CHAPTER FIVE

IMPORT RISK ANALYSIS - PURPOSE AND PROCESS

Objectives of Import Risk Analysis

5.1 International agreements entered into by Australia now require any quarantine import restrictions either to comply with international standards or to be justified through the import risk analysis process. An Import Risk Analysis [IRA] provides the scientific and technical basis for quarantine measures that determine whether or not an import may be permitted and any applicable conditions. AQIS describes the purpose of IRA's as follows:

> The principal aim of import risk analysis is to provide importing countries with an objective and defensible method of assessing the risks associated with the importation of aquatic animals, aquatic animal products, aquatic animal genetic material, feedstuffs, biological products and pathological material. The analysis should be transparent in order that the exporting country may be provided with a clear and documented decision on the conditions imposed for importation, or refusal of importation.
>
> Import risk analysis is preferable to a zero-risk approach because it provides a more objective decision, and enables Competent Authorities to discuss any differences in conclusion which may arise concerning potential risks.[1]

The International Standard for the Importation of Salmonid Products

5.2 Because whole, eviscerated salmonids are sold for human consumption internationally, the recommendation of the OIE is that there should be no health-

---

1 OIE International Animal Health Code, p 27

related impediment to trade in such fish.[2] In the view of one of the experts who participated in discussions with the Panel during the 1998 Panel process, if the baseline risk, or that generally internationally acceptable, is acceptable to the importing country then the IRA process is unnecessary. However, once the baseline risk is unacceptable to the importing country and additional safeguards are required, the IRA must assess the level of risk with the most stringent practical combination of safeguards in place and then demonstrate that the risks are still unacceptable.[3] The justification requirement for any restrictions/safeguards is therefore substantial.

The Role of Risk Analysis in Quarantine Policy

5.3 The OIE describes the underlying objective of the IRA process as follows:

> The principal aim of import risk analysis is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material. The analysis should be transparent. This is necessary so that the exporting country is provided with clear reasons for the imposition of import conditions or refusal to import.[4]

5.4 AQIS states that quarantine risk comprises two related factors - the probability of the disease agent entering and becoming established in Australia, and the expected impact of significance of such establishment.[5] AQIS argues that, by describing and addressing both in a standardised way it is possible to achieve consistency both in the management of quarantine risks and in the overall approach to risk management.[6]

5.5 Quarantine policy recognises the fundamental importance of the risk analysis process to the development of quarantine practices and the defence of those practices domestically and in the international arena. The Government Response on quarantine recognised this factor, stating:

> Risks need to be assessed objectively so we have a rational basis for making decisions and defending those decisions, not only to the Australian community but also internationally.[7]

5.6 AQIS primary role is the protection of Australian human, animal and plant life from exotic diseases and pests. However, there exists a parallel government objective to facilitate trade and the two objectives can be in conflict. In order to meet

---

2 AQIS, *Import Risk Analysis on Non-viable and Non-salmonid Marine Finfish*, July 1999, p 3

3 Dr Wooldridge, Joint Meeting with Experts, Annex 2 to Panel report, 4 February 1998, p 221

4 OIE, *Import Risk Analysis*, Article 1.4.1.1

5 AQIS, *Import Risk Analysis on Non-viable and Non-salmonid Marine Finfish*, July 1999, p 8

6 ibid

7 *Australian Quarantine – A Shared Responsibility: The Government Response,* August 1997, p 10

these potentially conflicting objectives, quarantine measures at a level more restrictive than international standards must be based on an import risk analysis, scientifically based, undertaken in an open and transparent manner and in consultation with stakeholders, in order that Australia remains in conformity with its obligations under international agreements.

5.7 Risk analysis in the area of aquatic animal health field is relatively new. Stuart McDiarmid, at a recent OIE conference, stated:

> In the animal health field, as in other areas, it has become apparent that risk analysis is a complex discipline and assessments often do not stand up well in an adversarial climate, such as frequently surrounds trade proposals…even in situations where risk can be quantified relatively objectively it may be difficult to attain agreement on what constitutes an acceptable risk.[8]

The IRA Process

5.8 The Nairn Committee, in its review of quarantine policy and procedures, recommended that a number of principles should apply to the conduct of import risk analyses. The Committee recommended that import risk analyses are to be:

a) Conducted in a consultative framework, with agreed priorities and timetables;

b) Scientifically based and politically independent;

c) Transparent and open, including peer review and public scrutiny components;

d) Consistent with Government policy and Australia's international obligations, to be achieved by reference to existing policies and procedures, international standards, guidelines and recommendations and through the contribution of participants;

e) Harmonised, by taking account of international standards, guidelines and recommendations; and

f) Subject to appeal on the process.[9]

5.9 The Government accepted all the Nairn Committee recommendations on the import risk analysis process, including the basic principles listed above. AQIS, in implementing the recommendations, standardised procedures to be followed for the

---

8 S McDiarmid, Abstract, Address to International Conference on Risk Analysis in Aquatic Animal Health

9 Nairn ME, Allen PG, Inglis AR and Tanner C, *Australian Quarantine - A Shared Responsibility*, 1996, pp 89-90

science-based analysis of risks associated with imported animals and plants and their products.

AQIS IRA Handbook

5.10 To improve community and stakeholder understanding of the process, AQIS developed the Import Risk Analysis Handbook. The Handbook sets out the framework for quarantine decision making and the consultation and appeal processes available to stakeholders. The Handbook is available on AQIS' website and was also provided to the Committee.

5.11 The Handbook sets out in detail the process followed by AQIS for the determination of an import proposal. That process is reproduced in Figure 5.1. For the purposes of the Committee's inquiry, the most significant processes are included in the non-routine pathway, in sections three and four of the document. The Committee's concern centres on the consultation processes in Section Three.

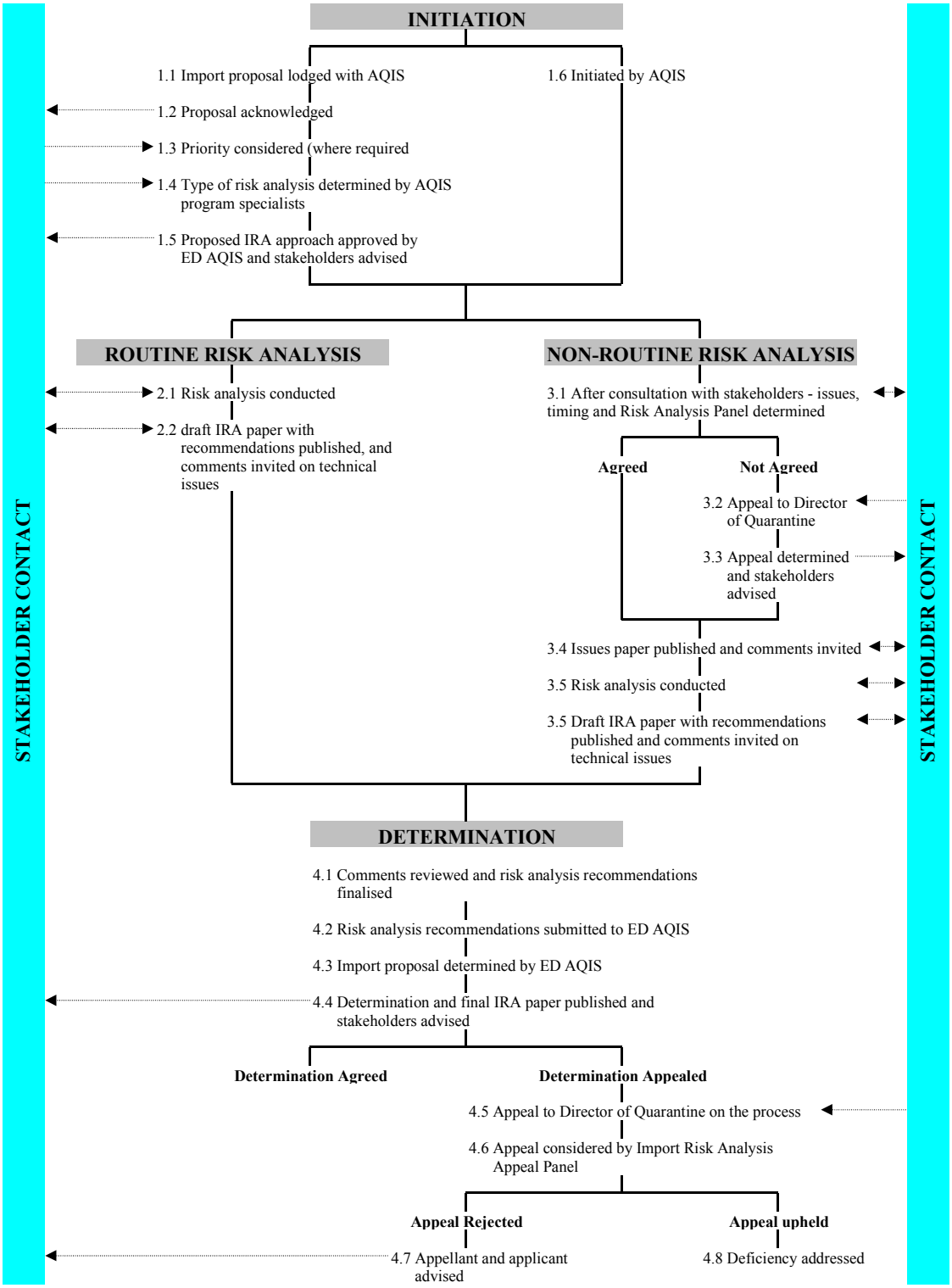
5.12 Section three provides for the establishment of the scope and timeframe of the IRA, appeal against the process, development and publication of an issues paper, the risk assessment, and publication of the draft IRA with recommendations. Section 3.6 states:

> 3.6 draft IRA paper with recommendations published and comment invited on technical issues
>
> At the completion of the [Risk Assessment Panel's] deliberations, AQIS circulates to stakeholders, for comment within 60 days, a draft IRA paper covering technical issues related to disease and pest risk, risk management options and a preliminary view on which option would achieve Australia's appropriate level of protection. AQIS also announces the release of the paper in the *AQIS Bulletin,* on the Internet homepage and to the WTO.[10]

5.13 Section four of the Handbook sets out the determination process, where comment is reviewed and the risk analysis recommendations are finalised and published.

10 AQIS IRA Handbook, 1998, p 17

Figure 5.1 - AQIS Import Risk Analysis Process[11]



11 Based on the table reproduced in the AQIS IRA Handbook, 1998

Appeals

5.14 Once the determination and final IRA paper is published, an appeal opportunity is available, but this is limited to an appeal on the process. Appeals are on the ground that the process outlined in the Handbook has not been properly followed, including failure to consider a significant body of relevant scientific or technical information. An appeal opportunity is also available at an earlier stage, following AQIS notification of the scope of the IRA, membership of any working groups and panels and the timing of the IRA.

Review of the Handbook

5.15 The Committee notes the proposal to undertake a review of the import risk analysis process and handbook.[12]

The Principles of Risk Analysis

5.16 The OIE, SPS Agreement and AQIS' own documentation all set out principles of risk analysis.

OIE Principles

5.17 The methodology used in both the 1996 and 1999 import risk analyses was modelled on that contained in the OIE International Animal Health Code. That Code identifies the principles of risk assessment as follows:

> a) Risk assessment must be flexible enough to deal with the complexity of real life situations, the variety of animal commodities, the multiple hazards that may be identified with an importation and the specificity of each disease, detection and surveillance systems, exposure scenarios and types and amounts of data and information;
>
> b) No single method is applicable in all cases - qualitative and quantitative risk assessment methods are valid;
>
> c) It must be based on the best available information that is in accord with current scientific thinking, well documented and referenced;
>
> d) Consistency in risk assessment methods should be encouraged and transparency is essential;
>
> e) It must describe the uncertainties, assumptions, and the effect of these on the final estimate;
>
> f) It must be amenable to updating.[13]

---

12 AFFA, Portfolio Budget Statements 2000-2001, p 62

13 OIE, *International Animal Health Code*, Article 1.4.2.1

5.18 The Code provides a standard method for undertaking risk assessments, or the evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a pathogenic agent within the territory of an importing country.[14] The analyses are required to be transparent, ie to include 'comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the risk analysis'.[15]

5.19 A risk assessment can be qualitative or quantitative:

> 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.[16]

Risk Analysis in the SPS Agreement

5.20 The articles in the SPS Agreement of most relevance are Articles 2 and 5. Article 2 requires members to 'ensure that measures are taken only to the extent necessary to protect human, animal or plant life or health, and measures shall not be applied in a manner which would constitute a disguised restriction on international trade'.

5.21 Article 5 of the Agreement defines the procedures and conditions for the development of an IRA and sets out specific factors to be taken into account:

a) Available scientific evidence;

b) Relevant processes and production methods;

c) Relevant inspection, sampling and testing methods;

d) The prevalence of specific diseases or pests;

e) The existence of pest or disease-free areas;

f) Relevant ecological and environmental conditions; and

g) Quarantine or other treatments.

---

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

15 ibid

16 D Vose, Abstract, Address to International Conference on Risk Analysis in Aquatic Animal Health, February 2000

The Assessment of Economic Impact

5.22 In assessing the risk to animal or plant life or health and determining the measure to be applied, the Agreement allows members to take into account the following relevant economic factors:

> a) The potential damage in terms of loss of sales in the event of the entry establishment or spread of a pest or disease;
>
> b) The costs of control or eradication in the territory of the importing Member; and
>
> c) The relative cost-effectiveness of alternative approaches to limiting risks.[17]

5.23 The assessment of economic impact is limited to the economic impact of a disease, and does not extend to the potential economic consequences of importation.[18] AQIS advised:

> The social and economic considerations arising from the potential impact of pests and diseases that could enter and establish in Australia as a result of importation are taken into account…Relevant economic considerations in quarantine risk analysis include the cost of programs required to manage disease and pest outbreaks, the cost to industry of an outbreak and the cost to industry of loss of markets due to an outbreak.[19]

5.24 Should domestic industries be subject to substantially greater import competition and consequent structural adjustment pressure, the Government may in such circumstances seek relevant economic analysis and consider options available for an appropriate response. AQIS advised that such considerations may occur in parallel with, but in no way influence, the import risk analysis performed in accordance with the procedures outlined in the IRA Handbook.[20]

The AQIS Approach

5.25 AQIS identified the requirements for a risk analysis as being:

> a) Identification of the diseases the entry, establishment or spread of which a WTO member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases;

---

17 *Agreement on the Application of Sanitary and Phytosanitary Measures*, Article 5, pp 3-4

18 ibid

19 AQIS, IRA Handbook, p 11

20 ibid

b) Evaluation of the likelihood of entry, establishment or spread of these diseases, as well as the associated potential biological and economic consequences; and

c) Evaluation of the likelihood of entry, establishment or spread of these diseases according to the SPS measures which might be applied.[21]

The 1996 Import Risk Analysis

5.26 The IRA process commenced in January 1994, when Canada formally requested GATT Article XXII consultations with Australia. Australia agreed to document an IRA on the quarantine issues of importing uncooked salmon meat from North America. A draft IRA was circulated in May 1995, recommending that importation of the product be permitted under specified conditions. Issues raised in responses included some matters not canvassed in the draft IRA and it was agreed that a revised draft IRA be distributed. This paper was circulated for public comment in May 1996.

5.27 The 1996 IRA considered the impact of importation of uncooked, wild, adult, ocean-caught Pacific salmon products from Canada and the United States. Restriction of the IRA to Pacific salmon was agreed to by Canada and the United States, as this was the product of greatest commercial interest. The methodology used in the IRA was modelled on the OIE recommended methods and addressed risk assessment, risk management and risk communication issues.

5.28 According to AQIS, the major points at issue in the 1996 IRA related primarily to:

a) The presentation and interpretation of the scientific information in the revised draft and its cover memorandum;

b) The interpretation and the weighting placed on some of the information provided and the meaning of acceptable risk;

c) The question of what was 'acceptable risk' and whether a full and proper process of determining what is acceptable had been followed.[22]

5.29 The final 1996 report noted the following:

> Australia is free of many of the major diseases of fin fish and aquatic invertebrates that occur in other countries. Furthermore, a disease that may not be considered 'major' in an overseas country…could have a significant impact on susceptible stocks in Australia. The unknown susceptibility of native salmoniforms and commercial species to a wide range of exotic

21 AQIS *Import Risk Analysis on Non-viable and Non-salmonid Marine Finfish*, July 1999, pp 3-4 and AQIS Policy Memorandum 1999/26

22 AQIS, *Salmon Import Risk Analysis,* 1996, para 1.1.4

disease agents is a central issue. Given this situation, a degree of caution is justified.[23]

5.30 At the outset, the report noted the following parameters:

a) The final IRA report needed to be considered in the context of Australia's quarantine policy and international obligations;

b) Despite recent advances in knowledge of diseases, aquatic animal quarantine policy remained significantly undeveloped and, in most instances, had not been subjected to the same scientific scrutiny as traditional livestock policy; and

c) The risk assessment process and methodology were consistent with international standards.[24]

5.31 AQIS listed the key considerations in reaching a decision on imports of salmon product as:

a) The large number of diseases being considered;

b) A lack of definitive scientific information on the disease agents, their hosts, their mode of spread and their prevalence in the fish populations proposed for export;

c) Difficulty in measuring and describing the level of risk, in part because of uncertainty about avenues for post entry exposure of Australian fish to introduced pathogens and difficulty in measuring the likelihood of exposure;

d) Limitations in estimating potential consequences of disease introduction for recreational and wild fisheries, aquaculture and the environment (including rare and endangered species); and

e) Problems in estimating whether the described risk represents an acceptable risk.[25]

5.32 The 1996 IRA report concluded:

a) Australia was recognised as having a favourable aquatic animal health status;

---

23 ibid, p 4

24 ibid, pp 3-4

25 ibid, para 1.3.1

b) Biological considerations were the key component in a quarantine risk assessment but there were major gaps in knowledge on salmonid diseases:

i) The biological data indicated 20 disease agents or strains present in the North Pacific Ocean rim of North America that had not been found in Australia;

ii) There were major gaps in knowledge in relation to these diseases, eg infectious dose rates, persistence of agents and host response;

iii) There were no reported occurrences of salmonid diseases being spread through uncooked products, although the extent to which the matter had been researched was uncertain;

c) There were risks of exotic disease agents occurring in salmon products, but the risk of establishment was low if suitable risk management interventions are mad;

d) The susceptibility of salmonids could be assumed to be high, particularly given a likely lack of disease resistance;

e) It was most likely any exotic condition would be ineradicable;

f) The potential socio-economic and environmental impacts of an exotic disease incursion could be substantial.[26]

5.33 The major cause for concern from Australia's viewpoint was the potential consequences of irreversibility of disease, should any pathogens enter Australia. In the view of the Australian representatives before the WTO, even a disease with a low probability of establishment presented cause for concern, given the seriousness of the consequences and the likely irreversibility of the introduction of disease.

5.34 The ultimate conclusion of the 1996 IRA was that entry of uncooked salmon products from Canada and the United States was not permitted. The report stated:

> On balance, given the unique circumstances, range of potential disease agents and potential socio-economic and environmental impacts, entry of uncooked salmonid products from Canada and the United States should not be permitted at this time.[27]

5.35 In the 1996 IRA, Australia gave a commitment to reviewing new information as it became available.

---

26 ibid, pp 4-7

27 ibid, p 7

The 1998 WTO Findings on the IRA

5.36 Following the release of the final 1996 report, Canada applied to the WTO for a Dispute Settlement Body Panel, which reported in June 1998. As noted in Chapter Three, the Panel found Australia had acted inconsistently with Articles 5.1 (measures to be based on an IRA), 5.5 (consistency), and 5.6 (not more trade restrictive than necessary), and Articles 2.2, (departure from international standards) and 2.3 (unjustifiable discrimination) of the SPS Agreement. The finding that Australia had breached Articles 5.6 and 2.3 of the Agreement was subsequently overturned on appeal.

Joint Meeting of Panel and Experts

5.37 During the deliberations of the Panel, a Joint Meeting with Experts was convened. At that meeting, the most criticised elements of the IRA as conducted by AQIS were considered to be:

a) The unsatisfactory methodology of the IRA;

b) The different conclusions reached from essentially the same data in the draft report and the final report; and

c) The less transparent nature of the final report as compared with the draft.[28]

5.38 The experts who appeared before the Panel comprised Drs Burmaster, Rodgers, Winton and Wooldridge. Representatives from Canada and Australia were also present. The representatives were primarily critical of the change in emphasis and amended conclusion in the final report to that appearing in the draft report. This difficulty appears to have been problematic for Australia.

The 1999 Import Risk Analysis[29]

5.39 The 1999 IRA considered the quarantine risks potentially associated with the importation to Australia of non-viable salmonid and non-salmonid marine finfish from any source country. The product at the centre of the dispute between Canada and Australia was fresh, chilled and frozen salmon product destined for human consumption that had not been subject to heat treatment according to certain prescribed durations and temperatures, prior to importation into Australia.[30]

The Scope of the 1999 Import Risk Analysis

5.40 The base products considered in the IRA were non-viable fish - eviscerated salmonids and whole, round (uneviscerated) non-salmonid marine finfish. Whole,

---

28 WTO Joint Meeting with Experts, 4 February 1998, Annex 2 to Panel report

29 Much of the following section is based on the WTO Panel Report released on 18 February 2000

30 WTO Panel Report, June 1998, p 2

eviscerated salmonids are sold for human consumption, while non-viable, uneviscerated non-salmonid marine finfish may be used for human consumption or as feed for fish, bait or for further processing (eg for pet food). The IRA did not cover canned or retorted shelf-stable fish product, live fish or their genetic material.[31]

5.41 The IRA as undertaken by AQIS was a generic import risk analysis, addressing all potential relevant pests and diseases, for all members of the family *Salmonidae*, and all other finfish species caught in marine or brackish waters. The 1999 IRA covered the ban on the importation of salmonids and the then largely unrestricted entry of the following range of imported marine finfish, many of which could carry diseases of concern to salmonids:

a) A range of fish species for human consumption, including herring, nile perch and barramundi, estimated at 60,000 tonnes per annum;

b) Fish species not for human consumption including herring and mackerel that may be used as bait, in fish meal, pet food, estimated at 47,000 tonnes per annum; and

c) Aquarium fish species such as goldfish, tetras and gouramis, estimated at 6.5 million per annum.[32]

5.42 The 1999 IRA identified the disease agents of concern requiring further consideration. A disease agent was given specific consideration in the 1999 IRA if it was infectious, and either exotic to Australia or present in Australia but subject to official control, and if the disease agent was OIE-listed or would be expected to cause significant harm in Australia. On the basis of these criteria, the disease agents of concern were categorised into those whose consideration is of higher priority (Group 1) or lower priority (Group 2).

5.43 The 1999 IRA stated that seven of the 15 "higher priority" diseases represented risks that were not acceptable to Australia without the application of additional risk management measures beyond evisceration. For the seven specified diseases, the 1999 IRA[33] identified various risk management measures which it considered could reduce the risk to an appropriate level considered.

---

31 AQIS, *Import Risk Analysis on Non-viable and Non-salmonid Marine Finfish*, July 1999, pp 2-3

32 AQIS, Evidence, RRAT, 24 September 1999, p 22

33 These are:

a) Infectious haematopoietic necrosis virus (IHNV);
b) Infectious salmon anaemia virus (ISAV) (for Atlantic salmon);
c) *Aeromonas salmonicida* (not for wild, ocean-caught Pacific salmon);
d) *Renibacterium salmoninarum;*
e) Infectious pancreatic necrosis virus (IPNV) (for juvenile salmonids only);
f) Yersinia ruckeri (for juvenile salmonids only); and
g) Myxobolus cerebralis (whirling disease) (for rainbow trout and all juvenile salmonids).

5.44 The 1999 IRA further considered the Group 2 diseases, and concluded that no additional measures beyond those for the Group 1 diseases were required to satisfy Australia's ALOP.

5.45 The 1999 IRA also indicated that as the seven diseases of concern are either not reported in New Zealand or (for whirling disease) occur at extremely low prevalence in New Zealand Pacific salmon, the selected measures did not apply to Pacific salmon from New Zealand.

The Effect of the Findings of the 1999 Import Risk Analysis

5.46 The effect of the measures introduced by AQIS following the IRA was an overall tightening of quarantine conditions, which are tighter than international standards and stricter than any other country[34]. The revised arrangements were set out in a series of Animal Quarantine Policy Memoranda, published over several months, following the release of the IRA. These are set out in Chapter One.

Measures for Non-Viable Salmonids

5.47 Revised arrangements were contained in AQPM 1999/51, published and effective as of 19 July 1999 and in AQPM 1999/69 of 20 October 1999, which clarified the conditions announced in the earlier memorandum with respect to documentation, recognition of competent authorities, definition of 'consumer-ready' product, verification and other requirements.

5.48 Salmonids could be imported subject to the following risk management measures:

a) The fish should be eviscerated;

b) The fish should not be derived from a population slaughtered as an official disease control measure;

c) The fish should not be juvenile salmonids or sexually mature adults/spawners;

d) The fish should be processed in premises under the control of a competent authority;

e) The head and gills should be removed and internal and external surfaces thoroughly washed;

f) The fish should be subjected to an inspection and grading system supervised by a competent authority;

34 AQIS, Evidence, RRAT, 24 September 1999, p 22

g) For farmed fish, the fish should be derived from a population for which there is a documented system of health monitoring and surveillance administered by a competent authority; and

h) Consignments exported to Australia should be accompanied by official certification confirming that the exported fish fully meet Australia's import conditions (as specified on an import permit issued by AQIS).[35]

5.49 These conditions cover the importation of uncooked salmonids from any country that meets Australia's quarantine requirements.[36] The measures do not apply to imports from New Zealand, as the diseases are either not found there or occur at low levels.

Measures for Non-Viable, Non-Salmonid Marine Finfish

5.50 The 1999 IRA concluded that 'the importation of non-viable finfish would be permitted, subject to risk management measures to reduce the probability of entry and establishment of specified diseases to an acceptably low level'[37]. The diseases of concern were those identified in the risk analysis as requiring risk management to meet Australia's ALOP.

5.51 For non-viable, non-salmonid marine finfish, the starting point for the risk analysis was the product that is traded internationally, ie whole, round (uneviscerated) fish. AQIS introduced new restrictions to reflect the risk associated with the commodity. Three options for imports are available:

a) **Option 1 -** no import permit required:

i) The fish must be processed in a premises approved by and under the control of a competent authority;

ii) The fish must be eviscerated;

iii) The fish must be individually sorted and packaged to facilitate inspection;

iv) The fish must be subjected to an inspection system supervised by a competent authority;

v) The head and gills must be removed and internal and external surfaces thoroughly washed;

35 AQIS, Submission 17, pp 77-78

36 AQIS, *Import Risk Analysis on Non-viable and Non-salmonid Marine Finfish*, July 1999, p 288

37 ibid, p 287

vi) The product must be free from visible lesions associated with infectious disease; and

vii) Consignments exported to Australia must be accompanied by official certification confirming that the exported fish meet Australia's import conditions in full.

b) **Option 2 -** no import permit required:

i) AQIS will not require an official health certificate for consumer-ready product that has been processed further than the stage described above.

c) **Option 3** - import permit required:

i) If neither options 1 or 2 applies, an importer must obtain a permit from AQIS before importing fish;

ii) The application for the permit should provide details of the finfish species to be imported, the waters in which the fish were farmed (if applicable) and harvested and the intended end use of the imported fish; and

iii) AQIS will assess the application in light of the quarantine risks it presents; if the Delegate concludes that the proposed importation is consistent with Australia's ALOP, a permit for the importation of single or multiple consignments during a specified timeframe would ordinarily be granted. [38]

5.52 The restrictions relating to non-viable, non-salmonid marine finfish are more restrictive than previously applied. Less restrictive arrangements apply to fish imported from New Zealand, provided that the fish were caught in New Zealand's Exclusive Economic Zone (EEZ) or in adjacent international waters and the consignment is the product of New Zealand.[39]

Measures for Live Ornamental Finfish

5.53 The risk analysis concluded that the importation of live ornamental finfish should be permitted, subject to risk management measures to mitigate the probability of entry and establishment in Australia of diseases of quarantine concern. AQIS noted that live animals generally present a greater risk than product and that there are significant gaps in the knowledge base of the diseases of ornamental finfish. For these reasons, AQIS supplies baseline risk management measures for all ornamental finfish imported and more stringent measures for goldfish.

---

38 AQIS, *Import Risk Analysis on Non-viable and Non-salmonid Marine Finfish*, July 1999, p 289

39 ibid

5.54 Each consignment of ornamental finfish must be accompanied by:

a) An animal health certificate from the competent authority attesting to the health of the fish in the consignment and the health status of the source population;

b) Certification from a competent authority that the premises of export or exporter are currently approved for export to Australia; and

c) Certification from a competent authority attesting that the fish had not been kept in water in common with farmed food fish.[40]

5.55 Each consignment must also be subject to:

a) Visual inspection of all fish on arrival to identify overtly diseased consignments and to ensure that the fish are of a species listed on Schedule 6;

b) Post-arrival quarantine detention for a minimum period in approved private facilities under quality assurance arrangements agreed with AQIS (3 weeks for goldfish, 1 week for other species); and

c) Quarantine security over procedures in quarantine premises, including the disposal of sick and dead fish, transport water, packaging materials and other waste.[41]

5.56 Other measures to address specific disease concerns include:

a) Health certification from the competent authority that the source of the fish was free of specified disease agents;

b) Treatment either of the source population of the fish or of the fish for export, to address the likelihood that unwanted disease agents may be present;

c) Testing of imported fish during quarantine detention, either on an ad hoc or routine basis, to validate the certification provided by overseas competent authorities, and/or to provide additional data to improve the targeting of risk management measures on imports generally;

d) Treatment of imported fish during quarantine detention by appropriate means if the presence of specific disease agents is suspected or confirmed following diagnostic testing; and

e) Increased post-arrival quarantine detention over the minimum required.[42]

---

40 ibid, p 290

41 ibid, p 290

5.57 These findings were the culmination of a series of consultations and import risk analysis reports, both draft and final.

Generic Risk Analysis Approach

5.58 AQIS adopted a 'generic' risk analysis approach for the 1999 IRA, addressing 'all relevant pests and diseases, to facilitate assessment of individual access requests according to the health status of the source country'.[43] AQIS elaborated on the basis for this approach:

> AQIS uses generic IRA's to address access requests covering multiple countries. The generic approach enables AQIS to use limited technical resources efficiently and, by covering all requesting or potentially requesting countries in a single IRA, we can respond to each country's request in a timely manner. The generic approach also provides for greater consistency in the application of risk management measures.
>
> From the WTO perspective, the generic approach is fairer and less trade restrictive in that it can provide for the establishment of import protocols that address access requests from all countries in a timely manner.[44]

5.59 AQIS noted that generic risk analyses are not always appropriate, eg in the case of many plant products, where differences between countries in number, significance and scientific knowledge of insect pests and plant diseases would render the generic approach unworkable.[45] AQIS' decision to undertake a generic approach to the salmon dispute in the light of the outcome of the WTO findings, which necessitated consideration of technical issues common to major salmon exporting countries. AQIS noted that, under the SPS Agreement, WTO members have equal rights and to not consider other countries would have left Australia open to claims of discriminatory treatment and retaliatory action.[46]

5.60 The generic approach has been criticised, with at least one submission arguing that the scope of an IRA should be confined to products where there is existing trade or where an organisation wishes to import, and that by widening the scope of the IRA unnecessarily, scarce public funds were being wasted.

5.61 The Committee considers that the AQIS approach to undertake a generic IRA was appropriate in the circumstances, both in terms of requirements under the SPS Agreement and in relation to the most efficient use of AQIS resources.

---

42 ibid, p 290

43 ibid, p xiii

44 AQIS, Correspondence to Committee, 1 March 2000, p 3

45 ibid, p 4

46 ibid. p 4

The Conduct of the Import Risk Analysis Process

5.62 The conduct of the process, as distinct from the findings, was criticised by many stakeholders. At a recent conference on risk analysis, Dr M Wooldridge emphasised the importance of an open and consultative process in the development of an import risk analysis:

> The source of the information for the risk manager is risk communication and this, ideally, means an open information exchange between risk assessors, risk managers, and all those affected by both the risk and the decisions taken. This is vital as those who benefit from a successful risky endeavour are usually a different group from those who will suffer if it goes wrong. If policies do not take this into account, they will be unpopular, not adhered to, and require extensive policing.[47]

AQIS IRA Process

5.63 Figure 5.1 on page 103 shows the IRA process as set out in the AQIS Handbook. The major phases are:

a) Initiation of the IRA, including:

i) Lodgement and acknowledgment of import proposal;

ii) Priority considered;

iii) Type of risk analysis determined;

iv) Proposed IRA approach approved by Executive Director and stakeholders advised;

b) Risk analysis, either routine or non-routine:

i) Routine risk analysis comprises preparation of draft IRA paper with recommendations published, comment invited on technical issues;

ii) Non-routine risk analysis comprising:

- following consultation with stakeholders, determination of issues, timing and Risk Analysis Panel [if not agreed appeal processes available];
- Issues paper published and comment invited;
- Risk analysis conducted;

47 M Wooldridge, Abstract, Address to International Conference on Risk Analysis in Aquatic Animal Health

- Draft IRA paper with recommendations published, and comment invited on technical issues;

c) Determination:

i) Comment reviewed and risk analysis recommendations finalised;

ii) Risk analysis recommendations submitted to Executive Director;

iii) Import proposal determined by Executive Director;

iv) Determination and final IRA paper published and stakeholders advised;

v) Appeal to Director of Quarantine on the process;

vi) Appeal considered by Import Risk Analysis Appeal Panel;

vii) Appellant and applicant advised;

d) Policy implemented.[48]

Consultation

5.64 The principal opportunities for stakeholder input occur during the initiation and risk analysis phases, with the opportunity to appeal against the process following the initiation and determination phases. Stakeholders are able to provide input on:

a) AQIS' plan for handling the IRA and any significant changes to the process which might take place during the course of the IRA;

b) For routine IRA's, the draft IRA and its recommendations;

c) For non-routine IRA's, the scope of the IRA, timetable and proposed risk assessment panel membership, any issues papers developed by technical working groups set up by a RAP, and the draft IRA and its recommendations.

The Transparency Requirement under the SPS Agreement

5.65 One of the principles of the SPS Agreement is transparency in the risk analysis process. Article 7 of the Agreement relates to the transparency requirement and states:

48 AQIS, IRA Handbook, pp 13-19

> Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with Annex B.

5.66 Annex B requires:

> a) All sanitary or phytosanitary measures to be published promptly in such a manner as to enable interested Members to become acquainted with them;
>
> b) A reasonable interval between the publication of regulations and their entry into force, to allow time for producers in exporting countries to adapt their products and methods of production to the requirements.

5.67 Annex B further requires Members to provide an inquiry point 'responsible for the provision of answers to all reasonable questions from interested members' as well as for the provision of documents, including those regarding sanitary and phytosanitary regulations adopted or proposed and risk assessment procedures and the determination of the ALOP.

5.68 The Annex further sets out notification procedures, which include detailed requirements to publish documentation where measures differ from the international standard and to notify Members about proposed changes and to supply them with the documentation. The full text of the SPS Agreement and the Annex are set out in Appendix 6.

5.69 Notwithstanding the requirements in Clause 5, it is permissible under the Agreement for a Member to omit such of the steps enumerated in the Agreement as it finds necessary for urgent problems of health protection. The omission of the steps is conditional on the Member taking the following steps:

> a) Immediately notifies other Members of the regulation and products covered;
>
> b) Provides copies of the regulation to other Members; and
>
> c) Allows other members to make comments in writing, discusses these comments and takes the comments and results of discussions into account.[49]

5.70 AQIS advises that the SPS Committee has not provided any guidance on what constitutes an 'urgent problem of health protection', although it has agreed on an 'Emergency Notification' format to be used in such circumstances.[50] It is noted that emergency notification has not been an issue to date.

---

49 SPS Agreement, Annex B, clause 6

50 AQIS, E-mail to RRAT Secretariat, 10 May 2000

AQIS IRA Procedures

5.71 The domestic procedures for the publication of documents relating to the IRA process and outcome are set out in the AQIS IRA Handbook:

> At the completion of the [Risk Assessment Panel's] deliberations, AQIS circulates to stakeholders, for comment within 60 days, a draft IRA paper covering technical issues related to disease and pest risk, risk management options and a preliminary view on which option would achieve Australia's appropriate level of protection. AQIS also announces the release of the paper in the *AQIS Bulletin,* on the AQIS Internet homepage and to the WTO.[51]

The WTO Secretariat Handbook on Transparency in the SPS Agreement

5.72 In March 2000 the WTO published a Handbook called *How to apply the transparency provisions of the SPS Agreement.* The Handbook is 'a practical guide for governments to facilitate the implementation of the transparency provisions of the SPS Agreement' and has as a primary purpose the provision of 'guidance on the establishment and operation of notification authorities and enquiry points'.[52]

5.73 The Handbook sets out the definition of the word 'transparency' in the context of the WTO agreements. So far as the SPS Agreement is concerned, the Handbook notes that:

> Under the SPS Agreement, notifications are used to inform other Members about new or changed regulations that affect their trading partners. Transparency under the SPS Agreement also implies answering reasonable questions and publishing regulations.[53]

5.74 It would appear that publication of final regulations, whether new or amended, is what is required, with adequate time for comment by interested and affected parties.

5.75 The Committee also notes advice from the Department of Foreign Affairs and Trade to Senator Murphy on the publication requirements under the WTO agreements. That advice states in part:

> Annex B Paragraph 1 requires Members to ensure that all sanitary and phytosanitary regulations are published promptly in such a manner as to enable interested Members to become acquainted with them. Paragraph 5 requires Members to allow reasonable time for other Members to make written comments, discuss these comments upon request, and take the comments and the results of the discussions into account.

---

51 AQIS, IRA Handbook, p 17

52 WTO Secretariat, *How to apply the transparency provisions of the SPS Agreement*, 20 March 2000, p 3

53 ibid, p 4

> The SPS Agreement does not require Australia to publish *draft* risk assessments and *draft* recommendations, or to provide these to other Members. It is only the final measures as intended to be applied which must be published.[54]

5.76 The Committee subsequently wrote to AQIS requesting responses to a number of questions on their procedures as set out in the Handbook. In response to the wide distribution of the draft IRA, AQIS stated:

> The AQIS import risk analysis (IRA) process reflects Government policy which addresses (but is not limited to) Australia's international obligations…. In response to the recommendations of the Australian Quarantine Review Committee, the Government decided that procedures would be implemented to ensure that import risk analysis is, inter alia, consultative and transparent. These procedures include the circulation of documents at various stages of the IRA process for stakeholder comment.
>
> As to the relevant international obligations, whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Paragraph 5 of Annex B of the SPS Agreement requires Members to publish a notice about the proposal "at an early stage, when amendments can still be introduced and comments taken into account" and to "allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account". In general practice, as the publication of the draft IRA paper is the stage of the AQIS IRA process which most closely aligns with the "proposed regulation" referenced in the Annex, AQIS notifies at this stage.[55]

5.77 However, AQIS confirmed to the Committee during Estimates hearings in May that their consultation arrangements went beyond that which was required under the SPS Agreement, that AQIS was not required to publish draft Import Risk Analyses, nor was it required to notify draft conclusions or recommendations during the risk analysis process:

> In relation to the proposition concerning publication of draft risk assessments, I think we would agree, Senator, that it is not necessary under the provisions of the SPS agreement to publish draft risk assessments, or indeed any risk assessments, although, as Mr Hickey said earlier, those risk assessments must be made available if called for under dispute settlement proceedings.[56]

---

54 Stephen Deady, DFAT, Correspondence to Senator Murphy , 27 March 2000

55 AQIS, material provided to Committee, 19 May 2000

56 AQIS, Evidence, RRAT, Estimates Hearings, 22 May 2000, p 25

> I agree that we do not have an obligation to publish anything other than the measure we intend to put in place. We do not publish our draft risk assessment, which supports that measure, as the result of a WTO obligation. We publish that draft risk assessment as a matter of government policy..[57]

5.78 AQIS asserted that broad publication was motivated by the requirement to give fellow member countries time to consider the proposed measure and to allow time for comment from them to be considered, that it was 'an appropriate way of proceeding in terms of the SPS Agreement':

> Annex B, if I may, Senator, says essentially that, where we are going to introduce a new standard or requirement in Australia, we are obliged to publish a notice at an early stage in such a manner as to enable interested members to become acquainted with the proposal and to notify other members, through the secretariat, of the products to be covered, together with a brief indication of the objective and rationale of the proposed regulation. It also says that such notification shall take place at an early stage when amendments can still be introduced and comments taken into account. It is those words in particular which cause us to take the view that the notification should take place when we are publishing a draft of our proposed measure rather than when we have completed all the processes and the government has made, through AQIS, its final decision on the matter.[58]

5.79 In response to written questions on how other countries inform fellow WTO members, AQIS advised:

> AQIS is unaware of any other country which follows a more clearly described and transparent stakeholder consultation process than the standard procedure which is followed in Australia. All issues papers, and draft and final IRA reports are readily available to domestic stakeholders and, by virtue of their being in the public domain, internationally. Other WTO Members may have less open consultation processes but all are under the same obligations of early notification and provision of relevant documents upon request.[59]

5.80 When questioned about whether AQIS had taken advice on the extent of their obligations under the SPS Agreement and the appropriate procedures to meet those obligations, AQIS advised that no legal advice had been sought 'since the IRA process is an administrative procedure which was not intended to have (and does not have) the force of law'.[60]

---

57 AQIS, Evidence, RRAT, Estimates Hearings, 22 May 2000, p 29

58 ibid, p 25

59 AQIS, material provided to Committee, 19 May 2000

60 ibid

The Accelerated IRA Process

5.81 The IRA process guidelines, as set out in the handbook, provides that, in exceptional circumstances, AQIS in consultation with stakeholders, can vary the process. The exceptional circumstances providing the basis for an accelerated process were the findings by the WTO in February 1999 that Australian quarantine regulations were not in conformity with its obligations under the SPS Agreement and that Australia was required to bring them into conformity by 6 July 1999. This timeframe necessitated the accelerated process.

5.82 AQIS issued AQPM 1999/24 on 30 March 1999, seeking submissions on the conduct of an accelerated IRA process, ie omitting the use of risk analysis panels, for non-viable salmonids and salmonid products, non-viable marine finfish products and live ornamental finfish. The Memorandum was sent to 514 stakeholders. AQIS received 15 submissions in response [3% of the total consulted], of which six supported proposed acceleration of the process, four did not oppose but offered comments and five or 1% opposed the accelerated process.[61] On this basis, AQIS proceeded with the accelerated process and the decision was published in AQPM 1999/27.

5.83 AQIS advised the Committee that its consultation process fulfilled the Government's commitment to an open and consultative approach to import risk analysis and included the following:

a) Public meetings in five capital cities;

b) Two meetings of key stakeholders in Canberra;

c) Making available each chapter of the draft reports on the AQIS Internet site.

5.84 AQIS further advised that they received 35 submissions on scientific issues on the non-viable salmonid product, non-viable marine finfish product and live ornamental finfish IRA's and a large number of representations, most of which restated the importance of maintaining the current prohibition on importation of uncooked salmon, but presented no scientific issues requiring consideration in the risk analyses.[62]

5.85 At public hearing AQIS outlined the steps taken to provide opportunity for stakeholders to have input into the process and to inform stakeholders of the current status of the IRA:

> AQIS's import risk analysis, or IRA process, is well documented. It provides for a high level of transparency and opportunity for stakeholder input at

61 AQIS, Submission 17, p 76

62 ibid, p 77

> various stages of the process. In the salmon case and associated IRAs, the process was accelerated for reasons that were set out in our policy memorandum of 23 April. Nevertheless, AQIS afforded stakeholders every possible opportunity for access to AQIS documents and input into the process.
>
> At page 76 of our submission, we have indicated the steps taken to ensure transparency, including receipt of submissions from stakeholders; a progress report on the consultation steps and scientific reviews of AQIS papers; publication of external consultancy reports relevant to the IRAs; a series of public stakeholder meetings in Hobart, Perth, Adelaide, Sydney and Melbourne; two meetings of key stakeholders in Canberra, and publication of sections of the draft risk analysis for progressive comment on AQIS's web site. In addition, AQIS arranged for input into the process by 14 independent scientists who advised on the completeness and accuracy of scientific information in the report; the balance and objectivity with which scientific information was treated; the extent to which the exercise of professional judgment in the report was supported by and consistent with relevant scientific information; and the consistency of professional judgments on scientific issues that were common to each risk analysis report.[63]

Submission Comment

5.86 A large amount of comment critical of AQIS was directed at the IRA process undertaken by AQIS and the fact that the accelerated process did not allow stakeholders sufficient opportunity either to comment or to have their comments considered. Comment in submissions and at public hearing considered the risk analysis process to be flawed, mainly for the following reasons:

a) AQIS approached the import risk analysis process as a trade issue rather than as a matter of quarantine administration;

b) The IRA process was not sufficiently consultative;

c) AQIS did not do enough to create positive and constructive relationships with stakeholders;

d) A rushed and inadequate IRA process; and

e) AQIS failed to address the WTO requirements or the SPS Agreement to which Australia is a party and therefore failed to meet its international obligations.

63 AQIS, Evidence, RRAT, 24 September 1999, p 24

Trade Considerations

5.87 Stakeholders believe that both the Commonwealth Government and AQIS gave undue emphasis in the 1999 IRA process to trade policy considerations over comprehensive quarantine assessments. This occurred, they contended, because of a number of incorrect assumptions and errors including:

> a) A failure to properly understand Australia's obligations under the WTO SPS Agreement and a subsequent failure to act to meet them; and
>
> b) A failure to appreciate the potential damage to Australia's longer term trading interests caused by a hasty response by AQIS and Australian agricultural sectors to the threatened action by Canada.[64]

The Accelerated Process and Consultation

5.88 DFAT advised the Committee that the eight months allowed Australia to respond (from the time first WTO ruling, thus effectively only four months) was based upon the precedent of previous arbitration awards. According to these precedents, a 'reasonable period' for implementing a WTO decision is defined as 'the shortest period possible within a WTO member's legal system' and that this period 'does not include the time taken for undertaking studies. Previous arbitration awards had determined that the time period for implementation by administrative decision making processes should be considerably shorter than for legislative decision making processes'.[65]

5.89 AFFA suggested that the short time allowed Australia for implementation necessitated the amendment of AQIS' normal consultation processes in order to complete the IRA process:

> Given the extensive scientific research already conducted into the risks posed by imported salmon, the advanced state of other imported fish risk analyses, the fact that the Nairn procedures followed by AQIS permitted the normal IRA process to be varied in exceptional circumstances and the very negative implications for other portfolio industries of failure to meet the 6 July 1999 deadline set by the WTO, the case for acceleration was compelling.[66]

Transparency of the Process

5.90 The requirement for an open and transparent process was a significant issue in relation to the consultation phase of the IRA. AQIS was heavily criticised for the widespread public release of documentation containing draft recommendations, prior to finalisation of stakeholder comment and full consideration of the implications of the proposals. The Committee considers that AQIS took a very broad [and generous in

---

64 Australian Fishing Tackle Association, Submission 36, pp 6-7

65 Department of Foreign Affairs and Trade, Submission 21, p 15

66 Department of Agriculture, Fisheries and Forestry, Submission 48, p 4

WTO terms] view of the requirement for an open and transparent process by circulating an early draft to all stakeholders, including members of the WTO. Industry operators in Tasmania were highly critical of AQIS' action, and advised the Committee that copies of the draft IRA were in the hands of the Canadian officials before they themselves had seen it.

5.91 In defence of the AQIS position, the Director General stated:

> In order to be able to assure people who are interested in our processes domestically and internationally that we are committed to those principles, there needs to be an adequate process of communication at various stages through what can often be a very lengthy process. Whether particular aspects of the current process may need to be changed is really a matter ultimately for the minister to decide, having regard to his general portfolio responsibilities for the administration of the Quarantine Act. To that end, we expect that the review we have foreshadowed in the handbook of the current import risk analysis process would ultimately lead to recommendations about any modifications that might be made. Certainly, I know the areas that you have been interested in—whether draft or preliminary conclusions ought to be included in a draft import risk analysis would be one of the areas—and any other comments that the committee might make in its final report would be specific issues that would need to be addressed as part of that review process. The entire process is not cast in concrete, but I would certainly stand by the existing principles that we operate under.[67]

Support for AQIS and the IRA Process

5.92 In support of AQIS, the NFF acknowledged the RRAT Committee's 1996 Report, which stated that the risk analysis process is probably one of the most controversial and misunderstood aspects of AQIS' operations. The NFF argued that public perception of risk is not objectively based, whereas 'the SPS Agreement imposes this fundamental approach to quarantine policy and practice in a more disciplined way', and that risk analysis guidelines are now being standardised such that these evaluations are probabilistic rather than intuitive, they are based on the latest scientific evidence'. [68]

5.93 Mr Brian Jeffriess, President of the Tuna Boat Owner's Association of Australia, defended the integrity of AQIS's approach to the problem and the IRA:

> While many of our members complain bitterly that it does not necessarily totally accord with the science and is done to meet the requirements of the WTO, in our view as a group, it is a rational and responsible response by AQIS to the science. If we want a scientific examination free of other influences, this is it. I cannot speak for salmonids in terms of science, but the quality of the IRA on the non-salmonids is the best we have ever seen. If

67 Evidence, RRAT, Estimates Hearings, 22 May 2000, p 24

68 National Farmers Federation, Submission 33, p 3

> you compare it with the overseas IRAs of similar nature, there is no question that this IRA on non-salmonids, in our opinion, is unsurpassed.[69]

Committee Comment

5.94 The Committee is concerned principally about AQIS' consultation procedures in general and the consultation process as undertaken by AQIS for the 1999 IRA. Recommendations on appropriate consultation procedures were made in both the Nairn report and the 1996 report of this Committee's inquiry into the Australian Quarantine Inspection Service.

5.95 Appropriate consultation is defined by Professor Nairn as follows:

> At QEAC we define consultation as having three elements: you have to have a structure where you get parties together; you actually have to listen to what they say; and, thirdly, if you do not agree with them you have to tell them why.[70]

5.96 The Committee acknowledges that the dual role of AQIS may be the source of some difficulty. The Pork Council of Australia highlighted the dilemma currently being experienced by AQIS, when it stated:

> The pork industry experience is that the relationship between industry and AQIS is improving. However, there is still a difference in dealing with the export area of AQIS compared with the quarantine area. In the export area, the relationship is closer to one of 'team Australia'. In the case of quarantine, the relationship can be one of 'us and them'. From an industry perspective, it is important for quarantine and export matters to be dealt with in a 'team Australia' way. Obviously, this requires a professional and genuine approach by both industry and AQIS in dealing with quarantine decisions.[71]

5.97 The Committee considers that consultation requires more than mere provision of information - it is a participative process. One of the major criticisms of AQIS was the lack of adequate consultation. The Committee notes that AQIS was diligent in its provision of information, but that its actual consultative actions were open to criticism.

5.98 Consultation does not, however, mean the broad publication of draft documentation. The publication of draft documents was extremely damaging to Australia's interests.

5.99 The Committee notes the review of the import risk analysis procedures and handbook, foreshadowed in the Portfolio Budget Statements. That review is due to

---

69 Evidence, RRAT, 11 November 1999, p 278

70 Evidence, RRAT, 23 May 2000, p 3

71 Pork Council of Australia, Submission 52, p 2

conclude in approximately September of this year. The Committee commends AQIS' initiative in commencing the review and expects that some significant changes will be made to AQIS IRA procedures, given the experience of the last several years.