IMPORT HEALTH RISK ANALYSIS: SALMONIDS FOR HUMAN CONSUMPTION

DECISION AND REVIEW OF SUBMISSIONS

ANIMAL HEALTH AND WELFARE

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1 EXECUTIVE SUMMARY

A transparent risk analysis process scientifically examining the aquatic animal health risks to New Zealand associated with importation of salmonids for human consumption has been completed. MAF Regulatory Authority (MAF Reg) concludes that importations of salmonids for human consumption under specified conditions present low disease risks to New Zealand aquatic animals.

Risk management measures discussed in the risk analysis provide an appropriate level of protection from these disease risks without requiring such imports to be subject to heat treatments. These measures are detailed within the *Import health standard for importation into New Zealand of salmonids for human consumption from specified countries (SHC)* which appears as Appendix 1. This document has been issued as an import health standard pursuant to the Biosecurity Act 1993 Section 22 by the Chief Veterinary Officer, acting under authority delegated by the Director General of MAF.

Context

The context of the risk analysis process includes:

- The Biosecurity Act 1993; in particular Section 22, which, in the current context, requires MAF to consult stakeholders on a risk analysis document examining the likelihood that risk goods will introduce organisms into New Zealand, and the nature and possible effects on people, the New Zealand environment and the New Zealand economy of any organisms which may be introduced;

- The World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS agreement); which, amongst other things, requires New Zealand to implement the least trade restrictive measures to provide an appropriate level of protection from zoosanitary risks during importation of animal products, and to provide scientific justification of those measures when they differ from the recommendations of the Office International des Epizooties (OIE);

- The OIE International Aquatic Animal Health Code; which contains the OIE's recommendations for sanitary measures during trade in aquatic animal products;

- A 1994 risk analysis performed by MAF Reg which examined the disease risks associated with importation of wild ocean-caught Pacific salmon for human consumption from Canada.

Import health risk analysis: salmonids for human consumption

In September 1997 MAF Reg released the document *Import health risk analysis: salmonids for human consumption* for a period of public consultation. The risk analysis described the aquatic animal health risks to New Zealand posed by importation of headed, gilled and gutted salmonid products for human consumption. Conclusions were reached regarding the

likelihood of disease introduction, the potential consequences of disease introduction, and the possible risk management measures which could be implemented. The conclusions can be summarised as follows:

1 Potentially severe adverse consequences to the valuable salmonid fisheries of New Zealand would result from the introduction of an exotic disease. Once introduced, eradication would probably not be successful.

2. The probability of an exotic disease being introduced through the importation of salmonids for human consumption is low. In order to illustrate the magnitude of the probability, the risk of introducing *Aeromonas salmonicida* (an organism many experts agree is the agent most likely to be introduced on such a commodity) was estimated with 95% confidence to be less than 10^{-7} per tonne imported.

3. The annual volume of product which would be imported if market access was granted was estimated to be 100-500 tonnes.

4. Considering the very low probability associated with disease introduction, continuing the ban on imports of uncooked salmonid products would not be justified.

5. Considering the potentially severe consequences associated with disease introduction, measures over and above the OIE recommendation of evisceration (gutting) are justified.

6. The risk management measures which are considered to provide an appropriate level of protection from risk include:
   - restriction of imports to specific source countries with appropriate regulation of fish production and processing industries by competent authorities, as assessed by MAF Reg;
   - certification of imports according to the model zoosanitary certification requirements of the import health standard, as negotiated between an exporting country's competent authority and MAF Reg;
   - no post-arrival restrictions on product imported into New Zealand in a form allowing direct distribution to consumers;
   - post-arrival quarantine restrictions on product imported into New Zealand in bulk form which require re-packaging and processing prior to distribution to consumers.

Expert review

Prior to public release, MAF Reg contracted nine fish health experts to review a draft of the risk analysis and provide technical criticism. The reviews by the experts were generally supportive of the risk analysis methods and conclusions. Their comments and suggestions regarding technical information presented were incorporated into the version of the risk analysis released for public consultation.

Public consultation

Between September 1997 and February 1998 MAF Reg distributed approximately 100 copies of the risk analysis. The original deadline for submissions was 30 November 1997. This deadline was extended to 13 February 1998 to allow the stakeholders of the salmonid fisheries in New Zealand to complete submissions. By the deadline MAF Reg had received 18 submissions, including submissions representing the major stakeholders of the salmonid fisheries of New Zealand as identified by the risk analysis.

MAF Reg contracted a fish health expert, Dr Alasdair H McVicar (Fisheries Research Services Marine Laboratory, Aberdeen, Scotland), to undertake a review of submissions. Dr McVicar's conclusions included that the overall validity of the risk analysis is not significantly affected by any of the points raised in the submissions. Dr McVicar's full review is included in this report as Section 3.

Within Section 4 MAF Reg identifies and responds to points noted within the independent review of submissions as requiring further consideration. MAF Reg has replied to each individual submission with a letter addressing the concerns which were raised in the submission.

2 DECISION ALLOWING IMPORTATION OF SALMONIDS FOR HUMAN CONSUMPTION

2.1 Decision

Risk management measures which MAF considers achieve New Zealand's appropriate level of protection against risk are detailed within the *Import health standard for the importation of salmonids for human consumption into New Zealand from specified countries (SHC)* at Appendix 1. This document has been issued as an import health standard pursuant to the Biosecurity Act 1993 Section 22 by the Chief Veterinary Officer, acting under authority delegated by the Director General of MAF.

2.2 Explanation of the trade conditions

As a result of the risk analysis process MAF concludes that importations of salmonids for human consumption present low disease risks to New Zealand aquatic animals. Risk management measures discussed in the risk analysis provide an appropriate level of protection from these disease risks without requiring such imports to be subject to heat treatments. Further information regarding the application of these measures within the import health standard follows.

2.2.1 Specified countries (SHC)

The term *specified countries (SHC)* used in the import health standard refers to the countries approved for importation of salmonids for human consumption. SHC is a unique code required by the Plant and Animal Quarantine Information System (PAQIS).

The countries listed at import health standard clause 6.1 are those assessed to date by MAF Reg as having salmonid production and processing industries which are regulated by competent authorities, such that risks will be managed to a level equivalent to that considered in the risk analysis. If there is demand for other countries to be assessed, MAF Reg will perform this assessment and it will be subject to further public consultation.

Export certification which meets the requirements of the model zoosanitary certification within the import health standard at section 12 will be agreed through bilateral negotiation between MAF Reg and the competent authority of the exporting country prior to commercial consignments being able to be imported.

2.2.2 Commercial consignments

A commercial consignment is defined as any consignment comprising product intended for distribution or sale in New Zealand.

All commercial consignments of imported product will be required to be accompanied by export certification issued by a competent government authority of the exporting country. The export certification will be approved by MAF through bilateral negotiation. The

requirements of the export certification are noted in a model zoosanitary certificate within the import health standard. The import health standard will be updated to include approved export certification as determined through bilateral negotiation with exporting countries.

The risk analysis has noted the potential for some forms of imported product to require re-packaging or re-processing in New Zealand prior to distribution or sale. This creates the potential for accumulation of packaging or scraps. The risk analysis has identified that any such accumulation may increase the risk of an infectious concentration of pathogen occurring in New Zealand as a result of importations. As such, MAF will require re-packaging or re-processing of imported product to be undertaken within premises operating a MAF- approved waste management plan.

As a result of these differing levels of post-arrival risk management, MAF will define two forms of imported product:

bulk form
This means product which is intended to be further processed and/or packaged in New Zealand prior to retail sale or use in the institutional trade. e.g. containers of more than one fish.

commercially packaged for direct retail sale
This means product not requiring further packaging and/or processing prior to retail sale or use in the institutional trade in New Zealand. e.g. retort pouch packaged single fish, hermetically sealed packages of fish portions.

Product which is commercially packaged for direct retail sale may enter New Zealand without post-import restriction. As such, there is no requirement for pre-import permits.

Product in bulk form must proceed from the border to MAF registered transitional facilities where re-packaging and/or re-processing will occur under MAF supervision. Waste from processing facilities, including packaging, scraps and waste water, must be disposed of according to MAF-approved methods. To ensure that appropriate facilities are registered and available to manage the post-arrival requirements, MAF will require importers to obtain a permit to import prior to importation. Issue of the permit to import will require the importer to demonstrate that appropriate post-arrival transitional facilities are available.

2.2.3 Private consignments

The importation of private consignments of salmonid products by airline passengers and through international mail has been identified by MAF as a special case. Such imports clearly constitute risks of a similar nature to those considered in the risk analysis. To date, MAF has treated all such importations in the same way as importations of commercial consignments, which has resulted in seizures of goods carried by airline passengers and intended for personal use in New Zealand. MAF considers that this practise is no longer justified, and that importation of private consignments should be allowed so long as the risks are managed to achieve New Zealand's appropriate level of protection.

The newly instituted risk management measures for commercial consignments are inappropriate for private consignments. In particular, export certification of private consignments by competent government authorities is not practical. However, the same post-arrival exposure pathways considered in the risk analysis act to reduce the likelihood of significant quantities of imported product contacting fish in New Zealand. MAF considers that if the volume of any single private consignment is restricted, and the form of the product and its packaging allow for MAF inspectors to conduct a visual inspection to ensure the product is lesion-free, New Zealand's appropriate level of protection against risk is achieved to a comparable degree as through the measures proposed for commercial consignments.

The import health standard defines private consignments as any consignment comprising product imported in an airline passenger's personal effects or by mail and not intended for sale in New Zealand. The maximum amount of product able to be imported as a private consignment is no more than 10 kg net weight. Private consignments must comprise headed, gilled and gutted fish in a skinless form, and must be packaged in a manner which allows visual inspection e.g. fish fillets in clear plastic retort pouch packaging. These measures will facilitate visual inspection of private consignments at the New Zealand border prior to biosecurity clearance being given.

3 COMMENTS ON PUBLIC SUBMISSIONS TO THE NEW ZEALAND IMPORT RISK ANALYSIS: SALMONIDS FOR HUMAN CONSUMPTION.

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A. Commission and Statement.

This review was undertaken in response to an invitation in March 1998 from M Stone, National Advisor, International Animal Trade, Ministry of Agriculture, Wellington, New Zealand. The following comments are the personal view of an independent reviewer, and do not necessarily represent the views or official position of the FRS Marine Laboratory or SOAEFD.

B. Comments on individual public submissions to the "Import health risk analysis: salmonids for human consumption".

1. Submission by P M Hine

P Hine uses his depth of knowledge of fish infections to indicate areas where he believes there are some inaccuracies in the RA, or that information is incomplete. These criticisms of aspects of the science are sound. Hine agrees with the overall conclusions of the RA and that the errors he found were not significant to these. In such a comprehensive document in a field where research is actively proceeding, it is inevitable that a review will be rapidly overtaken by new information. In addition, there are unresolved uncertainties in some aspects of the detail of the biology and taxonomy of different infective agents, with different experts favouring different opinions in their publications. Hine has undoubtably focussed on Myxosporean parasites reflecting his own particular area of expertise, and has given less attention to bacterial and viral pathogens, disease agents which probably pose greater risk. With *Aeromonas salmonicida* in UK, his comments reveal a lack of awareness of the true situation, as the research was undertaken as a parliamentary response to a new and serious epidemic being observed in wild salmonid populations, after the introduction of the disease.

Hine commented on Section 2 of the RA on the need for transparency in NZ policy and on the fact that removal of risk is impossible, unless trade is stopped. These comments are worthy of further consideration, as both aspects are enshrined in international agreements.

As suggested, there is little point in attempting to provide a full list of all known infections in the commodity (eg metazoans), as this is likely to be both incomplete, will rapidly become out of date and largely reflect past and current research effort. Many can be dismissed as of insignificant risk because of the nature of their biology, and their inclusion in the RA detracts focus from groups of pathogens where risk is greater. It is largely a political/policy decision, particularly in relation to trade agreements, how far the precautionary approach should be taken regarding risks from (a) as yet undiscovered diseases (and there are likely to be many in fish), (b) newly emerging diseases where there is yet insufficient information available on

their pathogenicity to provide a quantitative or even adequate qualitative assessment and © on diseases where the risk of transfer across species barriers is poorly researched. Several of the comments on pp 2,3 of Hine's submission refer to difficulties in these areas and highlight a need for further consideration of this general area in the RA.

2. Submission by T Warren.

Processing interests as represented by Warren naturally seek competition on existing sources of product to prevent anti-competitive strategies, but at the same time T Warren indicates that neither of the two dominant salmon farms is profitable. Consequently, is a likely consequence of importation the possible demise of the indigenous industry? Although anticompetitive matters and the impact on the sustainability of an indigenous industry may be involved in initiating an RA , such commercial consideration should not be a significant factor within the content of the biological aspects of the RA.

3. Submission by N Murray.

The comments made by N Murray are particularly pertinent and these sections he refers to in the RA are worthy of some reconsideration. In particular, as he suggested, the risk of legal challenge on the grounds of trade barriers could be reduced if, on disease grounds, more adequate justification is given for measures which exceed internationally recognised standards. There is a clear need to identify these diseases which the additional measures are designed to accommodate and to show good understanding how the measures will actually contribute to reduce the risk. If it is accepted that zero risk is not an option, there is a potential conflict with a full precautionary approach.

The practical problems of identifying and assessing risk from a particular disease, and the management of that risk, is highlighted by Murray. He suggests risk identification and risk management factors need to be more clearly differentiate in the RA. He proposed a logical methodology to address this area, although this still requires some further development. He also raises the question on how appropriate international (OIE) recommendations actually are and justifiably challenges the assumption being made that the current practices of importing headed, gilled and eviscerated carcasses will always continue. As qualitative risk assessment relies heavily on previous experiences of the consequences of particular commodity import practices, valuable information can be derived from current practices. However, this should not preclude an intent for steady progress towards a full quantitative risk assessment for diseases of concern.

Murray also raised the question about the justification for requiring a documented health surveillance programme and largely answered his own question. The concept of such surveillance programmes for specified fish diseases in both the exporting and importing areas is central to most international (and national) disease control legislation when the risk of transfer of infection is particularly high as with live fish and eggs. Justification to restrict free trade into an area is based on the demonstrated absence of a disease from that area and the continued absence demonstrated by a regular monitoring programme. Minimum recognised standards of sampling level, sampling frequency and diagnostic methodology are in place for the most important diseases. When the level of risk decreases with other types of commodity, the need to demonstrate absence of a disease in an exporting area

correspondingly decreases. Then management of the risk, for example by evisceration/removal of heavily infected tissue, becomes increasingly relevant. As the absence of surveillance does not equate to absence of a disease, the need to demonstrate continued absence of the disease in the importing area is required to justify restrictions. This concept links closely with exotic/endemic filters proposed by Murray and the practical assessment scheme he advocates. Although many of the questions he raises may not be readily answerable because of current lack of suitable data, the use of such a scheme could provide a good basis for development towards a more quantitatively based risk assessment (which should be an objective built in to any qualitative risk assessment).

4. Submission by M Yoshimizu, Hokkaido University, Japan.

Imitation is the sincerest form of flattery and M Yoshimizu's comments on the usefulness of the RA to the development of a salmon import risk analysis by the Japanese Fisheries Agency is an accolade and a good indication of the quality of the analysis. No comments on the content of the RA were made by M Yoshimizu.

5. Submission by C Michel, INRA, France.

C Michel makes several editorial and technical suggestions which are scientifically justified but which do not alter the conclusions of the RA. No criticism is made of the content.

6,7. Submissions by P Durham and by D Banks, AQIS, Canberra.

These should be considered together.

A need for an adequate documented and ongoing programmes on the causation of any substantial disease episode in the exporting country of concern to the importing country and the absence of health monitoring in NZ fish was noted by P Durham. In my view, there are three points inherent in this requirement which would need clarification:

- The imposition on exporters of disease testing requirements which are greater than these currently present in NZ could be difficult to justify.
- Aspects of the precautionary approach are being invoked where unknown/potential diseases could become justification to prevent imports. It should be clarified how this requirement fits with current OIE policy. OIE lists are recognised as the known diseases of international significance and countries are required to inform OIE of new episodes and new diseases of significance. Ideally, all countries involved in trade would have programmes in place to enable early warnings to be passed to OIE, but this may be considered to be unrealistic. It is not always possible to predict the emergence of new diseases (eg ISA in Canada, EUS in Asia) and only by banning trade could nil risk from similar episodes be achieved.
- Where disease surveillance programmes are not in place, it is logical for risk analysis to start with the assumption that the specified disease may be present ("suspected but not confirmed" in OIE terms). Even for listed diseases, ongoing disease surveillance programmes by an exporting country are not always required in some international regulations eg EU. Such requirements are usually put into place where a commodity carries a particularly high risk from a specified disease and there is limited opportunity to manage that risk to acceptably low levels. For example, the lack of surveillance for the parasite *Gyrodactylus salaris* in many European countries does

> not prevent the import to approved disease free areas, of carcasses on which risk of survival of the parasite is low, or of live eggs where the parasite can be killed by surface disinfection. These measures are considered to be sufficiently secure for the occurrence and level of disease in the commodity source to be of little significance. However, for live susceptible hosts, where the risk is particularly high, trade is only permitted from these areas where there is an agreed surveillance programme in place demonstrating the continued absence of the parasite.

In a similar vein, Durham also highlighted the stated need in the RA for more intensive disease monitoring of sea caged salmon as a consequence of their contact of wild fish and the difficulties in disease monitoring of these. From these comments, it is not apparent if he considers there should be a desire in the RA for certification of fish stocks as being disease free to reduce risk at source or for risk from specified disease to be managed. The former would fit with his suggestion of zones. It is normally recognised that either a prolonged period of intensive testing is required to achieve zone/area disease-free status or that the water supply and farm stocks are protected from outside disease contacts (whether in fresh water or the sea). Also linked to this is Durham's comments on the quantitative RA's calculated potential for a disease introduction where the difference between unachievable nil risk and managed risk could possibly have been better explained to avoid misinterpretation.

The discussion by Durham and Banks of serotype and strain differences in virulence of bacteria raises the question how robust is the use of such variations in RA. Most disease regulations are based on the diagnosis of species of infective agents and do not use strain variability as important criteria.

D Banks raised concerns regarding a lack of adequate definition of the terms used in allocating the levels of risk attributed to particular diseases and suggested a better frame of reference should be included in the RA. There are considerable difficulties in accurately specifying risk levels, particularly when using qualitative risk assessment. It may be considered preferable to leave these terms only broadly defined and to address refinements on an individual basis during practical situations as these will always be open to challenge and controversy. His disagreement with the level of risk assigned in the RA to particular diseases (EIBS, *Aeromonas salmonicida*) probably largely reflects this difficulty and the need to use best judgement practices based on current information.

The need to take into account changes in various aspects associated with the commodity which could affect calculation of risk was also stressed by Banks. Similar comments in other submissions indicate the need to have a regular programme of re-assessment of the validity of the RA.

Both Durham and Banks make several technical suggestions which would improve the accuracy and completeness of the RA.

8. Submission by J S Lumsden.

Attention is drawn by J Lumsden to the most recent information that HKS has the same aetiology as ISA although there are major differences in the pathology of the disease from its "typical" appearance in Norway. As there are no close associations between the Norwegian

and eastern Canadian salmon farming industries, the current assumption is that there is a natural source of the disease in both areas and that unknown factors have led to the emergence of the disease. This, and the upsurge in other disease conditions such as the Nodaviruses in Mediterranean fish, halibut and salmon when these were unknown until recently, serves to remind us that there are probably many as yet undiscovered disease agents in the aquatic environments. It is to be expected that a document such as the RA, will rapidly become out of date in a scientific field where research is active and its accuracy should only be judged in respect to information available at the time of writing. The wider issue arising from this observation is that the RA needs to be subject to frequent revision to incorporate new findings as they occur. For example, OIE usually revise their fish health documentation on an annual basis.

9. Submission by K Hayes CSIRO, Australia.

Complimentary comments were made by K Haynes on the quality of the RA and the only question raised was in relation to the possibility of the occurrence of unplanned events associated with the importation of the commodity which could significantly affect the level of risk. Risk management practices and contingencies are normally designed to deal with such events and worst case scenarios should take this area on board. Possibly, the relevant parts of the RA could be reconsidered in relation to these comments.

10. Submission by K H Amos, Department of Fish and Wildlife, Washington.

K Amos agrees with the RA conclusion that the risk from importation of wild Pacific salmon is not different from the USA and Canada. His comparison of the disease monitoring programmes for USA and Canada to support equal treatment of products from the two countries should be considered in relation to:

. whether or not such programmes are an essential component of risk analysis when meaningful management of risk during processing and transportation is possible.

. whether it is believed that the level of a specified disease in the source of the commodity can not be dealt with through risk management procedures and it is therefore the levels of disease in the source of the commodity which are of critical significance to the importer.

It has not been fully discussed in the RA, or by Amos, if the level of diseases important to NZ is the same in both Canadian and USA populations of salmon and that the handling, processing and shipment methods in both countries which could affect risk are the same.

There is considerable logic in the suggestion by Amos that aquaculture products could be considered for import on the basis of there normally being better knowledge of which diseases are present. Alternatively, as indicated in other submissions, it is generally accepted that the level of any diseases which may be present in aquaculture is likely to be higher than in wild fish. Also, it is in only a few exceptional cases that epizootics of acute disease have been detected in wild marine fish populations (as sick animals are usually removed by predation) but as most aquacultural operations use open waters, they are likely to share diseases with local wild fish populations and so reflect the health status of the local area. The RA may wish to take this aspect into consideration.

Many of Amos' comments were directed at IPNV, IHNV and VHSV. However, there is

controversy surrounding the relationship of some of these fish viruses to isolations of the same group of viruses from other local populations of marine organisms. There is a lack of basic knowledge of their identity and on their epidemiology and it is possible that at least some of these strains could represent different species. This has not been proven and they tend to be considered to be strains of the same species, treated the same by legislation (certainly in Europe). As a consequence, a quantitative risk analysis on these diseases, as suggested by Amos, would not be so robust as that which was undertaken in the RA with *Aeromonas salmonicida*, an organism which has probably been better studied than any other fish pathogen.

Amos' comments on the uncertainties surrounding Whirling Disease and its "spread" reflect most current thinking on this disease. It is not a good case on which to base trade restrictions and the authors may wish to reconsider the relevant section of RA.

Amos' comment that the recorded presence or absence of a disease in an area may be directly linked to the local research effort and diagnostic capability The requirement in the RA for a disease surveillance programme by the exporting area should be considered in relation to this statement.

11. Submission by G Meyer, US Agricultural Attache, Wellington.
Brief supportive comments of the RA of a political nature were made by G Meyer.

12. Submission by B Stillman, Office of US Trade Representative, Wellington.
The comments by Meyer were copied without comment.

13. Submission by I Price, DFO, Ottawa.
Price noted that it was not possible to provide a full evaluation of the RA, but supported the conclusion that dead, eviscerated salmonids represent a negligible or minimal risk of introducing infectious fish pathogens into the importing country.

14. Submission by N Boustead, NZSFA, Christchurch.
On behalf of the NZ salmon farmers, N Boustead noted that although the RA is factual in terms of the industry and disease aspects, with only minor changes suggested, he suggested that the interpretation of disease details was more subjective and open to question. The conclusions reached in the submission are generally straightforward and to a large extent already form an integrated component of the RA: absence of many diseases from NZ; risk of some pathogens still being present in the imported commodity; limitations in scientific knowledge of many pathogens; the unlikely opportunity to eliminate any diseases introduced; possible serious consequences on NZ wild and farmed fish ; possible impact on trade. The desire for zero risk is an underlying theme in the comments by Boustead, but this is recognised by RA generally not to be an achievable option.

The use of subjective assessments in the quantitative risk analysis is criticised by Boustead and it could be to the benefit of the RA that where tested numerical data are available, this is more clearly indicated. It is my understanding that it should be a stated objective of all risk assessments that there should be a move towards increasing use of quantified data. The

implication is that, particularly in the earlier stages of development, there will be intermediate types of RA. It would appear that this is the situation with the current RA.

The reference Boustead makes to piscirickettsiosis as an example of possible spread of disease with imported product into Norway and Ireland from Chile is not tenable. This must be related to the likelihood and volume of the importation of the Chilean product into these countries (zero or close to that). Current views are that there are as yet unidentified natural sources of the infection in these areas.

The statement by Boustead in paragraph 2.1 that farmed fish products will pose a greater risk than wild because of higher disease occurrence in the former is not necessarily true. While the level of individual diseases may be higher, the range of disease present is likely to be more restricted because of many factors such as diet, limited range distribution etc. It is necessary to specify the disease(s) posing the risk. Also, as indicated in the same paragraph, detection of disease in wild stocks (not only in the import area but also in the exporting areas!) is often inadequate.

The omission of Whirling Disease from detailed consideration in the RA is noted by Boustead, but in view of the current uncertainty surrounding this disease (see submission by Amos) this decision can be justified.

The implication in paras 2.7, 2.9, 2.10 of Boustead's submission is that all knowledge of specified diseases should be complete or that all possible disease conditions in the exporting area known before imports are permitted. This is unrealistic and could only be achieved by banning all imports. As recognised in the submission, new diseases continue to be found and gaps in knowledge become filled as research effort continues. However, as Boustead indicated in para 2.11, the function of the RA is to identify areas where unacceptably high risk occurs both in terms of disease types and localities and to build in appropriate safeguards.

The specific comments made by Boustead on parts of the RA text (section 3 of the submission) are generally factually sound, but do not alter the conclusions reached with respect to any disease. The need for the RA to have provision for change with the advent of new information was stressed with reference to P 104. It is surprising that Boustead listed *Ichthyophonus hoferi* as being absent from Europe in Table 1, as he worked on this disease while in Europe.

15. Submission by S Cotsilinis, NZ Federation of Freshwater Anglers, Wellington.

S Cotsilinis advocated that the RA should take more account of the effects of an introduced disease on the people, environment and economy of NZ. Additional figures on expenditure for recreational fisheries were provided. The complaint that the RA did not consider that uncooked flesh was the origin of farmed disease outbreaks in USA (WD?) and Norway (*Gyrodactylus salaris?*) is not supported by current scientific evidence.

16, 17. Submissions by M Britton, Fish and Game New Zealand, Wellington and G Pyatt, Taupo Fishery Advisory Committee, Turangi.

These submissions are similar in content. They should be considered together.

M Britton did not comment on the technical aspects of the RA but focussed on his organisation's conviction that the balance between risk and benefit from imports of untreated salmonid products was strongly weighted on the risk side, that generic consideration of risk was inappropriate with analyses needing to be performed on a case by case basis and that the sale of trout within New Zealand would have significant political implications regarding possible sales of local wild trout. This submission also indicated significant values for fisheries which could be affected by introduction of disease problems.

Britton's suggestion that there are sufficient differences in components of risk under different circumstances to warrant individual consideration does not take sufficient account of the inherent flexibility in the RA to separately investigate specified diseases/episodes of concern. As discussed with reference to other submissions, the examples of WD and *Gyrodactylus salaris* (GS) used by Britton as evidence of spread of disease with uncooked salmonid products does not have a scientific basis. The problems with WD was discussed by Amos and the risk from GS with carcasses is considered to be sufficiently low for no restrictions to be placed on their movement within the EU, despite the short distances of travel between infected and disease free zones.

The difficulty of unknowns in current knowledge of fish disease was raised by both Britton and Pyatt and although risk management aspects in the RA are designed to address such issues, it is largely a matter of policy under international regulations, rather than science, how these are dealt with.

18. Submission by Cameron, Department of Conservation, Wellington.
This is one of the most comprehensive assessments of the RA and deserves particular attention.

The Department of Conservation submission opposes relaxation of restrictions on the grounds of the uncertainties of the risk of disease in relation to the value of native stocks and recreational fisheries. Opposition is also expressed to the importation of wild Pacific salmon from the USA as it is their contention that sufficient similarity between that commodity to the disease status of wild Canadian salmon has not been established by the RA. Concern is also expressed by Cameron on the risks any trade in trout products may have on illegal trade of native stocks. He advocates a case by case consideration of risks associated with different commodities.

Cameron suggests that the risk from disease introductions outweighs benefits with the current methods which are available to reduce risk. This challenges the core statement of the RA and was extensively discussed in the document before reaching the conclusions made. Cameron does not raise any significant new points in his submission and essentially does not accept that the level of risk considered acceptable by the RA can be justified. As discussed in the RA, major disease problems can occur when new diseases are introduced (as with the Norwegian experience with *G salaris* cited by Cameron) but other countries have taken on board these risks and have introduced appropriate controls to reduce these risks to levels

acceptable to them. It is accepted by the RA that there are many unknowns in the field of fish disease and although scientific progress is being steadily made, there are likely always to be areas where more information will be desirable. The point where the perceived level of risk which may be considered to be acceptable is a matter for political debate within NZ. The consideration of specific difficulties presented individually by Cameron for different diseases is not reconsidered here , but instead the points of general concern are evaluated.

The submission by Cameron raises several scientific points where it is unlikely that finite quantitative answers will be readily achievable. Infective doses of agents (even these which have been extensively studied) are unlikely to be fully quantifiable for various biological reasons; hence the emphasis of the RA on qualitative assessment of this parameter where past experiences are taken into account. A similar approach has to be taken with susceptibility of different fish species to disease, as conclusive answers are unlikely to be obtained to take account of all species and all eventualities of environment and disease. However, this should not preclude attempts to progressively gain information on the areas perceived to be highest risk or on the most important fish species and diseases.

Cameron's point about an over-reliance on chlorinated water supplies to reduce risk should be taken into account in the RA as it is likely that some pathogens will survive such treatments. Experiences with quarantine facilities indicate that more aggressive disinfection methods are required to remove infection, especially when particulate material is present. The policing of controls on disposal of waste in processing units as outlined in the Appendix of the RA is clearly critical in this area.

The argument by Cameron that a natural local risk or occurrence of disease should not preclude restrictions because of that disease, has some justification. Some international and national legislation takes into account impact reduction at the local area/farm level, when a disease is already present in a zone. However, this type of regulation does take a secondary role to prevention.

In general terms, it is recognised that disease levels in farmed fish populations tend to be higher than in wild populations and this should be taken into account in the RA with reference to specific diseases of concern to NZ. Counter to Cameron's argument that there is an increased risk from disease from farmed populations due to the possibility of dumping of sick fish, is (a) the increased awareness of the disease situation in farmed fish, (b) the close link between types of diseases in farmed and local wild fish, and (c) the need to maintain high quality product to markets, particularly when the product has a high value. Cameron's criticism of the generic approach to qualitative assessment in the RA should be considered against the many common approaches which can be taken to dealing with a wide range of infective fish diseases. However, some agents of particular concern may warrant special attention to deal with risk. For example *Gyrodactylus salaris* risk is not significantly affected by evisceration whereas the risks from many disease such as ISA and VHS clearly are. Cameron does not suggest what practical difficulties could be associated with RA on a case by case basis for all diseases and products.

C. Summary of the main points in the submissions and impact on the validity of the RA.

1. The overall validity of the RA is not significantly affected by any of the points made in the submissions.

2. There are some technical omissions and errors, but these are generally of a minor nature. These usually reflect recent developments in the science of the topic since the RA was drafted or differences of opinion between scientists in the interpretation of the available information.

3. A recurring point through several submissions is the desire to seek zero risk, or at least a level of risk which would be considerably less than that suggested in the RA. As indicated, it is a policy or political matter how a level of risk which can be considered to be acceptable is determined, with transparency being essential. It was not always appreciated that:

. because a disease has not been recorded in New Zealand this, by itself, was not justification for trade restrictions and
. that the function of the RA was to identify and assess significant areas of risk and to indicate how these could be managed.

The wish to have levels of risk more clearly defined was expressed, but this could conflict with the equally strong desire for flexibility in the RA and to have risk assessed on a case by case basis.

4. The use of subjective assessments in the quantitative RA was questioned, suggesting the need for clarification in the document that increasing use of quantified data is a central objective of an RA. It is obviously not clear to some of the authors of submissions that the incompleteness of information on aspects of disease can be accommodated by qualitative risk assessment. This could be addressed more clearly in the RA.

5. The requirement of the New Zealand RA to go beyond internationally recognised standards was questioned, particularly the need for a documented health surveillance programme in the exporting country when this may not be present to the same level in New Zealand.

6. Several submissions emphasised the considerable evidence which exists for strain differences in the pathogenicity of different fish diseases, suggesting this was a basis for restrictions. This does not fit comfortably with various international fish disease control regulations.

7. Equating Canadian and USA commodity was questioned because of the lack of information presented. The visits by New Zealand experts to these countries could have been more fully reported in the RA.

8. There was a need stated for clearer distinction to be made in the RA between risk identification and risk management. In view of the separate discussion of these topics in sections 4 and 5 of the RA this would not appear to be justified.

9. Several submissions considered that inadequate account had been taken of the level of risk

in relation to the value of interests in New Zealand which could be impacted by disease.

10. The need to have capacity in the RA to change as new information becomes available was stressed by several submissions.

4. MAF RESPONSE TO ISSUES HIGHLIGHTED IN THE INDEPENDENT REVIEW OF SUBMISSIONS

An independent review of submissions examined each submission and identified the points the reviewer considered to be most important. Some of these issues were noted to have been fully discussed within the risk analysis or to be without scientific basis, and thus do not need further consideration.

The review identified certain issues that need further consideration by MAF. These issues are discussed below in the order in which they were raised by the independent reviewer. No priority is implied by the order or heading used.

4.1. New Zealand importation policy

The independent reviewer suggested that further clarification should be given regarding New Zealand's importation policy and that some consideration should be given to why zero risk is not possible.

The New Zealand economy is heavily reliant on international trade, and the New Zealand government is committed to free and fair international trade and to maintaining an open, internationally competitive economy. The government supports the development of rules-based trade through agreements under the World Trade Organisation, and is moving rapidly to eliminate tariffs and other restrictions on trade.

One principle of rules-based trading is that health-protection measures should be only applied when necessary, and not as a disguised restriction on trade. One of the WTO agreements, the SPS agreement, establishes principles which WTO members are committed to uphold when they work to protect health while trading in plants, animals and their products. Under the article 5.1 of the SPS agreement, countries are obliged to ensure that their sanitary measures are based on a scientific assessment of risk, taking into account the risk assessment techniques developed by the relevant international organisations. For trade in aquatic animals and aquatic animal products, the guidelines for risk analysis are presented in section 1.4 of the *International aquatic animal health code* of the OIE.

The Biosecurity Act 1993 provides New Zealand's legislative framework for development of import health policy. Section 22 (5) requires chief technical officers to have regard for the likelihood that imported goods will introduce organisms into New Zealand, and the nature and possible effect on people, the environment and the economy of any such organisms introduced. Section 22 (6) requires MAF to consult with persons considered to be representative of the classes of persons having an interest in the issue examined when it develops or reviews import health standards.

MAF considers that the risk analysis process examining measures to be applied during importation of salmonids for human consumption has met New Zealand's international obligations and national legislative requirements. The recommendations within the risk analysis are considered by MAF to achieve New Zealand's appropriate level of protection

against the risk of introducing aquatic animal diseases during importation of salmonids for human consumption.

4.2. New scientific information

The independent review of submissions identified that it is a political decision as to how far a precautionary approach is taken concerning incomplete information and as yet undiscovered diseases, and highlights a need for further consideration of this general area. The independent review of submissions indicated that it was necessary to have a regular programme of re-assessment of the validity of the risk analysis as new information comes to light.

MAF conducted this risk analysis using the best available scientific information. The policy of MAF is that as significant new scientific information comes to hand it will be assessed, and the risk analysis and import health standards reviewed accordingly.

An example of this process is provided at 4.5 below, which summarises MAF's assessment of the new information relating to infectious salmon anaemia which came to hand following public consultation of the risk analysis.

MAF acknowledges that there is incomplete information on many diseases of fish, but no gaps in knowledge that are critical were identified in the risk analysis.

Quantitative risk analysis techniques are internationally recognised as having the ability to deal with uncertainty. By applying distributions to probabilities, a quantitative risk analysis can model the uncertainty and allow decisions to be made on the basis of most likely outcomes. Where there is uncertainty or missing information, the distribution applied to a probability can reflect for example the range of experimental results that have been reported in the international literature or the range of opinion of recognised experts in the particular field in question. Both of these approaches were used in the Monte Carlo model for *Aeromonas salmonicida*.

4.3. Risk management measures

The independent review of submissions noted that it is important that the risk analysis clearly identifies the risk management measures, particularly when these are over and above international standards, and notes the basis for these measures.

(a) species of fish

The species of fish considered in the risk analysis are noted on page 16 as species within the genera *Oncorhynchus, Salmo* and *Salvelinus.* The original market access request from the USA was for wild Pacific salmon, which includes certain species within the genus *Oncorhynchus*. The range of species considered was expanded to account for species of fish which present risks of a similar nature and magnitude to those presented by wild Pacific salmon as determined by examination of the literature on salmonid diseases.

(b) health surveillance

The risk analysis required the salmonid fish which make up the commodity to be sourced from a population subjected to an aquatic animal health surveillance programme to ensure that fish would not be sourced from populations in which the prevalence of disease was outside the ranges considered in the risk assessments.

(c) disease outbreak

The requirement that fish not be sourced from populations slaughtered as an official disease control measure as a result of an outbreak of disease provides a level of assurance that fish will not be sourced from populations which may be experiencing prevalences of disease outside the ranges considered in the risk assessments.

(d) processing

The requirement that fish are processed in premises under the control of a regulatory body authorised by the government of the exporting country and approved by MAF, recognises the role of fish processing food safety standards in reducing aquatic animal health risks, by eliminating overtly diseased fish and ensuring compliance with the required outcomes of processing noted at (e) to (g) below. The regulatory body authorised by the government of the exporting country to control fish processing will typically also be the agency approved by MAF to provide export certification. Evaluation of competent authorities is noted in the OIE Code at Chapter 1.4.3.

(e) headed, gilled and gutted

The requirement that fish be headed, gilled and gutted results from the original description of the commodity for which market access was requested by the USA.

(f) inspection

The requirement that fish be individually inspected and graded to provide a product which is free from lesions due to infectious aquatic animal disease ensures that tissue concentrations of pathogens are within the ranges considered in the risk assessments to be likely to be present in imported commodity.

(g) sexual maturity

The requirement that fish be sexual immature or sexually maturing, but not sexually mature, recognises the increasing susceptibility to disease in sexually mature salmonids as a result of the stressors which occur during the sexual maturation process, particularly in anadromous salmonids. This increased susceptibility may lead to populations of fish experiencing prevalences of disease outside the ranges considered in the risk assessments.

(h) export certification

The requirement for export certification from competent government authorities ensures that imported commodity is as defined within the risk analysis.

(i) post-arrival measures

The requirement for post-arrival processing within registered transitional facilities provides an assurance that any accumulation of potentially contaminated scraps or waste water as a result of further processing of bulk imported commodity in New Zealand prior to retail sale and/or human consumption will not increase the likelihood of concentrations of pathogens sufficient to provide an infectious dose contacting a susceptible host.

4.4. Levels of risk

The independent review of submissions identified concerns regarding the subjective nature of terms used to describe risk, particularly in the qualitative risk assessment. The review noted the considerable difficulties in accurately specifying risk levels when undertaking qualitative risk assessment, and that increasing use of quantified data should be a central objective of a risk analysis.

The qualitative risk assessment concluded that for most diseases the risk of introduction through importation of the commodity was negligible, and that the risk of IPNV, IHNV, VHSV, EIBS, *Aeromonas salmonicida, Henneguya salminicola* and *Kudoa* sp. was low. The terms negligible and low were not defined.

The approach that MAF has taken within the risk analysis is similar to that taken in the previous MAF salmon risk analysis (MacDiarmid, 1994). That is, the risks for each pathogen were qualitatively assessed, leading to a conclusion that *A. salmonicida* represents the pathogen most experts agree is more likely than any other pathogen to be introduced through trade in the commodity. The risks of introduction and establishment of *A. salmonicida* in three trading scenarios were then estimated using a Monte Carlo simulation model which provided quantified risk estimates.

4.5. Infectious salmon anaemia

The independent review of submissions noted that infectious salmon anaemia virus (ISAV) has been aetiologically linked with disease outbreaks in Canada and Scotland. This is an example of new information coming to light after the risk analysis was completed. The review identified the need for continuing assessment of new information and its potential impact on the conclusions of the risk analysis, as discussed at 4.2 above.

An emergency report to the OIE of 17 December 1997 from the Director General of the Animal and Plant Health Directorate, Agriculture and Agri-Food, Ottawa, Canada, noted that ISAV may be involved in the aetiology of haemorrhagic kidney syndrome (HKS). OIE Disease Information Vol 11 No. 20 of 22 May 1998 indicates that ISAV is now also present in Atlantic salmon farms in Scotland.

The significance of these findings to the conclusions reached in the risk analysis regarding ISAV and HKS is as follows:

- Page 80-81, Section 4.1.5 Orthomyxoviridae. ISAV is now recorded outside of Norway, modifying conclusion 1.

- Page 183, Section 4.4.3 Haemorrhagic Kidney Syndrome. The report from Canada extends the classes of stock which may be affected by HKS, and suggests that isolation of ISAV may be significant in the aetiology of HKS. The conclusions drawn remain valid.

- Page 210-213, Section 4.6 Quantitative Risk Assessment: Actual Historical Data. The findings invalidate the first calculation on page 212, and the calculation relating to ISAV and the United Kingdom is also invalidated.

At present the origin of ISAV in Canada and Scotland is not known and it cannot be assumed that it was due to trade in eviscerated fish. It is appropriate to exclude the examples using ISAV from the risk assessment using actual historical data, but the risk assessment conclusions summarised in Section 4.8 page 220-221 are not significantly altered by this new information.

4.6. Exposure pathways

The independent review of submissions identified the possibility of unplanned events associated with importation of the commodity which could affect the level of risk.

The important exposure pathways are modelled in the risk assessment using a Monte Carlo simulation model. The exposure pathways modelled are considered by MAF to be the most realistic pathways for imported commodity to contact susceptible hosts in New Zealand. The modelling of a range of rare catastrophic events is possible in quantitative risk assessment. However, exposure pathways accounting for events such as transport accidents resulting in release of large quantities of imported commodity directly into salmonid fish habitats in New Zealand were not included within the model. This is because the probability of their occurrence is very difficult to estimate, but it was considered to be so low that the order of the risk estimate would be unlikely to increase.

4.7. Consequences

The independent review of submissions contended that additional figures on expenditure for recreational fisheries were provided in a submission. However, MAF considers that the figures provided in the submission have already been considered in the risk analysis, which summarised on page 32 the results of a National Research Bureau phone survey conducted in 1991.

The review identified several submissions which consider that inadequate account had been

taken of the level of risk in relation to the value of interests in New Zealand which could be impacted by disease. MAF contends that conclusion 7 of page 53 accounts for the possibility of severe adverse impacts to domestic salmonid fisheries as a result of disease introduction. Options to manage risk have been examined in Section 5 Risk Management, and the conclusions at page 230 reflect MAF's view of the measures which would achieve an appropriate level of protection against this risk.

4.8. Benefits

The independent review of submissions noted views within submissions relating to the perceived benefits of importation.

New Zealand government policy is that any person has the right to import goods subject to national legislation, the most relevant of which in this context is the Biosecurity Act 1993. The level and distribution of any benefits that might result is not an issue that MAF is able to take into account when processing applications to import. The only issues which MAF can consider when developing an import health standard are those relating to the biosecurity risks posed by organisms which might be introduced to New Zealand by imports permissible under the proposed standard.

Further, the SPS agreement does not provide for any benefits to be considered when governments assess risks to animal health and determine the sanitary measures to be applied to achieve the appropriate level of protection against such risks.

4.9. Trout poaching

The independent review of submissions noted concerns raised in submissions that importation and sale of trout may lead to poaching of domestic trout. MAF considers this matter to be outside the scope of the risk analysis. The consequences examined in the risk analysis are only those biosecurity risks arising from introduction of organisms with imported salmonids for human consumption.

However, MAF notes the report *3. Freshwater Fish Farming* by the Fishing Industry Committee 1970-71 (a parliamentary committee chaired by Mr. A. D. Dick which was set up to examine the issue of trout farming in New Zealand). The issue of poaching of local wild trout was examined within this report, as were other issues including those related to disease. It was alleged that poaching would result from allowing the farming and sale of salmon and trout in New Zealand. The Committee did not find these arguments sufficiently compelling, and the report recommended that farming and sale of salmon and trout be allowed in New Zealand.

4.10. Chlorination

The independent review of submissions noted that one submission considered the risk analysis to place too much reliance on chlorination to reduce risk.

The effect on pathogens of chlorination of water used to process the commodity was

discussed within the risk analysis at pages 74 and 145. On both occasions the risk analysis noted that not all New Zealand water supplies were chlorinated, and that organic matter would reduce the effectiveness of chlorine. Conclusions relating to chlorine were noted for IPNV and *Renibacterium salmoninarum*, two organisms which appear to be sensitive to the chlorine concentrations typically used in chlorinated water supplies. Use of chlorinated water during fish processing pre-export and after importation was noted as being likely to result in some deactivation of IPNV and BKD pathogens, particularly surface contaminants. Other factors contributed to the level of risk ascribed to both pathogens. The risk analysis did not suggest that use of chlorinated water was a sufficient risk management measure alone.

4.11. Discrimination

The independent review of submissions suggested that it may be justified to impose trade restrictions to prevent the introduction of diseases already present in a country. The review focussed on one submission which considered that whirling disease should be considered as a disease of potential concern because the North Island of New Zealand is a disease-free area.

It is the policy of MAF, in line with article 2.3 of the SPS agreement, that sanitary and phytosanitary measures applied to imports will not be any more stringent than those applied domestically. The fact that, as noted on page 47 of the risk analysis, there are no statutory controls on movement of dead fish into areas free of whirling disease in New Zealand means any measures applied to importations of dead fish in respect of the risk of whirling disease introduction would not be justified.

4.12. Sources of information

The independent review of submissions suggested that the visits by New Zealand experts to Canada and the USA could have been more fully reported, because equating Canadian and USA wild Pacific salmon was questioned on the basis of lack of information presented in the risk analysis.

The health status and disease prevalence data for wild Pacific salmon stocks supplied by the USA and Canada were noted in the qualitative risk assessment. The relevant legislation controlling fish health and fish processing in Canada and the USA were noted in Section 5 Risk Management. From this information the risk analysis concluded that the nature of the risk, the magnitude of the risk, and the options for managing risk during importation of wild Pacific salmon from the USA and Canada were sufficiently similar that any distinction in the level of sanitary protection deemed appropriate would be unjustified.

APPENDIX 1