiable' to the OIE which affect salmonids and non-salmonid marine finfish. There are seven others listed as "significant", but not included in the list of notifiable diseases 'because they are less important than the notifiable diseases; or because their geographical distribution is limited, or is too wide for notification to be meaningful, or is not yet sufficiently defined; or because the aetiology of the diseases is not well enough understood; or approved diagnostic measures are not available'.[5]

6.10 The four notifiable diseases are epizootic haematopoietic necrosis, infectious haematopoietic necrosis, oncorhynchus masou virus disease and viral haemorrhagic septicaemia. The seven listed as significant are viral encephalopathy and retinopathy, infectious pancreatic necrosis, infectious salmon anaemia, epizootic ulcerative syndrome, bacterial kidney disease, piscirickettsiosis and gyrodactylosis.

6.11 Australia has raised concerns about the way the OIE implements the definitions used for categorisation of diseases and the resulting exclusion of diseases that are of significant concern in countries like Australia, but which do not appear on the list because they are commonly found in Europe and/or North America:

> 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.[6]

6.12 The Executive Director of AQIS drew attention to the potential problems for Australia and the necessity to have input into the categorisation process:

> if you accept that our obligation is to start as the primary reference point for the relevant international standard there is in my mind a legitimate question about the issue of consistency across relevant international standards, which is the point that you are going to. In principle, I understand and accept the

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5 Aquatic Code, cited in AQIS, *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish*, July 1999, pp 4-5

6 WTO Panel Report, Joint Meeting with Experts, 4 February 1998, p 224

> point that you are making. There is work that needs to be done. I think Dr Wilson previously explained the work that is carried on through the code commission of the OIE to continually review all of the relevant international standards. One of the things that we clearly have to have regard to in terms of our interests in that review is that the relevant international standards address our interests.[7]

Diseases Considered in the IRA

6.13 The list of diseases included in the IRA was criticised by some stakeholders. However, AQIS advised that the diseases for inclusion in the risk analysis was the subject of specific consultation with the scientific reviewers and the final list of diseases was the result of a broad consensus of scientific opinion. AQIS further argued that no significant new information came to light to warrant changing the list and that AQIS was confident that all issues of quarantine significance had been properly considered.[8]

6.14 Attention was focussed on the following seven diseases:

a) Amoebic gill disease, which is currently present in Tasmanian salmonid aquaculture populations;

b) Renibacterium solmaninarum bacteria (bacterial kidney disease or BKD);

c) Viral haemorrhagic septicaemia virus [VHS];

d) Infectious pancreatic necrosis virus [IPN];

e) Infectious salmon anaemia virus [ISA];

f) Aeromanas salmonicida bacteria (furunculosis); and

g) myxobolus cerebralis protozoan (whirling disease).

6.15 Of these seven diseases, only amoebic gill disease is currently present in Australia. Of the remaining six diseases not currently present in Australia, BKD and VHS are listed by the OIE as notifiable diseases[9]. IPN and ISA viruses are listed by the OIE as significant diseases.

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7 Evidence, RRAT, 22 May 2000, p 28

8 AQIS, Supplementary Submission 62, p 3

9 Transmissible diseases that are 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 [AQIS *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish*, July 1999, p 4]

6.16 Furunculosis and whirling disease are not listed by the OIE, but were assessed in the IRA as 'significant' diseases, and accordingly subject to further analysis.

6.17 A brief description of the diseases follows.

Amoebic Gill Disease

6.18 AGD impairs the gill passages of Atlantic salmon, and is treated in Australia by routine washing of the gills in fresh water. This involves the removal of fish from their pens and their direct handling, placing additional stress on the fish. Dr Alistair Brown, fish veterinarian, noted that he knew of 'no comparable health management practice overseas'.[10]

Viral Haemorrhagic Septicaemia Virus

6.19 VHS causes haemorrhaging and rapid onset of mortality in rainbow trout, but is also known to infect other salmonids such as grayling and whitefish, together with non-salmonids such as pike. Mortality rates may be as high as 100 per cent in seawater, and 80 per cent in freshwater.

6.20 Outbreaks of the disease have occurred in Europe, Japan and North America. Various submissions to the Committee highlighted the attempt by authorities in the US to contain the spread of the virus after its discovery there in 1988. These efforts appear largely to have been unsuccessful.[11]

Renibacterium Solmaninarum Bacteria (bacterial kidney disease)

6.21 BKD is caused by infection with renibacterium solmaninarum, and is a serious, slowly progressing disease that leads to internal necrosis of the kidneys and haemorrhaging of the body wall and hind gut. The disease is endemic in wild salmonids populations of the Pacific coast of North America and has also been reported in Western Europe, Japan and Chile.[12]

Infectious Pancreatic Necrosis Virus

6.22 IPN is an acute disease of juvenile salmonids, and causes severe damage to the pancreas and other organs. Severe outbreaks have led to mortality rates as high as 100 per cent in other countries, especially under conditions of stress or high temperature. Fish that survive the disease develop immunity.

6.23 IPN is known to be distributed world wide, including continental Europe, Scandinavia, the UK, North America, South America and north Asia, but excluding

10 Ocean Wave Seafoods, Submission 55, p 3

11 AQIS *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish*, July 1999, p 61

12 ibid, p 63

Australia. It has also been reported in Chile after having been undetected for over 10 years.[13]

Infectious Salmon Anaemia Virus

6.24 ISA is a blood disorder occurring specifically in North Atlantic salmon, and then almost always in seawater. It is associated with severe mortality rates in affected stock through anaemia, ascites, congestion and enlargement of the liver and spleen, and general haemorrhaging.[14]

6.25 ISA was originally recorded in Norway in 1984, but has since been found in Scotland, and more recently in 1996 in Canada. AQIS disputes submissions to the Committee that the disease has also been found in Chile and Ireland.[15] The EU attempts to combat ISA by eradicating fish stocks when an outbreak is confirmed. By contrast, in Norway, farmers are only required to slaughter the fish in the same pen as an outbreak, and then only when mortality rates reach 0.05% per day.[16]

Aeromanas Salmonicida Bacteria (Furunculosis)

6.26 Aeromanas salmonicida is a bacterium that causes a number of acute to chronic disease symptoms in salmonids and other fish, most notably furunculosis. Furunculosis symptoms include anorexia, haemorrhaging of the viscera, softening of the kidney tissues and enlargement of the spleen. The disease has been diagnosed in North America, South America, Britain, Norway, Europe, Japan and South Africa.[17]

Myxobolus Cerebralis Protozoan

6.27 Infestation with myxobolus cerabralis causes the so-called whirling disease in salmonids. The spores of the parasite attack the nervous system of salmonids, causing death through paralysis and starvation.[18] AQIS notes that in newly hatched fry, mortality rates may reach 100%, while fish greater that 6 months of age show few effects. The disease has been reported in Europe, Asia, North and South America and New Zealand.[19]

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13 ibid, p 59

14 ibid, p 60

15 AQIS, Evidence, RRAT, 11 November 1999, p 338

16 The Hon. Paul Harriss MLC (Tas), Submission 53, pp 4-5

17 AQIS *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish*, July 1999, p 363

18 The Liberal Party of Tasmania, Submission 26, p 3

19 AQIS *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish*, July 1999, p 66

Risk Assessment

6.28 The level of acceptable risk is determined by undertaking a risk analysis, one of the components of which is risk assessment. The OIE defines 'acceptable risk' as the 'risk level judged by Member Countries to be compatible with the protection of animal and public health **within their country**, taking into account epidemiological, social, and economic factors. [20]

Quantitative and Qualitative Risk Assessment

6.29 Risk assessments may be either qualitative or quantitative:

> The risk assessment is the component of the analysis which estimates the risks associated with a hazard. Risk assessments may be qualitative or quantitative. For many diseases, particularly for those diseases listed in the *Code* where there are well developed internationally agreed standards, there is broad agreement concerning the likely risks. In such cases it is more likely that a qualitative assessment is all that is required. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making. No single method of import risk assessment has proven applicable in all situations, and different methods may be appropriate in different circumstances.[21]

6.30 A qualitative risk assessment is one where the outputs on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as high, medium, low or negligible.[22] A quantitative assessment uses probability theory, numerical values being assigned to outputs of the risk assessment to estimate the probability and potential magnitude of a risk. David Vose describes risk analysis and how the two approaches combine in risk analysis as follows:

> Qualitative risk analysis provides a textual description of the risk scenario, backed up by qualitative and quantitative information, and develops a logical argument for assessing the acceptability of a risk and the efficacy of any risk reduction measures that might be considered. Quantitative risk analysis builds on the information and arguments of a qualitative analysis, by using probability theory in an attempt to determine the probability of the risk event occurring and the magnitude of its consequence.[23]

6.31 The OIE states that qualitative risk assessments, those not requiring mathematical modelling skills, will be more commonly used for those diseases, particularly those listed in the Code, where there are well developed internationally

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20 OIE, *International Animal Health Code*, Article 1.4.1.1

21 OIE Import Risk Analysis Guidelines, Article 1.4.1.1

22 OIE, *International Animal Health Code*, Article 1.4.1.1

23 D Vose, *Qualitative versus quantitative risk analysis and modelling*, OIE Conference, Paris, February 2000

agreed standards, and there is broad agreement concerning the likely risks. The OIE argues that qualitative risk assessments will be more appropriate in areas of routine decision making, but also states that 'no single method of import risk assessment has proven applicable in all situations, and different methods may be appropriate in different circumstances'. [24]

6.32 David Vose supports the OIE guidelines, arguing that qualitative risk analysis 'offers a means of making quick, rational and reasonably defensible decisions about prospective risks', but 'it is often difficult to retain and demonstrate consistency between decisions made from qualitative risk analyses'.[25] This difficulty was evident in the criticisms of the 1996 IRA report. David Vose also argues that the language of qualitative risk analysis is a barrier to correctly communicating the probability of its occurrence - that the descriptive phrases used can mean different things to different people.[26] On the other hand, quantitative risk analysis yields a result which 'can be compared with other accepted and rejected risks'.

6.33 David Vose cautions against the inappropriate use of quantitative risk assessment. He states:

> Unfortunately, we have a very limited knowledge of the aquatic environment and its species making a quantitative risk analysis difficult and frequently impossible.[27]

6.34 David Vose argues that the method outlined in the OIE Aquatic Animal Health Code cannot usually be completed using purely quantitative data - the method requires subjective estimation of the probability of several steps or greatly exaggerating the risk by assuming the unquantifiable steps have a probability of one. He also notes that the Code, as an overview document, gives no indication of technical issues like the relationship between uncertainty and variability and various types of stochastic[28] interdependencies which are usually involved in the correct assessment of a risk.[29]

6.35 In 1997, David Vose undertook a quantitative risk analysis on 'the risk of establishment of *Aeromonas salmonicida* and *Renibacterium salmoninarum* in

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24 OIE, *International Animal Health Code*, Article 1.4.1.1

25 D Vose, *Qualitative versus quantitative risk analysis and modelling*, OIE Conference, Paris, February 2000

26 ibid

27 ibid

28 **stochastic** - determined by a random distribution of probabilities, governed by the laws of probability

29 D Vose, *Qualitative versus quantitative risk analysis and modelling*, OIE Conference, Paris, February 2000

Australia as a result of importing Canadian ocean-caught salmon'[30]. In his report, Mr Vose made some comments on quantitative risk analysis:

> Quantitative risk analysis will never be an exact science since one will always be faced with variables in a model that cannot be accurately quantified or where there is conflicting or incomplete information. However, where sufficient information is available, a quantitative analysis of appropriate parts of a model can be reasonably combined with logic and comparison arguments, to determine whether there is sufficient knowledge of the problem to be able to reach an informed and defensible decision. In the current case there is sufficient evidence to perform such an analysis.[31]

6.36 David Vose disagreed with AQIS' argument that because it was not possible to know exactly the true probability of risk, Canadian salmon should not be allowed into Australia.[32] He states in his analysis that the argument is not supported by the level of knowledge available at the time of undertaking the draft and final risk analyses.

6.37 AQIS decided on a qualitative as opposed to a quantitative approach to the conduct of the risk assessment component of its IRA:

> In the light of consultations with several independent scientists and risk analysts, AQIS conducted this risk analysis on a qualitative, rather than a quantitative basis…due to the complexity of the analysis (the large number of species and disease agents considered) and in recognition of the limited data on some key questions, such as the lack of data on prevalence of many pathogens, and the uncertainty about some important issues, such as the susceptibility of native species to the disease agents under consideration.[33]

6.38 AQIS advised that, 'in the absence of definitive, quantitative data on factors relevant to quarantine risk, AQIS applies appropriately conservative professional judgement based on available scientific information and the advice of experts in relevant fields'.[34] AQIS affirmed that this approach was scientifically valid, being adopted by quarantine authorities throughout the world and therefore consistent with international practice.

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30 This report concluded that, for the two diseases of greatest concern, BKD and furunculosis, the information available to Australia at the time of the draft and final 1996 IRA, was sufficient to show that the risk posed by importing Canadian salmon must be considered negligibly small.

31 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*, 11 December 1997, p 4

32 ibid

33 AQIS, Correspondence to Committee, 1 March 2000

34 ibid

Criticisms of Qualitative Risk Analysis in the 1996 IRA

6.39 In the context of the challenge in the WTO to the 1996 IRA and in response to the criticisms of its methodology, Australia argued that it was a highly subjective matter and that there was no obligation to undertake a quantitative risk analysis.[35] It was further argued that, after taking into account all available knowledge, there was insufficient data to undertake a quantitative analysis and that the approach was consistent with OIE recommendations and the obligations of WTO members.

6.40 However, as noted above, the OIE states in its guidelines that qualitative risk assessments, those not requiring mathematical modelling skills, will be more commonly used for those diseases, particularly those listed in the Code, where there are well developed internationally agreed standards, and there is broad agreement concerning the likely risks, and that qualitative risk assessments will be more appropriate in areas of routine decision making.

6.41 As part of the 1996 dispute settlement process, the Panel undertook a Joint Meeting with Experts to discuss some of the issues of concern in the case. The experts who participated in the meeting were:

a) Dr David E Burmaster, Alceon Corporation, United States;

b) Dr Christopher Rodgers, fish disease consultant, Spain;

c) Dr James Winton, National Fisheries and Research Center, US Fish and Wildlife Service, United States; and

d) Dr Marion Wooldridge, Department of Risk Research, Central Veterinary Laboratory, United Kingdom.[36]

6.42 The transcript of the Meeting with Experts was made public on 12 June 1998 with the documentation of the Panel's findings. The experts were critical of the methodology by which the IRA had been undertaken and the changes in emphasis and conclusions from the draft IRA to the final report.

6.43 At the meeting, it was suggested that quantitative risk analysis was the appropriate method for the type of risk analysis being undertaken by AQIS in relation to salmonids:

> …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

35 Mr R Wells, Joint Meeting with Experts, Annex 2 to Panel report, 4 February 1998, p 224

36 WTO Panel Report, June 1998, p 95

> 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 puts 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.[37]

6.44 One of the arguments advanced by AQIS for undertaking the analysis qualitatively was the complexity and immensity of the task before it, particularly the multiple fish diseases requiring consideration. However, some of the panel of experts disagreed with this stance. Dr Burmaster argued that it would not be necessary to undertake a risk assessment in relation to every disease, but that a smaller number would suffice.[38] Dr Rodgers supported Dr Burmaster's argument, stating that an analysis of a higher risk disease to obtain an answer, rather than looking at every individual disease in turn would be appropriate.

6.45 Dr Winton acknowledged the difficulty created by the gaps in the scientific knowledge for undertaking a quantitative assessment. However, he added that New Zealand 'had made a good effort given the existing scientific information of trying to quantify those risks'.[39]

6.46 At that meeting Dr Wooldridge set out the appropriate circumstances for the two types of risk assessment:

> 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 cannot 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

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37 Dr Burmaster, WTO Joint Meeting with Experts, Annex 2 to Panel Report, 4 February 1998, pp 211-212

38 Dr Burmaster, WTO Joint Meeting with Experts, Annex 2 to Panel Report, 4 February 1998, p 211

39 Dr Winton, Joint Meeting with Experts, Annex 2 to Panel Report, 4 February 1998, p 218. The report referred to was released in September 1994 by the New Zealand Ministry of Agriculture and Fisheries, through the MAF Regulatory Authority (Animal Health and Welfare), and was entitled *The risk of introducing exotic diseases of fish into New Zealand through the importation of ocean-caught Pacific salmon from Canada*. The report used both qualitative and quantitative methods, concluding that the overall risk of introducing disease through the importation of headless, eviscerated, wild, ocean-caught Pacific salmon appropriately certified by Canadian authorities as to origin and grade was negligible and posed no threat to New Zealand's fisheries.

> 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.
>
> 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.[40]

6.47 Dr Wooldridge highlighted the difficulty of qualitative risk assessment compared with quantitative risk assessment by comparing the comments on the environmental survival of the *renibacterium salmoninarum* in the draft and final reports:

> 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

40 Dr Winton, Joint Meeting with Experts, Annex 2 to Panel report, 4 February 1998, pp 219-220

> assessment and you cannot get to an agreement, I think you are then forced to proceed down the route of attempting a quantitative assessment.[41]

6.48 Dr Wooldridge, in describing the problems of qualitative analysis, argued that ' if you are 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'.[42] It is argued that there would be a clearer basis for negotiation and challenge and/or agreement or disagreement if the debate were centred around numbers or probabilities or probability distributions.[43]

6.49 AQIS, in defending its approach to the risk analysis, stated:

> I think we would say that the application of risk analysis to any topic in the quarantine field is unique to the particular issue we are addressing and always presents some difficulties. Those difficulties are not so much methodological difficulties - although they exist - but there are very often problems created by the absence of data. That is a problem in all risk analyses, not merely in the case of salmon. In the case of salmon, and in fact other fish, we have collected a vast amount of information and we have devoted very large resources to the preparation of a series of import risk analyses, these are state-of-the-art import risk analyses in this field, and I believe they are recognised as such internationally. The fact is that risk analysis of this kind has not been performed worldwide in relation to pests and diseases of all fish, and that is a matter which the OIE believes requires greater attention.[44]

6.50 In answers to questions on notice, AQIS further defended its use of qualitative risk analysis methodology, advising that the criticisms of the 1996 IRA were not based on Australia's failure to adopt a quantitative approach to the risk analysis, but on its failure to meet SPS requirements because certain judgements, including the interpretation of some data and the conclusions of the analysis were not sufficiently supported by scientific evidence contained in the report.[45]

Committee Comment

6.51 The Committee considers that the conclusions in the IRA may have been more readily defensible, if supported by quantitative data, at least to some extent. The Committee notes the analyses undertaken by New Zealand and David Vose and the criticisms of the AQIS approach. Notwithstanding the groundbreaking work of these analyses, the Committee considers that, if it is to be truly in the forefront of risk

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41 Dr Wooldridge, Joint Meeting with Experts, Annex 2 to Panel report, 4 February 1998, p 220

42 ibid, p 235

43 Drs Wooldridge and Burmaster, Joint Meeting with Experts, Annex 2 to Panel report, 4 February 1998, p 237

44 Hansard, Consideration of Estimates, 8 February 2000, p 219

45 AQIS, Correspondence to Committee, 1 March 2000

analysis methodology, AQIS should be more prepared to undertake quantitative risk analysis as part of the risk assessment process. The Committee recognises that quantitative risk assessment is not applicable to all stages of the risk analysis, but does consider that it is highly applicable at the risk assessment stage. More of an emphasis on quantitative assessment at this stage may assist in ensuring the integrity of the risk analysis.

The IRA Matrix

6.52 In the 1999 IRA, AQIS developed a 'risk evaluation matrix, with the objective of providing a standardised process for evaluating quarantine risk'.[46] For each disease agent, the combination of probability and consequence can be represented by a cell in the matrix. The matrix measures the probability of the establishment of a disease in Australia on the vertical axis and the significance of the consequences of the disease entering Australia on the horizontal axis. Figure 6.2 sets out the matrix as set out in the IRA.

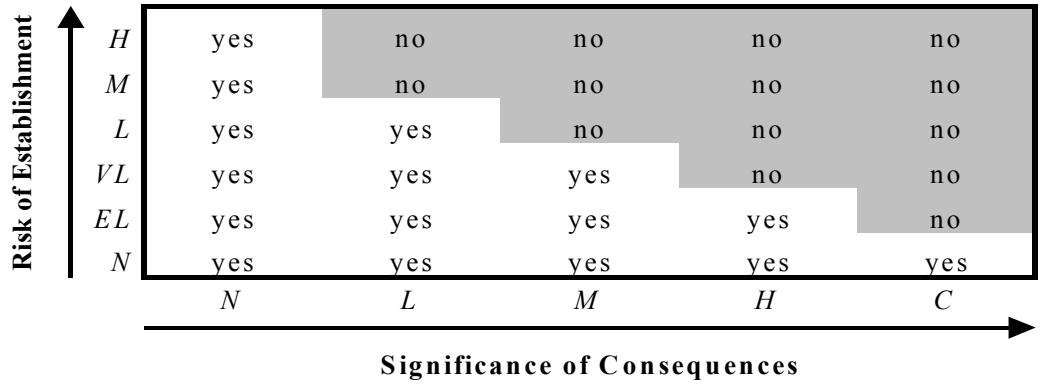
6.53 AQIS describes how the matrix can be used as follows:

> The risk determined on the basis of 'no risk management' is the *unrestricted estimate of risk*. If this is in line with Australia's ALOP, the risk would be considered acceptable without specific management ['yes' in the risk matrix…] and the importation would be permitted.
>
> However, if the unrestricted risk exceeds the ALOP, ['no' in the matrix] the next step is to consider whether or how risk management measures may be applied to reduce the quarantine risk to the point where it conforms with Australia's ALOP. If the application of risk management measures cannot reduce the risk to an acceptably low level, the importation would not be permitted. If after applying risk management measures the risk was in line with Australia's ALOP, the risk would be considered manageable…and the importation would be permitted. It should be noted that, where the probability of establishment of a disease is negligible, importation would be permitted regardless of consequences.[47]

46 AQIS, *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish,* July 1999, p 12

47 ibid, pp 12-13

Figure 6.2 Risk Evaluation Matrix



Yes' = the risk is acceptable and importation can be permitted.
No' - the risk is unacceptable and importation cannot be permitted without further risk management.

6.54 Terms used in the IRA to describe the **probability of an event occurring** were:

a) **High** event would be expected to occur

b) **Moderate** there is a less than even chance of the event occurring

c) **Low** the event would be unlikely to occur

d) **Very low** the event would occur rarely

e) **Extremely low** the event would occur very rarely

f) **Negligible** chance of event occurring is so small that it can be ignored in practical terms.

6.55 AQIS noted that these categories are not equidistant from each other, most falling within the range of zero probability to less than 50% probability.[48]

48 ibid, p 11

6.56 The significance of a disease was assessed through the following key factors:

a) Biological effects on aquatic species;

b) Availability, cost and effectiveness of methods for control/eradication;

c) Economic effects at an enterprise/industry/national level, including effects on marketing of the product; and

d) Effects on native species and the environment, including any loss of social amenity.[49]

6.57 Terms used in the matrix to describe **the level of significance** or severity of the impact were:

a) **Catastrophic** associated with the establishment of diseases that would be expected to significantly harm economic performance at a national level. Alternatively, or in addition, they may cause serious, irreversible harm to the environment;

b) **High** associated with the establishment of diseases that would have serious biological consequences (eg high mortality or high morbidity and causing significant pathological changes in affected animals). Such effects would normally be felt for a prolonged period (greater than or equal to a normal production cycle) and would not be amenable to control or eradication. These diseases would be expected to significantly harm economic performance at an industry level. Alternatively, or in addition, they may cause serious harm to the environment.

c) **Moderate** associated with the establishment of diseases that have less pronounced biological consequences. These diseases may harm economic performance significantly at an enterprise/regional level, but they would not have a significant economic effect at the 'whole industry' level. These diseases may be amenable to control or eradication at a significant cost, or their effects may be temporary. They may affect the environment, but such harm would not be serious or may be reversible;

d) **Low** associated with the establishment of diseases that have mild biological consequences and would normally be amenable to control or eradication. Such diseases would be expected to harm exogamic performance at the enterprise or regional level but to have negligible significance at the industry level. Effects on the environment would be minor or, if more pronounced, would be temporary;

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49 ibid, p 12

e) **Negligible** associated with the establishment of diseases that have no significant biological consequences, may be transient and/or are readily amendable to control or eradication. The economic effects would be expected to be low to moderate at an individual enterprise level and insignificant at a regional level. Effects on the environment would be negligible.[50]

6.58 For each of the 15 "higher priority" diseases (Group 1 diseases), the IRA also considered the probability of a disease agent entering and becoming established in Australia. This probability depends on:

a) The probability of the disease agent being present in the source country/region of the commodity, and if present, its prevalence. The 1999 IRA stated that in examining the available data, account was taken of the extent of surveillance and monitoring by competent authorities in the exporting countries;

b) The probability of the disease agent being present in an infective form in the commodity on entering Australia. This includes consideration of lifecycle stages (for example, the higher prevalence of disease agents in juvenile and/or sexually mature fish); the origin of the fish (i.e. wild vs. farmed); local dispersal of some disease agents, and time of the year, as well as of inspection and grading of fish. Washing, cold storage or other handling procedures may reduce some risks. Also relevant in this regard is the probability of a disease agent being present in the particular tissues imported, including the blood, skin, etc;

c) The probability of the disease agent in an infective form entering the aquatic environment of Australia. This depends on the processing, end-use and disposal of the commodity and the capacity of the disease agent to persist, in an infective form, in the commodity after processing, use or disposal. The 1999 IRA details the possible pathways which might be followed by a product imported for human consumption eventually reaching the aquatic environment. With regard to salmon for human consumption, the 1999 IRA identifies as of greatest concern the risks associated with disposal of wastes from the further commercial processing of salmon within Australia.

d) The probability of the disease agent, having entered the aquatic environment, establishing infection in susceptible hosts. This depends on the capacity of the disease agent to survive in the aquatic environment, in an infective form, and the ease of infection of susceptible hosts and subsequent transmission of infection to others within a population. [51]

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50 ibid, p 13

51 ibid, p 11

6.59 The 1999 IRA identified the biological and consequential effects of the establishment of a new disease agent on the affected fishery industry and on the environment. In considering the "consequence assessment", the 1999 IRA indicated that the effects of a disease can generally be ameliorated by the adoption of methods for control or eradication, but that these measures have associated costs which must also be taken into consideration under the WTO agreements.

6.60 The 1999 IRA noted that the biological effect of the establishment of disease is normally evaluated in terms of morbidity and mortality rates, and the costs associated with controlling or eradicating the disease. The economic effect of the establishment of disease is normally evaluated in terms of the costs arising from the biological effects and the commercial implications for domestic and international marketing of affected animals and products. The establishment of disease may also affect the environment in ways which are not easily evaluated in economic terms.

The Risk of Salmonid Disease Agents entering Australia

6.61 The IRA conducted by AQIS considered five factors which influence the likelihood of disease agents entering Australia, based on the OIE Aquatic Code:

a) The probability of the disease agent being present in fish in the waters of origin;

b) The probability of the disease agent being present in the particular fish harvested;

c) The probability of infected or contaminated fish/product passing inspection or grading;

d) The probability of the disease agent surviving processing, transport and storage;

e) The probability of the disease agent being present in the particular tissue imported.

<u>The probability of the disease agent being present in fish in the waters of origin</u>

6.62 The standard of surveillance and reporting of disease in aquatic animals varies from country to country. In preparing the IRA, AQIS generally accepted assessment of the presence or absence of disease by those countries with a 'competent authority'. For those countries without 'competent authorities', AQIS generally assumed the presence of widely distributed diseases, except where diseases are known to have a well-defined distribution that have changed little over time.[52]

52 ibid, pp 16-17

6.63 During conduct of the inquiry, the Committee was alerted to the difficulty of detecting some diseases. For example, the presence of ISA in Canada was not detected and reported until 6 months after the emergence of indicative haemorrhagic kidney syndrome. In the IRA, AQIS stated:

> AQIS acknowledges that the emergence of ISA in Canada was only reported to the OIE after many months of investigation. However, scientific knowledge on ISA and particularly diagnostic methods for it have improved greatly since this time. Therefore, AQIS expects that OIE Member countries would make a definitive diagnosis faster and report disease more promptly in future.
>
> Accordingly, there would be a negligible probability of salmonids (or other finfish) from areas that have not reported the presence of ISA or HKS being infected with ISAV.[53]

6.64 Various submissions to the Committee were highly critical of AQIS for adopting this position. The submission from Tassal labelled it a 'leap of faith' and 'scientifically naive in the extreme'. Tassal argued that over the past few years, new regions have been 'reporting' ISA sporadically at a rate reflecting detection capability and monitoring effort, rather than occurrence of the virus. As evidence of this, Tassal cited Canadian and US salmon farms just a few kilometres apart in the Bay of Fundy which respectively report and do not report the presence of ISA.[54]

6.65 Other submissions also questioned AQIS' assertion that diagnostic methods for ISA have improved. In his written submission, the Hon Paul Harriss MLC noted:

> In contrast to most other viral diseases, definitive methods for the detection of the ISA virus are not properly validated. Two examples illustrate this. Firstly, isolation of the virus in tissue culture in not always successful even in confirmed cases. Secondly, the indirect fluorescent antibody test (IFAT), carried out on kidneys, occasionally gives a false positive result (about 1 in 70 tests). [55]

6.66 As a result of these difficulties, Mr Harriss noted that ISA is identified in the UK and EU simply according to clinical signs and post mortem changes. The international reference laboratory for ISA in Oslo, Norway, indicates that the following criteria need to be satisfied to confirm the presence of ISA:

a) Fish must show clinical disease;

b) There must be visual changes consistent with ISA, including evidence of anaemia, when fish are dissected and examined;

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53 ibid, p 82

54 Tassal Ltd, Submission 41, p 3

55 The Hon. Paul Harriss MLC (Tas), Submission 53, p 3

c) Microscopic changes must be seen in tissues examined under the microscope, especially in histological sections of the liver; and

d) There must be evidence of the presence of virus, as shown by IFAT, and tests for virus genetic material or virus isolation in tissue.[56]

6.67 Evidence was also presented to the Committee by Mr David Bucke, a freelance consultant specialising in fish and shellfish diseases, of the difficulties involved in detecting other diseases:

a) There is a reliable test for BKD, but it is to culture the organism which generally takes eight and sometimes 20 weeks;

b) Furunculosis is detectable at the clinical and sub-clinical stages, but very difficult to detect at the covert carrier stage;

c) There are now some very good tests for VHS, but they are still not accurate in every instance; and

d) Because whirling disease is a disease of fingerlings, there is not a reliable test.[57]

The probability of the disease agent being present in the particular fish harvested

6.68 Juveniles and/or sexually mature salmonids are more likely to suffer disease than market-size salmonids, and that this may be used to control disease in salmonids. In hearings, Dr Kahn [AQIS] noted that in Scotland, fry and fingerlings are raised in artificial environments to prevent infestation with disease, thereby breaking the disease cycle.[58]

6.69 Huon Aquaculture questioned in its written submission the decision of AQIS to allow the importation into Australia of skin-on fillets from young fish of less that 450g, given the greater likelihood of disease being carried in the skin than in the flesh.[59]

The probability of infected or contaminated fish/product passing inspection or grading

6.70 The 1999 protocols allow the importation into Australia of non-viable salmonid products from farms that are known to carry diseases other than ISA. In response to Committee concern about this arrangement, whereby salmon from farms in Canada with a known furunculosis infection could nevertheless be passed for

56 The Hon Paul Harriss MLC (Tas), Submission 53, p 3

57 Mr David Bucke, Evidence, RRAT, 22 November 1999, p 375

58 AQIS, Evidence, RRAT, 24 September 1999, p 45

59 Huon Aquaculture Company Pty Ltd, Submission 19, p 7

import into Australia, AQIS confirmed the arrangement, but noted that the protocols also require that fish consignments be accompanied by a health certificate from the competent authority in the exporting country. That health certificate is required to indicate that the fish have been subject to visual inspection and grading, are free from visible lesions associated with infectious disease, and are fit for human consumption.[60]

6.71 Two concerns arise from this arrangement. Firstly, the only inspection of imported salmon consignments will be by the relevant authority of the exporting country. Inspection at the port of entry into Australia will only be to ensure that the fish are as described on the health certificate. Dr Kahn indicated that this approach is consistent with Australia's quarantine practice on the importation of products of animal origin for human consumption:

> We do generally accept the health certification that is provided by a competent authority, and we conduct inspections from time to time to verify that the systems are in place to support the provision of proper certification. That is pretty much the approach across the board. It is not unique to fish.[61]

6.72 Secondly, the visual inspection of salmonid products entering Australia was raised in submissions as a poor abatement strategy. The Australian Freshwater Fisherman's Assembly submitted that pathogens may be present in the blood, flesh and bone of fish well before visually detectable effects on the host animal become apparent, thereby creating a dangerous window period.[62] Similarly, the submission by Huon Aquaculture cited a finding by Willoughby that 'the vast majority of Norwegian farmed fish (about 70 to 80%) are carriers of IPN without showing any clinical symptoms.'[63]

6.73 The Committee raised with Mr David Bucke the likelihood of detection by visual inspection of lesions, indicating the presence of diseases like furunculosis. Mr Bucke responded:

> You can obviously see a haemorrhaging lesion with your eye. Whether you would see one underneath the skin if the skin was on, is another matter; I do not think you would see it in the muscle if it was a very small lesion. But when you start looking at histology sections of the various organs and muscle and things, you can actually see clumps of bacteria in the muscle bundles, very small foci of bacteria. You would not see these by eye at all, it is just not possible.[64]

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60 AQIS, Evidence, RRAT, 11 November 1999, p 340

61 ibid, p 342

62 Australian Freshwater Fishermen's Assembly, Submission 31, p 5

63 Huon Aquaculture Company Pty Ltd, Submission 19, p 7

64 Mr David Bucke, Evidence, RRAT, 22 November 1999, p 369

The probability of the disease agent surviving processing, transport and storage

6.74 It is noted in the 1999 IRA that the presence of disease agents in non-viable salmonid products may be reduced through evisceration, removal of the head, gills and skin, and washing of internal and external surfaces. These precautions remove a large portion of the pathogens generally found in the bone, cartilage, skin and retobulbar tissue of the head.[65]

6.75 Dr Alistair Brown agreed that evisceration, removal of the head, gills and skin, and washing of internal and external surfaces is an appropriate means of reducing the risk of disease transfer:

> I believe that by only allowing skinless, boneless fillets into Australia we would also significantly reduce the potential for importation of most of the pathogens listed in the IRA.[66]

6.76 The persistence of disease agents in salmonid products may also be limited through the transport and storage process. Commissioned research conducted by Aquaculture Development and Veterinary Services for the 1999 IRA indicates that cold storage, either freezing or chilling, may inactivate some bacteria, although most viruses persist at low temperatures for hours or days and are quite stable at freezing temperatures. Cooking at temperatures of 55 – 70 degrees is recognised as far more likely to inactivate aquatic pathogens.[67]

The probability of the disease agent being present in the particular tissue imported

6.77 The IRA states that infectious diseases are likely to be found in particular tissues according to the mode of infection and pathogenic characteristics of the disease. Some diseases are highly specific to certain cells, such as BKD. Other diseases use cell surface receptors that occur in many tissues of the body. The submission from Huon Aquaculture stated that at least 15 diseases of concern are carried in the flesh of salmonids, as opposed to the head, skin, cartilage, bone, kidneys and so forth.[68]

6.78 AQIS also indicated that for diseases such as BKD, evisceration is likely to reduce but not necessarily eliminate the presence of pathogens. Some blood rich organs such as the remnants of the anterior kidney and the retobular tissue of the head remain after evisceration and are unlikely to be removed by washing alone. AQIS

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65 AQIS *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish*, July 1999, pp 20-21

66 Dr Alistair Brown, Evidence, RRAT, 11 November 1999, p 331

67 AQIS, *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish*, July 1999, pp 21-22

68 Huon Aquaculture Company Pty Ltd, Submission 19, p 7

advised that scrubbing or high pressure water sprays can be used to substantially remove residual kidney tissues.[69]

The Risk of Transmission of Salmonid Disease Agents within Australia

6.79 The IRA conducted by AQIS considers three factors which influence the likelihood of disease agents having entered Australia, becoming established in Australia, once more based on the OIE Aquatic Code:

a) The probability of imported product entering the aquatic environment;

b) The probability that imported product entering the aquatic environment initiates an infection;

c) The probability of disease becoming established in Australian salmon.[70]

The probability of imported product entering the aquatic environment

6.80 In the 1999 IRA, AQIS investigated four principal means by which disease agents may enter the aquatic environment.

6.81 The first is through human consumption. AQIS argued that cooking is an effective method of killing parasites in animal tissue, and although salmon may also be consumed raw as sashimi or cold smoked salmon, most infectious organisms will also be destroyed in the human gastrointestinal tract.[71]

6.82 The second means AQIS identified by which disease agents may enter the aquatic environment is via wastewater disposal of unprocessed product. AQIS noted that:

> the processing of wastewater in the domestic sewerage system would not completely inactivate any aquatic pathogens present in imported product. However, the physical conditions in the sewerage system, including the presence of chlorine and other microorganisms, and competition from other microorganisms for nutrients would be expected to limit the survival of many of the aquatic pathogens considered in this risk analysis.[72]

6.83 However, AQIS did acknowledge that in certain situations, the proximity of some salmonid fish populations near wastewater discharge points might present a disease risk. For instance, the discharge of treated waste into the marine waters in and around Hobart may pose a higher risk than such discharge into the marine waters of

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69 AQIS, *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish*, July 1999, pp 20-21

70 ibid, p 25

71 ibid, pp 26-27

72 ibid, p 28

mainland Australia, given the various salmonid farms and a large run of brown trout in Macquarie Harbour.[73]

6.84 The third means AQIS identified by which disease agents may enter the aquatic environment is via disposal of solid salmonid waste such as heads, gills, tails, cartilage and skin. AQIS stated that if this waste is moved to properly designed and maintained landfills, the risk to the aquatic environment is extremely low, although in other cases the risks might be more significant.[74]

6.85 The disposal of solid salmonid waste received considerable attention during hearings. Professor Nigel Forteath submitted that in Australia, the majority of household offal enters open refuse tips frequented by birds, rodents and feral cats, which can disperse the offal and packaging considerable distances. His submission also noted the risks from disposal of waste by campers directly into waterways.[75]

6.86 Although noting the risk of disease transmission from solid waste, AQIS argued that the likelihood of disease agents entering the aquatic environment via this means is small. Citing calculations of salmonid disposal in Melbourne, AQIS estimated that salmonid products would constitute a very small proportion of total solid waste produced in a major Australian city. Furthermore, aquatic pathogens at waste disposal cites may be destroyed by ultraviolet radiation, low oxygen levels, variations in temperature and competition from other microorganisms for nutrients.[76]

6.87 The fourth means AQIS identified by which disease agents may enter the aquatic environment is through the importation, with minimum prior treatment or quarantine restriction, of fish feed or fish bait. [77]

6.88 Fish imported into Australia as feed include whole pilchards and herrings, which are used extensively to feed farmed southern bluefin tuna. As stated in hearings by Mr Jeffriess from the Tuna Boat Owners Association of Australia:

> The fact is that something like tuna farming, which is three times the size of the salmon industry, depends 90 per cent on imported bait. There are no alternatives available in Australia.

6.89 Fish imported into Australia as bait include whole or head only fish such as mackeral, travally, north sea herring, kawahai, barracouta, sardines and orange

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73 ibid, p 30

74 ibid, p 30

75 Omlas Pty Ltd, Submission 13, p 4

76 AQIS, *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish*, July 1999, p 31

77 ibid, p 32

roughy. These bait are imported to support the rock lobster industry, Australia's largest seafood export industry.[78]

6.90 The IRA indicated that there is little risk of disease agents entering Australia via the importation of fish feed or fish bait:

> … there is no definite evidence that the importation of fish bait into Australia has resulted in the establishment of any exotic diseases to date.[79]

6.91 The evidence presented to the Committee on this point is uncertain. Mr Tonkin from the Institute of Freshwater Anglers presented evidence from the NSW Fisheries that the recent disease outbreaks amongst pilchards in NSW and Victoria most likely arose from the importation of pilchards and herrings as fish food for tuna:

> There was also insufficient factual evidence to take the matter any further, but the most likely cause arose from the importation of bait used in tuna fishing.[80]

6.92 However, Mr Jeffriess argued against this position, stating that there was no scientific evidence that the 1995 and 1998 disease outbreaks amongst pilchards were the result of introduced pathogens:

> The latest scientific assessment by the critics is that the actual 1995 mortality started through a tuna towing pontoon in the middle of the Great Australian Bight. We have shown that there was no towing pontoons anywhere near that area at that time. They now claim the second lot of mortalities started from a snapper farm feeding imported bait. We have shown that there is no snapper farm where they said there was a snapper farm, et cetera. You can do no more.
>
> The fact is that there is not one record of a dead pilchard anywhere near Port Lincoln where all the farms are situated. The answer to that from the critics is that every last pilchard that has been infected has swum right into the middle of the Great Australian Bight and died there. That is just not sustainable. Despite all that, we just do not know. What we are saying is that proper, rigorous science needs to be done.[81]

6.93 Mr Jeffriess also argued that there is no scientific evidence to indicate that a disease such as ISA, which is specific to salmon, would be transferred to Australia via the importation of fish feed:

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78 DPIE December 1996, *Report of the National Task Force on Imported Fish and Fish Products: A Report into the Implications Arising from Aquatic Animal Imports*, AGPS

79 AQIS *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish*, July 1999, p 32

80 Mr Rodney Tonkin, Institute of Freshwater Anglers, Evidence, RRAT, 24 September 1999, p 91

81 Mr Brian Jeffriess, Tuna Boat Owners Association of Australia, Evidence, RRAT, 11 November 1999, p 283

> There is no historical scientific evidence of ISA transferring to other species like that. We have plenty of emotive members as well who strongly complain about the quality of the IRA, not the integrity of it. But the reality is that is what the best science available tells us. As soon as we start to not question the science but oppose a proper scientific analysis itself, we have little future.[82]

6.94 The Committee notes however that tuna are not susceptible to the same range of diseases that affect salmon, meaning that there are no risks to tuna farming in Australia from the importation of pilchards infected with disease.[83]

The probability that imported product entering the aquatic environment initiates an infection

6.95 The IRA noted that water temperature influences the transmission of salmonid disease. For example, the transmission of VHS virus mostly occurs at water temperatures ranging from 1-12 degrees, but not above 15 degrees. In the UK, the seasonality of BKD is well recognised, with the result that fish with the disease are only removed from aquafarms during spring and autumn.[84]

6.96 Various other submissions reiterated this point. As stated by Dr Brown:

> A number of fish pathogens thrive at warmer temperatures, for example, the optimum temperature for the incubation of *Aeromonas salmonicida* is 22 ^{o}C. Infections at low temperatures are more likely to result in carrier status rather than high mortalities, however, as the temperature rises to the optimum for the pathogen, clinical disease is likely to be expressed. [85]

6.97 Similarly, Mr Bucke noted:

> The temperature is going to make a difference. A lot of these diseases do not clock in until 15 degrees, 18 degrees, 20 degrees.[86]

6.98 There was considerable criticism of the IRA, for failing to give sufficient consideration to the high water temperatures in Tasmania and the need to physically wash salmon in Tasmania during the summer months to combat AGD. This activity places salmon under considerable stress, thereby increasing their susceptibility to disease. As stated by the Tasmanian Salmon Growers Association:

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82 ibid, p 279

83 AQIS, Evidence, RRAT, 11 November 1999, p 286

84 AQIS, *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish*, July 1999, p 19

85 Ocean Wave Seafoods, Submission 55, p 2

86 Mr David Bucke, Evidence, RRAT, 22 November 1999, p 368

> The issues of the importance of the different climatic conditions, and warmer waters combined with the changed farming practices has not been accepted by AQIS.[87]

6.99 The 1999 IRA did acknowledge that higher water temperatures and the need to handle fish are problems in Tasmania. However, the report argued that the lower stocking densities used by management in Australia and the unpolluted Tasmanian waterways offsets these problems. In support of this position, AQIS noted that Australian salmonids grow to market size in 12 months, compared to 18 – 24 months in most salmonid producing countries. As AQIS concluded:

> Without evidence from experimental infections, it cannot be said with any degree of certainty that the salmonids in Australia are any more or less susceptible to any of the diseases that are stock of those species elsewhere in the world.[88]

6.100 Various submissions to the Committee rejected this argument, indicating that water temperatures in Tasmania reach the extremes of salmonid tolerance during the summer months. The submission from Houn Agriculture noted that the optimum water temperature for salmon is 17 degrees, with 19 degrees the upper limit over long periods of time. Tasmanian waters are frequently 18 degrees, and can reach 22 degrees at the surface.[89]

6.101 In addition, although handling of salmon is not recommended, Dr Brown indicated to the Committee that there is no alternative:

> A further point that has significance for salmonid farming in Australia is that diseases that are considered minor or not significant overseas can cause serious problems here. The best example is AGD, in Tasmania this condition requires regular monitoring and treatment to prevent mortalities. The same condition has been recognised in New Zealand and Ireland however it doesn't cause problems at their normal temperatures. On occasions when sea temperatures have become unseasonally high in these countries, mortalities due to AGD have occurred.[90]

6.102 Finally, evidence was also presented to the Committee to suggest that salmonids in Tasmania are more susceptible to disease that fish in other countries due to their relative isolation. Huon argued that 'it is not apparent in AQIS' risk assessment process that any consideration has been made of likely disease epidemiology in Australian conditions'.[91]

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87 Tasmanian Salmonid Growers Association, Submission 46, p 7

88 AQIS *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish*, July 1999, p 36

89 Huon Aquaculture Company Pty Ltd, Submission 19, p 6

90 Ocean Wave Seafoods, Submission 55, p 4

91 Huon Aquaculture Company Pty Ltd, Submission 19, p 11

6.103 The evidence on this point is uncertain, however Dr Brown noted that in personal communication, it had been indicated to him that Tasmanian stock imported from Scotland display increase susceptibility to a range of endemic diseases. Dr Brown also noted the finding of Gjedrem *et al* (1991) that resistance to furunculosis could be effectively improved by selective breeding of Atlantic salmon.[92]

The probability of disease becoming established in Australian salmon

6.104 Infection of disease free aquaculture populations is most likely to occur via the movement of live, infected hosts or parasites from infected areas to disease free areas.

6.105 The Tasmanian Government advised that the transfer of diseased fish from freshwater hatcheries provided one means by which disease can spread between populations. In Tasmania, farming of Atlantic salmon involves the production of early-stage salmon in freshwater facilities. After 12-18 weeks they are acclimatised to seawater, and are transferred to estuaries and sheltered coastal waters.[93]

6.106 Dr John Purser from the University of Tasmania cited the example of the parasitic lamprey, of which there are two species found in Tasmania. As adults, lamprey attach themselves to the exterior of fish to feed. By doing so they may potentially transmit diseases. Lamprey are also diadromous, moving from the sea to freshwater in spring and summer to spawn, after which the larvae spend a number of years feeding off micro-organisms before moving back to the sea to attach themselves to a host adult.[94]

6.107 Dr Purser also advised that the IRA largely ignores movement of fish between freshwater and marine systems. For example, Dr Purser noted that the native species which comprise the whitebait run in Tasmania – the galaxids, Tasmanian whitebait, smelt and grayling – are related to salmon, and could be affected by diseases and act as carriers. Significantly, all these species are diadromous, moving between freshwater and saltwater during their lifecycle. [95] Similar concerns were also expressed by the Tasmanian Government:

> Tasmanian coastal and inland fisheries are closely linked by species that migrate between fresh and salt water. If disease were to develop in a coastal area, fish such as whitebait or sea-run trout could transport the disease inland or vice versa. Tasmanian Whitebait run up most of our estuaries to their fresh water spawning grounds. Sea-run trout follow them up and would

92 Ocean Wave Seafoods, Submission 55, p 1

93 Tasmanian Government, Submission 42, p 14

94 Dr John Purser, Submission 28, p 2

95 ibid, pp 1-2

provide an ideal host for transferring disease to the unprotected wild fishery'.[96]

Risk Management

6.108 The OIE sets out principles of risk management in its IRA guidelines:

> 1 . Risk management is the process of deciding upon [an acceptable level of risk in the particular circumstances associated with an importation] and implementing [appropriate] measures [that are considered] to achieve the Member Country's appropriate level of protection [determined by the decision], whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage risk appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of disease incursions and their consequences and its desire to import goods and fulfil its obligations under international trade agreements.
>
> 2. The international standards of the OIE are the preferred choice of sanitary measures for risk management. The application of these sanitary measures should be in accordance with the intentions in the standards.[97]

6.109 The Guidelines also set out risk management components as follows:

> 1. **Risk evaluation** - the process of [deciding upon the acceptable level of risk and] comparing [it with that] estimated in the risk assessment with the Member Country's appropriate level of protection.
>
> 2. **Option evaluation** - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures in order to reduce the risk associated with an importation in line with the Member Country's appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood and/or magnitude of adverse biological and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the risk assessment and then comparing the resulting level of risk with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the risk management options.
>
> 3. **Implementation** - the process of following through with the risk management decision and ensuring that the risk management measures are in place.
>
> 4. **Monitoring and review** - the ongoing process by which the risk management measures are continuously audited to ensure that they are achieving the results intended.[98]

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96 Tasmanian Government, Submission 42, p 12

97 OIE IRA Guidelines, Article 1.4.2.5

6.110 If the risk from proposed importation of a commodity is determined to be greater than Australia's ALOP, implementation of risk management measures must be considered, consistent with Section 70 of Quarantine Provisions 1998. In developing risk management measures AQIS must:

a) Ensure that they are the least trade restrictive necessary to meet the ALOP;

b) Consider the practicability and ease of implementation;

c) Consider the cost of compliance;

d) The cost effectiveness of the measures and impact on trade.

6.111 Additionally:

a) Under Article 4 of the SPS Agreement, if the exporting country can demonstrate that measures other than those proposed will deliver the level of protection, the alternative measures should be acceptable;

b) Quarantine measures must be specified and applied in a way that does not discriminate between the commodities of different exporting countries;

c) There must not be any arbitrary or unjustified distinctions in the level of assessed risk for imported commodities - the consistency requirement.[99]

6.112 According to AQIS, there are two principal means of reducing the level of risk:

a) Reducing the likelihood of disease agents entering Australia in imported product by imposing conditions relevant to the source population; and

b) Reducing the likelihood that susceptible host species in Australia would be exposed to imported product or derived waste.[100]

Pre-import measures

6.113 Pre-import measures are likely to include inspection, grading and processing practices, such as washing, evisceration, removal of head and gills, skin and fins, filleting and processing of product to a consumer ready state. Official certification

98 OIE IRA Guidelines, Article 1.4.2.6

99 AQIS, *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish,* July 1999, pp 140-141

100 ibid, p 141

confirming the application of such procedures may be provided by exporting countries.

6.114 Certifying authorities providing assurances must have systems in place to support the issuance of 'accurate, valid certification'.[101] The key elements of such systems are:

a) Legislation, providing for notification and control of animal diseases;

b) Official programs for disease surveillance and monitoring;

c) Animal health services supported by competent diagnostic laboratories;

d) Systems for the inspection of animals and product, including for approval and control of premises processing product for human consumption; and

e) Legislation concerning the issuance of certification, with appropriate sanctions.[102]

6.115 AQIS advised that importing countries have the right to take appropriate steps to verify that certificates and certification systems are reliable.[103]

6.116 An exporting country may provide certification on matters such as:

a) The nature and source of exported fish/product;

b) The health status of populations from which the fish/product was derived;

c) Results of health surveillance and monitoring;

d) The processing of the product; and

e) The system of inspection and grading to which the product was subjected.[104]

Post import measures

6.117 Post import measures include:

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101 ibid, p 142

102 ibid

103 ibid

104 ibid

a) Restricting the type/presentation of product, to increase the probability of it being used in a low-risk manner;

b) Restricting the type/presentation of product to reduce the amount of waste generated after arrival in Australia;

c) Processing the product to reduce the likelihood of it containing aquatic pathogens in an infective form; and

d) Restricting the distribution or end use of imported product.

6.118 The specific risk management measures for the seven Group 1 priority disease agents that do not meet Australia's ALOP are set out in section 5.3 of the IRA.

Submission Concerns

6.119 The major concerns expressed in submissions included:

a) The conclusions in the IRA lacked scientific validity, the science was incomplete and uncertain and that is some cases the science presented by AQIS did not support the conclusions reached;

b) Insufficient consideration of the increased susceptibility of native species to exotic disease agents, ie their naivity and the affects of an outbreak of disease on domestic fish populations;

c) The risk management measures proposed by AQIS to deal with an outbreak of disease;

d) Specific concerns in relation to such diseases as ISA; and

e) Environmental concerns.

Criticisms Relating to the Science

6.120 The major criticisms of the science do not relate so much to the actual science as set out in the IRA, and which has now been endorsed by the WTO, as to the uncertainty of the science and the concern that too little is known about disease incursions in fish. In this event, it was argued that the appropriate quarantine approach should be governed by the precautionary principle, ie that quarantine measures should not allow the importation of products unless the extent of risk is known.

6.121 The IRA risk evaluation matrix establishes a chain of events that must occur for a disease to be introduced and become established in Australia. However, stakeholders highlighted to the Committee various scientific concerns which they argued were not adequately addressed by AQIS in the IRA. These included:

a) Difficulties in the initial detection of diseases in salmonid populations overseas;

b) The possibility that pathogens may pass quarantine inspection and enter Australia, either legitimately or because the pathogen is not detected;

c) The possibility that pathogens may survive processing (ie evisceration, washing, freezing);

d) The increased susceptibility of salmonids in Tasmania to diseases due to the high summer water temperature and the need to treat for AGD;

e) The various avenues by which disease may spread amongst salmonids in Tasmania, including potentially through the import of fish bait and fish feed; and

f) The severity of the impact of any disease outbreak on the salmon farming industry in Tasmania and the trout farming industry in Victoria.

6.122 AQIS advised that it compiled the IRA following a thorough consideration of all issues:

> AQIS considered all scientific issues raised in the submissions of respondents and sought the advice of the independent scientific reviewers on significant points in the submissions. All submissions were taken into account in preparing the reports. For each risk analysis, AQIS reviewed each part of the report in light of stakeholder submissions.
>
> The scientific information reviewed in these IRA reports is comprehensive and up-to-date and the independent scientific reviewers have agreed that the scientific analysis is accurate, objective and balanced.[105]

6.123 Where the scientific evidence is unavailable or uncertain, AQIS stated that it took an appropriately conservative approach, but argued that a lack of evidence did not justify the adoption of no-risk measures or refusal to make a decision.[106] AQIS further stated that ' no witness presented significant new scientific information that warranted re-examination of the risk analysis or changes to the new salmonid quarantine policies'.[107]

6.124 AQIS advised that almost all the scientists with relevant expertise had been involved in this process over the years and outlined the extent of the scientific consultation in developing the IRA in its submission:

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105 AQIS, Submission 17, p 77

106 AQIS Policy Memorandum 1999/26

107 AQIS, Supplementary Submission 62, p 4

> The findings of the risk analyses are based on a comprehensive analysis of relevant scientific literature, including (for non-viable products) scientific information in previous reports of the Australian Government and a report of the New Zealand Government on the importation of non-viable salmonids into New Zealand. AQIS also obtained detailed comments from a number of experts in fish health and quarantine in Australia and overseas. AQIS took several steps to ensure the scientific validity of the risk analyses, including considering the reports of consultancies (most of which were commissioned in 1998) on identified gaps in information relating to these risk analyses.[108]

6.125 AQIS argued in a supplementary submission that throughout the whole process, it had been careful to support its arguments through consultation with independent scientists in Australia and overseas to ensure proper consideration of the scientific evidence and the use of professional judgement in the IRA report.[109] The IRA was subjected to independent review by 14 scientists. The scientists were requested to assess the draft report and to advise on:

a) The completeness and accuracy of scientific information in the report;

b) The balance and objectivity with which scientific information was treated;

c) The extent to which the exercise of professional judgement in the report was supported by and consistent with relevant scientific information;

d) The consistency of professional judgements on scientific issues that were common to each risk analysis report (where appropriate).[110]

6.126 AQIS countered the criticisms of the 1999 IRA with the claim that much of the criticism before the Committee was 'assertion, not supported by substance or is incorrect':[111]

> Many of the current arguments against importation have been previously presented and re-presented to AQIS in the course of the risk analyses conducted in 1995-96. More recent information, including on the spread of diseases since 1996, was available through stakeholder submissions made in May/June and from overseas scientists. All relevant scientific issues have been specifically addressed and AQIS's scientific analysis is robust and comprehensive.[112]

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108 AQIS, Submission 17, p 76

109 AQIS, Supplementary Submission 59, p 2

110 AQIS, Submission 17, pp 76 - 77

111 AQIS, Supplementary Submission 59, p 3

112 ibid

6.127 In response to the questions raised by Professor Forteath at public hearing concerning the scientific analysis, AQIS advised that it had further consulted with a number of independent scientists, who had advised AQIS on the risk analysis. Those who responded were of the view that Professor Forteath had identified no scientific issue that was not considered in the risk analysis, nor had he raised any matter that warranted specific further consideration.[113]

The impact of a disease outbreak

6.128 Comments on the assessment of disease outbreaks related to:

a) Underestimation of the risk establishment of disease in both farmed and native salmonids, including the naivety and increased susceptability of salmonid populations within Australia;

b) The difficulty of eradication and containment measures;

c) The differences between the susceptibility of salmon and trout populations.

6.129 One of the major criticisms of AQIS by stakeholders was that AQIS had underestimated the probability of disease organisms entering and becoming established in Australia as a consequence of importation of salmonid product. AQIS responded:

> In keeping with accepted scientific practice, the risk analysis identified the pathways by which imported product could enter the aquatic environment and took into account the probability (classified as 'probable'), 'less significant' or 'exceptional') of products following these pathways. The risk assessments of each disease take into account the probability of establishment and the significance of the consequences in each case.
>
> For salmonids other than Pacific salmon from New Zealand, AQIS will only release from quarantine imported products that are ready for the consumer to cook or eat, such as salmon cutlets, fillets and pan-size, head-off, gilled and gutted fish. There is minimal uncooked waste likely to derive from these products, so that the probability of material containing any organisms being discarded into water containing susceptible fish is extremely low.[114]

6.130 Dr Alistair Brown stated:

> In my opinion the IRA underestimates the consequences of the establishment of a number of diseases assessed in the IRA, particularly in relation to the ability to control these diseases. One of these is as a result of not fully taking into account the circumstances that are unique to the

113 ibid

114 ibid, p 17

> Australian salmonid farming industry, that being the effect of temperature.[115]

6.131 However, a slightly different view was put by Dr Rodgers, at the Panel of Experts Meeting in February 1998:

> 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.[116]

6.132 AQIS, in advising whether the warmer water conditions increased vulnerability, stated:

> But the SPS agreement does allow us to take into account in evaluating the risk all of those considerations, including the differences in water temperature, the different vulnerabilities of fish, stocking rates, whatever it is. That all goes into the analysis of what is their risk from product coming into the country. So, yes, we are allowed to take that into account, then we have to make a judgment about what measures we need to apply in order to reduce that assessed risk to an acceptably low level—that is, to reduce it so that it conforms with our appropriate level of protection.[117]

6.133 Dr T D St George, an ex CSIRO scientist, argued:

> The basing of imports of raw salmon products on probabilities of it containing live virus is based on a false reasoning. If the chance is one in one million that a particular shipment contains live virus, this shipment may be the first shipment or the last shipment or any one in between. It does not mean that one million shipments have to be imported before there is a risk. There is not control on persons purchasing fish to dispose of any uneaten portions in a safe way.
>
> The risk analysis should be based on the probabilities of eliminating the risk of disease and cost to the industry or the nation once it has been introduced.[118]

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115 Dr Alistair Brown, Evidence, RRAT, 11 November 1999, p 326

116 Dr Rodgers, WTO Joint Meeting with Experts, Annex 2 to Panel report, 4 February 1998, p 213

117 AQIS, Evidence, RRAT, 24 September 1999, p 42

118 Dr T D St George, Submission 1, p 1

6.134 It is noted in the IRA that the consequences of serious pathogens such as furunculosis and ISA becoming established amongst aquaculture populations here in Australia 'would be at least as serious as those reported overseas'.[119] However, various submissions argued that this assessment by AQIS still understates the consequences of transmission of disease agents to Tasmania. Mr Weir, stock manager for the Huon Aquaculture Company, expressed similar sentiments:

> It is my contention, based on my experience of farming these fish in different environments around the world, that if some of the diseases listed in the draft AQIS IRA were to enter Australian waters, the Australian salmonid aquaculture industry would be destroyed. The only debatable issue would be whether this would occur in two, three of four years' time'.[120]

6.135 The submission from the Victorian Trout Association (VTA) expressed concern that the IRA largely ignored the impact of diseases on the Victorian trout industry. In particular, the VTA noted that in many instances, freshwater trout are more susceptible to disease, and more likely to carry disease, than salmon. In turn, the establishment of disease amongst rainbow trout in Victoria would increase the likelihood of disease spreading to salmon in Tasmania.[121]

6.136 As with salmon in Tasmania, rainbow trout farming in Victoria during the summer months is conducted at the biological limits of rainbow trout tolerance, again placing constant stress on the fish, and increasing their susceptibility to disease. In particular, Mr Rogers from the VTA highlighted during hearings the susceptibility of rainbow trout to VHS, prolific kidney disease (PKD), rainbow trout fry syndrome (RTFS) and steptococcosis.[122]

6.137 One of the major concerns of the recreational trout fishermen was that the 1999 IRA ignored trout and the different potential for disease incursion and the impact of the incursion.[123] The VTA expressed concern that diseases which were of significance to the freshwater trout industry, but which did not affect salmon, were not discussed in the risk management assessment of the IRA:

> This disease [VHS] is not significant to the salmon industry, where we feel a lot of the disease information has been slanted to try to justify the lack of the impact on the salmon industry, without giving due consideration to the possible impact to the freshwater trout industry, especially as we are so close to a major metropolitan populace.[124]

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119 AQIS, *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish*, July 1999, p 39

120 Huon Aquaculture Company Pty Ltd, Supplementary Submission 54, p 4

121 Victorian Trout Association, Submission 32, p 2

122 Mr Rogers, Victorian Trout Association, Evidence, RRAT, 11 November 1999, pp 297–300

123 Mr Miles Rogers, Victorian Trout Association, Evidence, RRAT, 11 November 1999, p 303

124 Mr Miles Rogers, Victorian Trout Association, Evidence, RRAT, 11 November 1999, p 295

6.138 The representatives of the VTA were concerned about the impact of VHS on the freshwater rainbow trout and the AQIS conclusion that there would be only a moderate risk to the Australian environment of the disease:

> AQIS has mainly targeted the marine version of this disease. There are four strains. The freshwater European strain of VHS is highly virulent within fresh water. AQIS also states that it is highly pathogenic, particularly in farmed rainbow trout. This significance has been understated in the IRA due to the heavy leaning of the report towards the potential threat to the marine salmon farming industry where the significance of VHS is low or irrelevant. However, a potential outbreak of VHS in the Australian freshwater trout industry would be disastrous on a national level due to 80 per cent of the production coming from one small geographic area.[125]

6.139 In response to these concerns, Dr Kahn from AQIS defended the IRA assessment, noting that the report acknowledges that rainbow trout is the salmonid species most susceptible to disease in Australia. AQIS believes the measure put in place such as evisceration and the removal of head and gills is sufficient to address the risks associated with rainbow trout, while noting that it does not provide a zero risk setting.[126]

Risk Management Measures

6.140 Some submissions expressed concern about the extent to which risk management practices were an appropriate mechanism for potential prevention and control of disease incursion, with accusations that AQIS has placed undue emphasis on its ability to put in place risk management practices that will reduce the likelihood of those diseases:

> AQIS has placed emphasis on their being able to minimise the risk of disease introduction with risk management strategies. IFA rejects this approach as irresponsible given all the circumstances, and not in the best interests of Australia.[127]

6.141 Given the concern expressed at the potential effects of disease on introduced and native salmonids in Australia, there was general agreement in submissions to the Committee that once diseases became established in Australia, they would be virtually impossible to eradicate.

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125 ibid, p 293

126 AQIS, Evidence, RRAT, 11 November 1999, p 353

127 Institute of Freshwater Anglers [NSW], Submission 30, p 4

6.142 The IRA states that those diseases that have been difficult or impossible to eradicate overseas such as ISA, BKD and whirling disease would be equally difficult to eradicate here in Australia.[128]

6.143 There is also doubt about the possibility of eradicating disease from hatchery sites. Mr David Bucke cited to the Committee an attempt in the UK to establish disease free trout farms. The five-year programme required that the farms be cleaned out, disinfected and stocked only with certified eggs. However, in the end Mr Bucke stated that 'all of them got one of the diseases – IPN, bacterial kidney disease or whirling disease'.[129]

6.144 Even containing disease outbreaks in Tasmania would be likely to be very difficult. Dr Brown raised the possibility that in Australian conditions where ambient summer water temperatures routinely exceed 19^{o}C, there is every chance that vaccines used internationally would fail to work. This is because vaccines work by stimulating the immune system to respond to specific antigens, however in temperatures above the tolerance limits of farmed salmonids, immune functions are suppressed:[130]

> Vaccination works by stimulating the immune system. However, salmonids in Australia have to deal with summer temperatures above their optimum range. This results in stress. This stress would be further exacerbated by concurrent diseases such as amoebic gill disease in Tasmania or white spot in Victoria, and the associated practices required to treat these diseases. Stress leads to immunosuppression, which in turn can lead to vaccine breakdown.[131]

6.145 If vaccines were to be successfully used in Tasmania, their use in response to a widespread bacterial disease outbreak in Australia would seriously damage the clean, unpolluted image of Tasmanian salmon in the Japanese market. As stated by the Tasmanian Government:

> Tasmania's 'clean green' image is our competitive advantage. If this image were tarnished, access to lucrative markets and high sales prices would be denied. Tasmania's environmental status has opened the doors around the world and if we can retain this image, it will continue to do so.[132]

Infectious salmon aneamia

6.146 The 1999 IRA states that the consequences of serious pathogens such as furunculosis and ISA becoming established amongst aquaculture populations here in

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128 AQIS, *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish,* July 1999, p 39

129 Mr David Bucke, Evidence, RRAT, 22 November 1999, p 374

130 Ocean Wave Seafoods, Submission 55, p 3

131 Dr Alistair Brown, Ocean Wave Seafoods, Evidence, RRAT, 11 November 1999, p 327

132 Tasmanian Government, Submission 42, p 16

Australia 'would be at least as serious as those reported overseas'.[133] However, various submissions argued that this assessment by AQIS still understates the consequences of transmission of disease agents to Tasmania. Professor Nigel Forteath stated:

> I have absolutely many, many hours and days of experience from two countries, Scotland and Denmark, and from here. I can assure you that it is simply the husbandry practice that we put into place here, and the lack of furunculosis and IPNs, et cetera, that allows us to get through that.[134]

6.147 Mr Innes Weir expressed similar sentiments. Prior to working in Tasmania, Mr Weir had worked in Scotland for Norsk Hydro GSP, where he managed the world's largest Atlantic salmon farm producing 2.7 million fish per annum. Mr Weir advised that he had previously dealt with outbreaks of sea lice, furunculosis outbreaks, pancreas disease, IPA, and ISA, which was first isolated in Scotland on one of the farms of Norsk Hydro GSP. In his submission, Mr Weir stated:

> The fact is that Tasmania is not the ideal environment for the farming of Atlantic Salmon. Farming is done here at the upper limits of temperature tolerance for these fish and is dependent for its success on freedom from disease and very intensive fish husbandry practices.[135]

6.148 Mr Weir elaborated on his submission at public hearing, commenting specifically on the potential consequences of an outbreak of ISA locally. Mr Weir stated:

> ISA can remain virtually unnoticed for months. Mortalities happened with us back in Scotland when the water temperature changed in the spring, when the temperature increased quite suddenly over a small amount of time. In Tasmania the banding water temperature of that increase is substantially larger than what it would be in Scotland. Therefore, the virus, which is being carried within the population, will expand rapidly. It does not matter what stage the fish are at. Because the temperatures get so hot it would just decimate the industry.[136]

Furunculosis

6.149 In his submission, Mr Weir also commented on the impact of an outbreak of furunculosis disease in Tasmania. He indicated that if furunculosis disease were present in Tasmania, it would prohibit washing of the fish 'for risk of them dying'. However, failure to wash the fish would in turn expose them to death from AGD

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133 AQIS, *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish*, July 1999, p 39

134 Professor Nigel Forteath, Omlas Pty Ltd, Evidence, RRAT, 5 October 1999, p 143

135 Huon Aquaculture Company Pty Ltd, Supplementary Submission 54, p 3

136 Huon Aquaculture Company Pty Ltd, Evidence, RRAT, 5 October 1999, p 161

during the summer months, since the only effective treatment of AGD is hand washing in freshwater.[137]

6.150 Similar concerns were expressed by Dr Alistair Brown:

> … the presence of a novel disease such as furunculosis, would make the procedure of controlling AGD impossibility. As an example, the combination of the concurrent stress of AGD causing gill damage, furunculosis causing a haemorrhagic septicaemia, low oxygen levels due to high water temperatures and naïve stock will undoubtedly result in mass mortality'.[138]

6.151 Dr Brown on the significance of the impact of furunculosis:

> I believe that the impact of furunculosis, should it become established in either the trout industry in south-eastern Australia or in the salmon industry of Tasmania, would have a catastrophic level of significance as these are the national centres for these industries. We would also not be able to eradicate the disease from the environment.[139]

6.152 Dr Brown further noted that during the early 1990s, authorities in Scotland attempted to control furunculosis through the use of antibiotics, all-in, all-out stocking of farms, lower stocking densities and water based vaccines. However, he stated that 'during the summer months when the water temperature reached 15 degrees the disease was barely under control'. Rather, Dr Brown indicated that control of furunculosis in Europe only became successful following the introduction of oil based vaccines in the mid-nineties, but that such control in Australia would be compromised by the summer temperatures.[140]

6.153 In the light of these concerns, the Committee raised the possibility of testing the impact of various diseases on Australia's farmed salmonid aquaculture populations prior to any decision being taken on the importation of non-viable salmonid product into Australia. At present, there is little research to provide guidance on this point, especially given the particular circumstances under which salmonids are farmed in Australia.

6.154 AQIS acknowledged these concerns in its supplementary submission to the Committee, but nevertheless reiterated that its risk management assessment took into account the costs associated with controlling or eradicating diseases, having regard to the relevant scientific factors:

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137 Huon Aquaculture Company Pty Ltd, Supplementary Submission 54, p 4

138 Ocean Wave Seafoods, Submission 55, p 3

139 ibid, p 327

140 Dr Alistair Brown, Evidence, RRAT, 11 November 1999, pp 326-327

> Diseases which would not be amenable to control or eradication or those which are amenable - at a significant cost - are considered as having a moderate or more serious impact and AQIS has imposed strict risk management measures, as warranted by the conclusions of the risk analysis, in relation to these diseases. [141]

Environmental concerns and the impact on native salmonids

6.155 In assessing the impact of disease agents on native salmonids, AQIS assumed that pathogens that infect a wide and non-specific range of hosts, including species that are related or similar to Australian species, would have consequences at least as severe as those reported overseas.[142]

6.156 Various submissions to the Committee were again critical of the AQIS assessment for failing to test the impact of various diseases on native salmonids. For instance, Mr Richards from the Northern Tasmanian Fisheries Association noted in hearings that:

> No detailed scientific study has been done by AQIS on susceptibility of native species, or on the consequences and impacts on their population and viability.[143]

6.157 In response to the suggestion that AQIS should conduct specific investigations of the susceptibility of native fish to exotic disease agents, AQIS advised the following:

> a) Such testing would be unlikely to justify any tightening of quarantine policy because AQIS has generally assumed that native species would be at least as susceptible to disease as similar species overseas;
>
> b) Such proposals are impractical because definitive answers to the questions raised by witnesses would require the importation of live exotic disease agents for use in tests on native fish under conditions that plausibly mimic the situation in the natural environment. To secure the biosecurity of such experiments would require that such tests be conducted in high level containment facilities such as the Australian Animal Health Laboratory (AAHL) and approval to import such disease agents would be unlikely to be obtained.[144]

6.158 However, while AQIS argued against such a study, Dr Purser stated that it would not be difficult to conduct controlled tests of the reaction of native fish to

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141 AQIS, Supplementary Submission 59, p 23

142 AQIS, *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish*, July 1999, p 42

143 Mr Peter Richards, Evidence, RRAT, 5 October 1999, p 128

144 AQIS, Supplementary Submission 59, p 3

diseases, given that a number of disease testing protocols are established for such purposes.[145] By contrast, while noting that native species could be 'incredibly susceptible' to introduced diseases, Professor Forteath stated that testing for diseases could be a 'very expensive and long-term business'.[146]

The Policy Implications of the IRA

6.159 Given the range of concerns expressed regarding aspects of the 1999 IRA, various submissions to the inquiry concluded that there is no scientific justification for reversing Australia's previous prohibition on the import of non-viable salmonid products. The submission from Tassal expressed concern that:

> The IRA handles the exposure assessment for the relatively new disease Infectious Salmon Anaemia (ISA), considered to be the equivalent of Foot and Mouth Disease, in a similarly dismissive manner. Section 4.3.1.2 of Chapter 4 lists among key findings that:
>
> - Flesh, even from carrier fish, may be highly contagious,
> - If introduced, the disease would be expected to spread readily but slowly,
> - The minimum invective dose for the ISA virus is not known.
>
> It then somehow concludes that the likely-hood of infection would be low.[147]

6.160 Further concerns were expressed by various parties at the perceived failure of AQIS to modify their IRA in response to new information.

6.161 The draft 1999 IRA noted that the intermediate host for the *Myxobolus Cerebralis* protozoan which causes whirling disease, the freshwater worm *Tubifex tubifex*, is not widely distributed in Australia:

> *T. tubifex* is not common in Australia. Where it does occur, it is in association with bottom substrates that have high organic content, such as occur in grossly polluted streams…juvenile salmonids are more susceptible to infection than older fish.[148]

6.162 Subsequently, following consultation with Dr A Pinder, the author of a key publication on oligochaetes in Australia, AQIS revised its assessment of the distribution of *T. tubifex* in Australia. AQIS acknowledge that *T. tubifex* is to be found widely in Australia, 'but is not at a sufficiently high prevalence to be described as common or ubiquitous'. In his final report, Dr Pinder stated:

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145 Dr John Purser, Evidence, RRAT, 5 October 1999, p 176

146 Professor George Forteath, Omlas Pty Ltd, Evidence, RRAT, 5 October 1999, p 143

147 Tassal Ltd, Submission 41, p 3

148 AQIS, Supplementary Submission 59, p 14

> *T. tubifex* has a widespread distribution in Australia, including in regions where there are rainbow trout; although *T. tubifex* is present at a much lower density than other oligochaetes.[149]

6.163 On this basis, AQIS was criticised for failing to revise its assessment of the risk posed by whirling disease following its acknowledgment that *T. tubifex* is found widely in Australia:

> An example is the statement in relation to whirling disease, that the host tubifex worm was not common in Australia. The Victorian trout industry submitted information showing that this was not correct. The presence or otherwise of a host capable of transmitting the disease is a major factor in assessing risk, yet the correction of this factor did not result in a change in the AQIS assessment of the risks associated with whirling disease.[150]

6.164 Given such concerns, the AQIS reversal of the position from that recommended by the 1996 IRA, that the prohibition on the importation of wild, ocean-caught Pacific salmon from North America 'remain in place' was of concern to stakeholders. Nortas Aquaculture stated:

> AQIS has decided to allow imports thereby reversing a decision of only three years ago, based on an Import Risk Assessment (IRA), to maintain the ban on uncooked imports. This reversal has not occurred because of a lessening of the disease threat (in fact the disease threats are greater now than three years ago) or because the consequences of disease introduction have reduced (the potential economic losses alone are now at least double the levels of three years ago).[151]

6.165 The TSGA stated:

> In 1996, a decision was made to effect that the importation of Canadian wild caught Pacific Salmon was too dangerous. …Three years later, not only has this decision been overturned, but a decision has also been made to permit the importation of salmon from other areas and other sources (e.g. farmed salmon) all of which represent a greater level of risk. In the meanwhile, there has been a major deterioration in salmonid health world wide.[152]

6.166 It was noted during hearings that the 1996 IRA did not include an assessment of ISA. The 1996 IRA indicated that ISA was present in Norway, but was 'still unknown in North America and the European Union'. By comparison, the 1999 IRA

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149 AQIS, *Import Risk Analysis on Non-viable Salmonids and Non-Salmonid Marine Finfish,* July 1999, p 126

150 Tasmanian Salmonid Growers Association Ltd, Submission 46, p 7

151 Nortas Pty Ltd, Submission 37, p 3

152 Tasmanian Salmonid Growers Association Ltd, Submission 46, p 7

notes that ISA has since been identified in Canada and Scotland, and that it is a 'significant disease'.

6.167 At a public hearing on 22 November, Mr David Bucke was asked whether there had been any changes in the science of salmonid disease since the 1996 IRA which would justify the change in the AQIS position. Mr Bucke made the following statements in reply:

> I am aware of some changes that have occurred since 1995 and also since the Canadian reply to the 1995 AQIS report, which was in 1996, I believe. First of all, the disease ISA has been identified in Scotland, including the Shetlands, in 1998 and again in Canada in 1997. Bacterial kidney disease has been identified in Denmark in 1997. Pancreas disease, a virus disease of salmonids, has been reported throughout western Europe, including Norway, and North America. Other diseases that are spreading or have been reported to be spreading include piscirickettsiosia, which has been reported in North America and Europe, but it is only still severe in Chile. There have been new vibrio species reported in Atlantic salmon, reported by Brian Austin at the 1999 European Association of Fish Pathology Conference.
>
> Also, there are other things that seem to be happening now. In the case of VHS or viral haemorrhagic septicaemia, there are different viruses found in marine fish in European waters and nobody really knows whether these are virulent for salmonids, so I think a lot of things are happening. It is still, I think, a dangerous thing to import.[153]

The Import of Non-viable Salmonid Product from New Zealand

6.168 The importation of non-viable salmonid product from New Zealand under the new 1999 AQIS protocols received particular attention during submissions. As noted in Chapter One, the new protocols do not require that New Zealand Pacific salmon entering Australia be processed beyond evisceration.

6.169 The New Zealand salmonid industry is generally regarded as free of most diseases affecting salmon, and thus comparable to the Tasmanian industry. The exception is the presence in New Zealand of whirling disease.

6.170 The supplementary submission from AQIS noted that the prevalence of whirling disease in New Zealand is very low. Since whirling disease was detected in New Zealand in 1966, clinical disease[154] has been reported on only two occasions, in rainbow trout in 1966 and 1980, and has never been reported in salmon. Surveillance

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153 Mr David Bucke, Evidence, RRAT, 22 November 1999, p 366

154 Clinical disease differs from infection. Pacific salmon may be infected with whirling disease, but are unlikely to display the clinical symptoms. Rainbow trout are most likely to express the disease because they are more susceptible than the other types of salmonids.

and monitoring of export farms in 1992-1996 detected only one infected sockeye salmon in a total of 5,700.[155]

6.171 Nevertheless, various parties expressed concern during hearings at the importation of head-on Pacific salmon from New Zealand into Australia. Professor Forteath stated:

> I find it extremely odd that originally the heads could come and the gills. Why? It does cause problems. It should be quite clear to New Zealand that they have to be responsible too, whether they like it or not. We can go on playing statistics till the moon is made into cheese. The fact is that they do have whirling disease there; they have not got rid of it. There are probably far more fish with it than we imagine, but it is just one of those things we have not had to worry about.[156]

6.172 Similarly, in response to the proposition that removing the head and gills would be 'a step in the right direction as far as risk is concerned', Dr Purser stated:

> Yes, that is right. I do not see the relaxation of the New Zealand importation in allowing Australian fish with heads on as being in the right direction. … should be in reverse. If anything, Australian fish should have their heads off to comply with the New Zealand fish coming in here with heads off.[157]

6.173 Finally, Mr Orr from the Tasmanian Professional Trout Guides Association argued in relation to whirling disease:

> The fact is that New Zealand have it – they have what is seen as a small amount; I do not know that you can class nine rivers as a small amount – and eventually it will move through their fisheries. It has been found in salmon. AQIS will tell you it was one fish tested in 5,000. Does than mean it is two fish in 10,000 and four fish in 20,000? If it is, it is four fish too many.[158]

6.174 In response, AQIS reiterated that prohibiting the import of head-on salmon from New Zealand 'is not warranted on quarantine grounds', AQIS also argued that such a prohibition would necessitate under WTO regulations the imposition of far more restrictive policies on other non-viable fish products imported into Australia.

6.175 In subsequent hearings on 11 November, Dr Kahn restated that the prevalence of whirling disease in New Zealand remained very low, even though New Zealand authorities had done extensive testing. Consequently, she stated that the risks posed

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155 AQIS, Supplementary Submission 59, p 12

156 Professor George Forteath, Omlas Pty Ltd, Evidence, RRAT, 5 October 1999, p 152

157 Dr John Purser, Evidence, RRAT, 5 October 1999, p 177

158 Mr Kenneth Orr, Tasmanian Professional Trout Guides Association, Evidence, RRAT, 5 October 1999, p 124

by importation of wild Pacific Salmon from New Zealand, as opposed to rainbow trout or young fish generally, are 'vanishingly small'.[159]

6.176 Rather than seeking to prohibit the import of head-on Pacific salmon into Australia from New Zealand, AQIS made representations to the New Zealand Ministry of Agriculture and Forestry to permit the import of head-on Australian salmon into New Zealand. This permission was granted on 28 September 1999.[160]

159 AQIS, Evidence, RRAT, 11 November 1999, p 343

160 AQIS, Supplementary Submission 59, p 22