Quarantine and Biosecurity Review

April 2008

Submission from

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Almost all of Australia's farmed salmonids are grown in Tasmania, and the Tasmanian Salmonid Growers Association Ltd (TSGA) represents the interests of the entire Tasmanian salmonid farming industry. This is a rapidly growing industry, with sales over the last five years growing from $120M to $250M. On behalf of its members the TSGA was heavily involved in discussions and lobbying against the proposal to import non-viable salmonid material, a process which started with the AQIS "Salmon" Import Risk Analysis (IRA) in 1995/96, proceeded to a challenge by Canada under WTO in 1997, and culminated with a second "Salmon & finfish" IRA in 1999. The "Salmon" IRA and WTO dispute were in many ways a test case. The conclusion was that Australia lost the case and fresh or frozen salmonid product was allowed into Australia with only a modicum of constraints. Fortunately for TSGA members, the Tasmanian Government took a stance to protect a significant industry, and continued to ban uncooked/untreated imports into Tasmania.

Most of TSGA's experience in dealing with AQIS, and later with Biosecurity Australia and AQIS in their redefined roles, therefore comes from the "Salmon IRA" and subsequent episodes dealing with salmonid and/or other fish imports.

During the course of the Salmon IRA dispute and subsequent the TSGA has raised literally dozens of concerns in detail (some attached as appendices), but from TSGA's perspective there are three fundamental flaws in AQIS/Biosecurity Australia's methods and practices for handling import risks and quarantine which have directly affected our industry.

1) Application of the Risk Evaluation Matrix in establishing ALOP

The Risk Evaluation Matrix frequently used in several Australian IRAs is appears logical and is therefore intuitively attractive. The example below is in fact reproduced from the Biosecurity Australia's 2003 IRA for pilchards.

Risk estimation matrix (page 16)

Likelihood of entry and exposure	*Negligible impact*	*Very low impact*	*Low impact*	*Moderate impact*	*High impact*	*Extreme impact*
High likelihood	**Negligible risk**	**Very low risk**	**Low risk**	**Moderate risk**	**High risk**	**Extreme risk**
Moderate Likelihood	**Negligible risk**	**Very low risk**	**Low risk**	**Moderate risk**	**High risk**	**Extreme risk**
Low likelihood	**Negligible risk**	**Negligible risk**	**Very low risk**	**Low risk**	**Moderate risk**	**High risk**
Very low likelihood	**Negligible risk**	**Negligible risk**	**Negligible risk**	**Very low risk**	**Low risk**	**Moderate risk**
Extremely low likelihood	**Negligible risk**	**Negligible risk**	**Negligible risk**	**Negligible risk**	**Very low risk**	**Low risk**
Negligible likelihood	**Negligible risk**	**Negligible risk**	**Negligible risk**	**Negligible risk**	**Negligible risk**	**Very low risk**

Consequences of entry and exposure

The nomenclature for the qualitative likelihoods is translated to fixed bands of uniform distribution. The following is also taken from BA's 2003 IRA for pilchards (percentage probabilities added for this submission).

Nomenclature for qualitative likelihoods (page 20)

Likelihood	Descriptive definition	Probability (P)
High	The event would be very likely to occur[1]	Range= 0.7 → 1 ie. 70 – 100%
Moderate	The event would occur with an even probability	Range= 0.3 → 0.7 ie. 30 – 70%
Low	The event would be unlikely to occur	Range= 0.05 → 0.3 ie. 5 – 30%
Very low	The event would be very unlikely to occur	Range= 0.001 → 0.05 ie. 0.1 – 5.0%
Extremely low	The event would be extremely unlikely to occur	Range= 10^{-6} → 0.001 ie. 0.000001 – 0.1%
Negligible	The event would almost certainly not occur[3]	Range= 0 → 10^{-6} ie. 0 – 0.000001%

These bands are used by Biosecurity Australia in assessing all likelihoods that are considered in an Import Risk Analysis, except for those where there exist sufficient data of measurement or observation to justify the use of that data.

One consequence of that is that the scaling of probabilities is not adjusted for the significance of an event. This leads to results which are counterintuitive and arbitrary – and which we doubt that policy makers relying on IRA reports fully understand.

One use of these bands is to attribute a value to the likelihood of very small steps in the importation pathway.

When they are used in this way the categories Low and Moderate between them span a large range of probabilities (5 to 70%) which could be usefully divided into finer graduations, and the categories Negligible to Very Low cover a narrow band of probabilities. (These apparently trivial criticisms become more meaningful when their effects on the final outcome are examined – See Appendix 2b).

The same bands are used to translate the assessed annual likelihood of establishment of a disease in Australia to a qualitative value.

It is in this use that the bands lead to a major lack of transparency. It will be recalled that Australia's ALOP is described as being qualitative and "very low but not zero".

The use of the bands leads to the following being assessed as meeting Australia's ALOP:

[1] A probability of 1 means the event will occur and a probability of 0 means the event will never occur. A probability of 10^{-6} corresponds to a one in a million chance of an event occurring.

AUSTRALIA'S ALOP AS DEFINED BY PROBABILITY BANDS		
Likelihood disease will establish in any one year	Level of risk assessed on national basis	Result on Australia's ALOP
Up to 30%	Low impact	Meets ALOP
Up to 5%	Moderate impact	Meets ALOP

A 29.9% probability of the establishment of a disease of substantial quarantine concern being established in any one year is not "low odds".

This conclusion is reinforced when it is considered that in order to assess the level of impact of the establishment of a disease, Biosecurity Australia discounts the effects of diseases which impact on industries that are concentrated in one state only (see discussion below). Consequently, the adverse impacts on the Salmonid industries of quarantine diseases will always be discounted because those impacts will be felt peculiarly within Tasmania.

Secondly, a further flaw in the application of the generic Risk Assessment Matrix becomes apparent in its application to Consequence Assessment. The example below is again taken from BA's 2003 IRA for pilchards.

It is a direct consequence of this matrix that even a significant impact on a state-based industry sector would not register as significant on a national scale. Thus the wipe-out of the Australian salmonid farming sector based almost entirely in Tasmania, or the Southern Bluefin Tuna farming sector based almost entirely in South Australia, would not register as significant enough on a national scale to contravene Australia's Appropriate Level of Protection (ALOP). This methodology is highly unsatisfactory from the perspective of the salmonid farming and probably other aquaculture sectors in Australia.

Assessment of direct or indirect impacts on a national scale (page 49)

Impact score	National	State or Territory	District or region	Local
G	**Highly significant**[1]	–	–	–
F	**Significant**		–	–
E	**Minor**			–
D	Unlikely to be discernible	**Minor**		
C	–	Unlikely to be discernible	**Minor**	
B	–	–	Unlikely to be discernible	**Minor**
A	–	–	–	**Unlikely to be discernible**
			Level	

[1] Shaded cells with bold font are those that dictate national impact scores

Finally, both direct and indirect environmental impacts are repeatedly and arbitrarily shown in various IRAs as "not discernable". In many cases this categorisation is used as a surrogate for uncertainty or complete lack of knowledge in the consequence assessment.

While in assessing likelihoods Australia's risk assessment methodology has numerous steps to cater for uncertainty, the method for assessing consequences assumes that all elements of the assessment are known and certain.

This approach fails to account for the inevitability that in quarantine decision making it will very often be the case that the impacts of a new pathogen on a naïve host will be unknown.

In the case of Australian marine species, the impacts of many pathogens are both unknown and unknowable.

In such cases it is inappropriate for consequence assessment to proceed on the basis that impact is "not discernable". There is no impact category to cover "unknown" but it is both rash and misleading to assign the lowest category of impact to an event of unknown impact. It is not necessary to rely on the precautionary principle to conclude that where a regulator has no idea of the likely biological impact of a pathogen it should not assume there will be no discernible impact. The transparent approach to dealing with this issue would be to publish an IRA based on a sensitivity analysis using the assumptions of no discernible biological impact, through to the impacts that would flow if the biological impacts were as bad as they might be.

In the IRA on Non viable Salmonids (AQIS 1999) the consequence assessment of *Piscirickettsia salmonis* (at Box 4.8) states:

> While the effect on the environment cannot be discounted, there is no reason to expect that the establishment of *P salmonis* would affect the survival of any vulnerable or endangered species in Australia.

That conclusion was presumably stated because those vulnerable and endangered species had never been exposed to *P salmonis*. The consequence assessment that flows from that conclusion reflects a level of confidence about the possible consequences which is incapable of being supported by any scientific observation or analysis.

2) Unquestioning reliance on Competent Authority of exporting country

A second fundamental flaw in AQIS/Biosecurity Australia's methods and practices for handling import risks and quarantine is the extent of reliance on statements made by the Competent Authority of all exporting countries. Whilst we accept that international protocols have to be followed and professional courtesies observed, we must not gloss over the fact that the competencies and indeed the integrity of disease monitoring, surveillance, and export certification systems in many countries is not of as high a standard as Australia's.

That should not be a surprise. Australia and New Zealand have much higher quarantine standards than the rest of the world. It necessarily follows that Australian administrative practice and the links between Australian quarantine regulators and industry place greater emphasis on quarantine compliance than occurs in other countries.

In 1994, during a joint AFFA – Industry study tour of potential import risks, TSGA members viewed first-hand the "examination of salmon for clinical disease" at Canadian and Alaskan fish processing plants which consisted of an inspector viewing eviscerated fish passing along a conveyor belt at the rate of one every two seconds, which were later certified as disease free. As a number of serious salmonid diseases do not necessarily present gross external lesions or overt clinical signs it is difficult to accept such cursory examination as adequate for disease-free certification.

At one point AQIS was prepared to accept one country's claim of freedom from the highly infectious disease Infectious Salmonid Anaemia despite the disease having been diagnosed on farms in a different jurisdiction separated by just two nautical kilometres (Maine in US vs New Brunswick in Canada). The international salmon farming community is aware of a number of exotic diseases now occurring in Chile which could only have come from imported material, albeit live, but certified as "disease free" by other salmon producing countries.

Discussions with our counterparts in other relatively small primary production sectors have revealed similar discomfort with AQIS/BA ability to check currency of OIE certification in countries wishing to export to Australia. Expecting farm workers to "brush pest off full hands of bananas"; believing the exporting country's assertion without evidence that a root-attacking fungus of bananas "would not spread more than a few feet"; expecting "high-pressure washing" of fruit to dislodge all pests; expecting to manage White Spot Virus in green prawns by declaring imports were for "human consumption only"; are all examples of a misplaced willingness to accept inadequate measures claiming to address biosecurity concerns. These and other examples are well documented in the NSW Farmers Association submission "Crisis of Confidence in Quarantine" dated February 2006, and partially considered at the Biosecurity Summit in July 2006 in Canberra.

There is an urgent need to develop a practical; facts based approach to assessing to what extent reliance can be placed on the assurances of trading partners.

The development of such an approach need not involve any improper, imprudent or impolite questioning of trading partners. Rather, it would assess against Australian standards the administrative and scientific systems to be employed by our trading partners and the levels of industry, administrative, and political support necessary for a robust and credible certification program.

During the Biosecurity Summit of February 2006, TSGA made itself familiar with Barrister, Mr Tom Brennan's Memorandum of Advice to the NSW Farmers Association on Legislated Structure for Australian Government Quarantine Agencies. This Memorandum addressed a number of high level criticisms of the adequacy of current governance arrangements for quarantine functions and recommended direction for reform, which TSGA understood and supported. We are also aware of the basic elements of the Reform of the IRA process announced in October 2006, but given our limited interaction with BA on import issues since the Salmon IRA we are unsure of the impact these reforms would have on future requests for salmonid imports into Australia.

In early 2006 we were advised by BA that a request by Chile to export salmon product to Australia had been recently re-activated. Being aware of the prevalence of some particularly significant salmonid diseases in Chile, some of which had emerged since the Salmon IRA and some which had sharply increased in severity, the TSGA promptly activated an information gathering and risk assessment exercise of its own. Our investigation focussed on the one disease (*Piscirickettsia Salmonis - PS*) believed to present the greatest risk (probability X impact), and we engaged the services of Professor Tony Pettitt (Head of School of Mathematical Sciences at the Queensland University of Technology – widely acknowledged as an expert on statistical risk analysis) for relevant advice. Three salient documents were produced:-

1. a retrospective critique on the statistical robustness of the 1999 Salmon IRA (Pettitt report - attached as Appendix 1),
2. a review of findings on PS since the 1999 Salmon IRA (being held as a confidential document at this stage), and
3. a recalculation of the risk presented by *PS* as compared to the 1999 IRA in light of the latest published information (attached as Appendix 2a).

In the last twelve months it has emerged in the industry press and other public media that the Chilean salmon farming industry has suffered very significant losses, reported as high as 30% of annual production, to a combination of *PS*, sealice, and the newly established disease Infectious Salmon Anaemia. The effect has been closures of whole farming regions, large scale job losses, and severe degrading of share value in some of the world's largest salmon farming companies (See Editorial on Chile attached as Appendix 3).

TSGA understands from BA that the request from Chile to export has been shelved. Given that the Chilean regulators have patently been unable to control the spread of very significant diseases in their own jurisdiction there remains for us the discomfort of wondering how BA might have treated the application if it had been active in the "all is well" period of say two years ago, and indeed whether BA's scrutiny of freedom from disease claims will be more rigorous in the future.

3) Poor Border and Post-border monitoring for fish pathogens and residues.

TSGA is of the view that whilst the export regulating arm of AQIS is admirably vigorous in ensuring that Australian seafood exports meet the highest standards of freedom from pathogens, residues, and contaminants, the import inspection arm fails to provide domestic growers with equivalent protection from imported biosecurity risks. The highly visible sniffer dogs and Quarantine personnel at Australian ports of entry are legendary, but border and post-border monitoring of commercial imports "certified" as clean are often inadequate.

Of direct concern to the TSGA are events such as the batch of fresh chilled salmon from Norway visibly carrying the dreaded European sealice (found by chance examination at Sydney airport), and photographic evidence of seagulls scavenging from a garbage skip of fish material being handled "under post-import quarantine" in Sydney. We remain deeply concerned that the millions of live aquarium fish being imported annually from South East Asia are only subjected to a cursory visual examination by one of a very limited number of fish inspectors before being released into quarantine at commercial distributors' premises. During the development of Aquaplan and other national forums dealing with aquatic animal health the TSGA has repeatedly called for periodic, random testing by AQIS of imported seafoods for significant fish pathogens as well as selected residues; this has been dismissed as non-core function. We are aware that similar representations made by other sectors such as Australian prawn farmers have also been refused. We believe that such random testing for targeted pathogens and residues falls within the Commonwealth Governments duty of care, and should be a core activity of AQIS.

Summary.

While the Biosecurity Australia methodology for Import Risk Analysis has been used several times over the past few years for making a determination of the risk posed by import of several agricultural products, this methodology is under considerable challenge by risk management experts on biological, mathematical and legal grounds.

Over and above the objectively debatable biological, mathematical, and legal arguments, there is a high degree of political subjectivity in relation to Consequence assessment, which in turn drives the determination of the Appropriate Level of Protection (ALOP) adopted by Australia.

These findings by a broad spectrum of smaller primary production sectors and their advisers together with TSGA's own experience in dealing with AQIS / BA on imported risk issues lead us, and we believe others, to the inescapable perception that Australia has in the past two decades been seeking to trade biosecurity for market access. Such positioning favours the large sectors which export most of their product (beef, wool, lamb, etc) at the expense of

small primary production sectors (apples, bananas, avocado, prawns, pork, etc) which rely largely on domestic sales and stand to lose a great deal from exotic diseases introduced via imported product.

We have 4 concerns with this approach.

First, it is neither required by, nor consistent with the SPS Agreement. After all, the SPS Agreement's primary purpose is to articulate a rules-based approach to quarantine decision making. It is inconsistent with a rules-based approach to seek to trade off market access into one market against quarantine decision making in another.

Second, there is no factual basis to lend support to any argument that the approach works. As far as TSGA is aware none of Australia's trading partners have committed to adopting any of the systems for quarantine decision making which are used by Australia. No doubt those trading partners are pleased to see Australia adopt a system which lowers quarantine barriers. That provides no basis to conclude that there will be any improvement in market access. For example, the fact that Australia permitted the importation of pig meat from the EU, Canada and USA in circumstances where it was earlier banned has not resulted in any discernible improvement in market access for any Australian products to any of those markets.

Another example is the development of the concept of Areas of Low Pest Prevalence. TSGA understands that Australian officials were influential in developing and steering this experimental concept through the development of a draft International Standard for Phytosanitary Measure; only to see Australian officials then use the concept in proposing measures to permit the importation of bananas in a draft IRA which was subsequently withdrawn. TSGA is not aware that any other country has proposed to use the concept in its quarantine decision making.

Third, it is incompatible with the expressed policies of Australian governments.

Fourth, it causes friction and division between Australian primary industries in circumstances where there is no rational basis for that.

TSGA is concerned with paragraph 28 of the Issues Paper published by the Review which states:

> It is important to note that Australia exports approximately two-thirds of its agricultural production. Compliance with the SPS rules and obligations allows Australia to expect similar compliance from its trading partners. This provides Australian exporters with significant benefits of access to overseas markets.

Australia is entitled to expect compliance with the SPS Agreement from every WTO member because they are WTO members and are legally bound by the terms of the agreement. Australia's compliance does not affect a trading partner's obligations.

There is no basis in international law, or in the practice of quarantine, for Australia to expect any trading partner's compliance with the SPS Agreement to be "similar" to Australia's compliance. Indeed the essence of the SPS is that a country's form of compliance will be determined by its objective pest and disease status and its articulated level or levels of acceptable risk. On both counts Australia markedly differs from most of its trading partners.

We understand that there have been changes since the 2006 Reform but we remain uncertain as to whether changes are or will be meaningful enough to provide equitable protection from import risk for smaller primary production sectors such as ourselves.

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Assessment of the Methodology used in "Import Risk Analysis of Non-viable Salmonids and Non-salmonid Marine Finfish", Australian Quarantine & Inspection Service, 1999.

Professor A.N. Pettitt
School of Mathematical Sciences
Queensland University of Technology - Brisbane
May 2006.

This assessment has been requested by the Tasmanian Salmonid Growers Association.

Summary

In the IRA (AQIS, 1999) the qualitative approach is used which defines probabilities and consequences in terms of descriptors such as high, moderate, low and so on. These descriptors are not defined in quantitative terms but remain undefined leading to ambiguities. The probabilities and consequences of establishment are then combined using a set of rules which are themselves arbitrary to determine a level of risk which is either acceptable for importation or not. It is my view that, by its very nature, the qualitative approach as used by AQIS in this report is not transparent and not good science. Consequently decisions made on the basis of the risk assessments presented in the IRA (AQIS, 1999) are unsound. This is a major shortcoming of the IRA.

Probabilities of establishment of disease and risks are affected by the amounts of produce which are imported per given period of time. The period of time considered for assessment affects probabilities, so that the longer the period of time the greater the probability of establishment. Also the impacts of the importation can be determined over a period of time, say one year, or ten years, or twenty years. These three aspects have not been taken into account in the IRA (AQIS, 1999) and necessarily lead to inaccurate risk estimates. These are major short comings of the IRA.

The Qualitative Approach of the IRA

It is stated that "… IRA which is a structured transparent and science-based process that provides the scientific and technical basis for quarantine policies" (p xiii, AQIS,1999) . In the IRA (AQIS, 1999) the qualitative approach is used which defines probabilities and consequences in terms of descriptors such as high, moderate, low and so on. These descriptors are not defined in quantitative terms but remain undefined using a set of terms such as 'high', 'moderate', 'low' and so on. AQIS (1999, p xiii) states that the qualitative approach is used because

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

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The literature on risk analysis describes two methods for risk assessment, namely the qualitative method and the quantitative method (see for example Vose, 2000; Vose et al, 2001; Murray, 2002; Aven, 2003) whilst a more recent method, semi-quantitative risk assessment, is described by Vose et al (2001).

The qualitative method of risk assessment involves the use of qualitative descriptors on a descriptive ordinal scale (such as 'high', 'medium' and 'low') to describe the probabilities and consequences, and relies on arbitrary rules for combining probabilities and consequences to obtain risk. For example, in assessing possible quarantine arrangements for in-coming passengers to Australia's airports with respect to influenza pandemic, passengers from Europe with flu-like symptoms might be assessed as having 'flu with negligible likelihood, whereas those from China might be assessed to have moderate likelihood. The consequences of allowing a passenger into Australia with 'flu and being allowed to mix freely might be assessed as high. If the IRA Report's risk evaluation matrix (Figure 1.1 on page 14 of the AQIS, 1999) is used then we obtain a 'yes', allow entry, for a passenger from Europe whereas it is a 'no', do not allow entry, for a passenger from China. The qualitative method appears to be commonly used for routine decision making and in preliminary stages of a quantitative assessment (Vose et al, 2001, page 816; Murray, 2002, page 27).

The quantitative method of risk assessment involves describing uncertainty using probability and consequences using monetary values. For example, the likelihood that foot and mouth disease might enter Australia through animals brought to northern Australia illegally in a given year might be estimated as 0.01 with the cost or consequences of such an entry estimated at $1 billion. The risk is evaluated as 0.01 times $1 billion or $10 million.

It is my view that, by its very nature, the qualitative approach as used by AQIS in this report is not transparent and not good science. It is good science to explicitly express unknowns on a quantitative basis and the uncertainty about the unknowns, resulting from the inherent variability of observational data together with a lack of knowledge due to little or no data. The uncertainty is expressed in terms of probability and then this is incorporated into risk analysis. By doing this decisions are more soundly based and transparent in that there is no ambiguity about assessments of unknowns. The qualitative approach adopted by the IRA leads to unsound science.

In later IRAs carried out by Biosecurity Australia, for example the draft apple IRA (BA, 2004) and the latest draft apple IRA (BA, 2005), a semi-quantitative approach to risk analysis is used. I find this unsatisfactory but it is an improvement on the qualitative approach. In these IRAs the knowledge about disease prevalence for example is expressed quantitatively and its uncertainty incorporated and expressed through a probability distribution. Complexity is overcome by breaking the process down into simpler steps. How animals or plants may react to disease pressure in Australia is inferred from evidence from overseas. The process is modelled using an Excel spreadsheet add-on called @Risk.

The @Risk software is extensively used in industry work to carry out quantitative risk analysis. New Zealand's guidelines for import risk assessment for animals and animal products (Murray, 2002) gives a detailed description of quantitative risk assessment being described in eight of the twelve chapters of the report with extensive reference to @Risk software.

No single method of import or quarantine risk assessment has proven applicable in all circumstances. Murray (2002, pages 41 to 52) gives an example of a qualitative risk

assessment and risk management for the importation of horses into New Zealand (presumably for breeding or racing purposes) with respect to African horse sickness virus. Risk management measures are described for an imported horse. In terms of import or quarantine risk assessment this example is relatively straightforward and does not show the complexity of the analysis involved in the salmonid IRA report. Methods of quantitative risk analysis and the outcome of particular evaluations are regularly presented in scholarly papers that are published in *Risk Analysis*: *An International Journal* and topics are as diverse as quality of drinking water, air and land contamination, the safety of foods and drugs, automobile and infrastructure safety, risk associated with weapons of mass destruction and global catastrophes. Examples of industry projects using quantitative risk analysis can be found at www.risk-modelling.com for agriculture, banking and finance, power and food, for example.

I conclude that the conclusions of the IRA (AQIS, 1999) for risk assessment are not sound in that there is an arbitrariness inherent in the qualitative approach with respect to estimates of the probability of establishment and the degree of the consequent impact and therefore subsequent risk evaluation.

The Conservative approach

The IRA on page 8 describes how to deal with uncertainty and the following gives the detail.

General note on dealing with uncertainty and gaps in data

Many of the observations and assumptions in this risk analysis are generalisations and, as such, stakeholders may challenge them. However, AQIS contends that it is valid to generalise, provided that the nature of factors that may affect the applicability of key assumptions is understood and the implications of such factors for the analysis are properly taken into account. In the absence of definitive, quantitative data on factors relevant to quarantine risk, AQIS applies appropriately conservative professional judgment based on available scientific information and the advice of experts in relevant fields. This is a scientifically valid approach that is adopted by quarantine authorities throughout the world in the face of limited scientific data. Thus, AQIS's approach is consistent with international practice.

In the absence of good information derived from data, the standard approach is to assess the views of experts using elicitation methods. Generally, an expert's knowledge, based on all available information to him/her, can be elicited, as the term is called, to obtain a probability distribution representing the expert's uncertainty about the aspect in question; (see, for example, Garthwaite & O'Hagan, 2000; Vose, 2000; O'Hagan, 1998; Kadane & Wolfson, 1998;Van Der Fels-Klerx *et al.*, 2002; Murray, 2002). Such a distribution could be described by its most likely value, or mode, and by a selection of values which divide the distribution into given amounts of probability for smaller and higher values, known as percentiles or quantiles.

When the so-called 'conservative approach' is used then it is not clear how conservative 'conservative' is; what is the change that is taken into account? It is better to attempt the elicitation process referred to in the above paragraph otherwise arbitrariness is introduced into the process.

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Risk Evaluation Matrix

In the IRA risk is evaluated by combining the probability and consequence of establishment using the risk evaluation matrix (Figure 1.1 on page 14 of the AQIS, 1999, and reproduced below). The values of 'yes', the risk is acceptable and importation is permitted', and 'no' in the risk evaluation matrix are arbitrary as well with no reason given as to why a particular combination of probability and consequence gives a risk which is acceptable, a 'yes', and another does not, a 'no'.

Figure 1.1
Risk evaluation matrix

PROBABILITY OF ESTABLISHMENT	N	L	M	H	C
H	yes	no	no	no	no
M	yes	no	no	no	no
L	yes	yes	no	no	no
VL	yes	yes	yes	no	no
EL	yes	yes	yes	yes	no
N	yes	yes	yes	yes	yes

SIGNIFICANCE OF CONSEQUENCES

'Yes' = the risk is acceptable and importation can be permitted.
'No' = the risk is unacceptable and importation cannot be permitted without further risk management.
Level of probability: H=high, M=moderate, L=low, VL=very low, EL=extremely low, N=negligible.
Level of significance: C=catastrophic, H=high, M=moderate, L=low, N=negligible.
Source: AQIS (prepared for this IRA, 1999).

Figure 1.1 on page 14 of the AQIS, 1999

Factors affecting the probability of a disease agent entering and becoming established in Australia

In Box 1.3 (p 11, AQIS, 1999) the probability of a disease agent entering and becoming established in Australia is simplified into four steps and the overall probability can be obtained by mathematically multiplying each probability together provided these are assessed properly taking the rules of probability into account. These probabilities and their uncertainties should be assessed quantitatively by scientists with specialist knowledge of the context and the relevant scientific literature. This should have been the approach carried out in AQIS (1999).

In subsequent IRAs, such as the apple IRA (BA, 2004), the methodology was applied with error in some instances (and partially corrected in BA, 2005) as the appropriate probabilities were interpreted incorrectly as marginal probabilities rather than conditional probabilities, and consequently their values erroneously determined so that the overall risk assessment was in error.

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Terms used to describe the probability of an event occurring.

In Box 1.4 (p 11, AQIS, 1999) the terms used to describe the values of the probability of an event occurring are given in purely descriptive terms so that these are completely open to individual interpretation and different interpretation in different contexts. Use of such a scale to give the basis for the reasons for making scientific decisions is certainly not transparent and not sound science. In Box 1.4 there is no reference to any numerical values, except in a footnote, "These categories are not equidistant from each other; most fall into the range 0<probability<50%".

This footnote gives very little assistance in knowing how to interpret the terms used to define the scale for describing probabilities but implicitly recognises that probabilities should be defined quantitatively.

Terms used to describe the severity of the impact

Box 1.6 (p 13, AQIS, 1999) gives the terms used to describe the severity of the impact of the establishment of disease. The terms used go from 'catastrophic', 'high' to 'negligible'. I have argued in industry submissions concerning the final Pig Meat IRA and draft Apple IRA(BA, 2005) that consequences should be assessed in quantitative terms using a monetary or more generally a utility scale. The scale described here is qualitative and lacks rigour. It is very much open to personal interpretation as to what these terms mean.

So, for example, in the 'high' category, it is stated

> **High:** associated with the establishment of diseases that would have serious biological consequences (eg high mortality or high morbidity and causing significant pathological changes in affected animals). Such effects

Earlier in the IRA, on pages 11 and 12, the following describes how morbidity and mortality are assessed.

> The biological effect of the establishment of disease is normally evaluated in terms of morbidity and mortality data. In this risk analysis, AQIS took into account the standard epidemiological approach to classification of morbidity and mortality rates. For example, a high mortality rate could be defined as one that is more than two standard deviations (SD) greater than the expected mortality rate for that population over a short period (less than one month) or a rate that is more than 1 SD greater than the expected mortality rate for that

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There is no reason why the scientists involved in the IRA process could not have taken an approach so that the quantitative effects such as mortality could have been assessed as 'high' using the quantitative definition above and using expert knowledge and the consequent uncertainties expressed using probability distributions as was done in BA (2005), for example with respect to diseases of apples. These assessments could have been reported and used by AQIS.

Release Assessment

The release assessment described on p 14 (AQIS, 1999) involves five probabilities as follows.

1. The probability of the disease agent being present in fish in the waters of origin.
2. The probability of the disease agent being present in the particular fish harvested.
3. The probability of infected or contaminated fish/product passing inspection or grading.
4. The probability of the disease agent surviving processing, transport or storage.
5. The probability of the disease agent being present in the particular tissues imported.

These probabilities are probabilities for events that occur sequentially, one after the other, and consequently have to be assessed as conditional probabilities. As mentioned above subsequent IRAs failed to apply the appropriate probabilistic reasoning in similar instances and were in error.

Risk assessment for the specific disease *Piscirickettsia salmonis*

This report considers the risk assessment for *P. salmonis* imported from Chile.

The release assessment is given on pages 105-106, AQIS (1999). Mention is made of *P. salmonis* affecting sea farmed salmonids but there is no data given concerning prevalence amongst the most common group, "smolts 10-12 weeks after transfer to sea". In the "key findings" section words such as "most common", "serious disease", "high mortality", "less likely", "few if any", "high likelihood", "many … cells", "may be in the somatic musculature at a low level" are used without giving any quantitative assessment of values. Such descriptions are very imprecise and largely arbitrary.

The exposure assessment (pages 106-107, AQIS, 1999) mentions "higher" and "high" minimum infective doses without quantifying the amounts. It also mentions that

For fish to become infected with *P. salmonis*, fish of a susceptible species and lifecycle stage would need to be exposed to a sufficient dose of the pathogen for a sufficiently prolonged period. Infection would need to

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Here “sufficient” and “sufficiently” are left undefined and imprecise. Also it is mentioned

> Repeated high level exposure of susceptible fish to a significant titre of *P. salmonis* (for example, from regular discharge of untreated effluent from a salmon processing plant) could result in the establishment of infection. However, sporadic or isolated entries of

Here “high” and “significant” are left imprecise and “could result” is vague. For the consequence assessment, quantitative information is given about mortality rates and economic loss. Also it is stated

> that the establishment of *P. salmonis* in Australia would have limited consequences, similar to the situation in

There is no quantitative assessment given to the consequences. It is also stated that

> higher than in the northern hemisphere. If *P. salmonis* caused similar effects in Australia as in Chile, the consequences would be significant.

There is no data presented to indicate what is meant by “significant”.

APPENDIX 1

Unrestricted risk estimate of the importation of salmonids

Details are given on pages 108-109 and Box 4.8 (p 109) of AQIS (1999). There is no substantial evidence or explanation presented in the IRA as to why these particular values of the probabilities are determined as such in the IRA (AQIS, 1999) and as such would appear largely to be "plucked out of the air". Such an approach is not scientific and not transparent. Similarly why the consequences are assessed as "low to moderate significance" is not supported in the text.

The overall risk assessments are given in Box 4.8 and reproduced as below.

Box 4.8
Risk assessment — *Piscirickettsia salmonis*

RELEASE ASSESSMENT (R)

The unrestricted probability of *P. salmonis* entering Australia as a consequence of the importation of eviscerated, marine-farmed, adult salmonids would be very low.

Because piscirickettsiosis is primarily clinically expressed and there is a greater probability of a significant viral titre in juvenile salmonids, the probability associated with the unrestricted importation of this lifecycle stage of eviscerated, marine-farmed salmonids would be low.

For eviscerated, freshwater-farmed, adult salmonids the probability would be extremely low, while for freshwater-farmed, juvenile salmonids the probability would be very low.

For eviscerated, wild-caught salmonids the probability would be negligible.

EXPOSURE ASSESSMENT (E)

If *P. salmonis* entered Australia, the probability of susceptible fish in the marine environment being exposed to a dose sufficient to cause infection would be very low. In the freshwater environment, the probability would be extremely low.

PROBABILITY OF DISEASE ESTABLISHMENT (R + E)

The probability of *P. salmonis* becoming established in Australia as a consequence of the unrestricted importation of eviscerated, marine-farmed salmonids, including juveniles, would be very low (VL).

For the unrestricted importation of eviscerated, freshwater-farmed, adult salmonids the probability of establishment of *P. salmonis* would be extremely low (EL). For freshwater-farmed, juvenile salmonids the probability would be very low (VL).

For wild-caught salmonids the probability of establishment of *P. salmonis* would be negligible (N).

CONSEQUENCE ASSESSMENT

The consequences of the establishment of *P. salmonis* in Australia would be low (L), due to the absence of coho salmon and the limited effects of piscirickettsiosis on Atlantic salmon and rainbow trout in *P. salmonis*-infected countries. However, if piscirickettsiosis caused similar effects in Australia to those reported in Chile, the consequences would be moderate (M), due to the effect on the commercial rainbow trout and Atlantic salmon industry.

While the effect on the environment cannot be discounted, there is no reason to expect that the establishment of *P. salmonis* would affect the survival of any vulnerable or endangered species in Australia or have any significant effect on the natural environment.

UNRESTRICTED RISK ESTIMATE FOR IMPORTATION OF EVISCERATED SALMONIDS

From Figure 1.1 (risk evaluation matrix):

- probability of establishment = VL (eviscerated, marine-farmed salmonids, including juveniles and freshwater-farmed, juvenile salmonids) to EL (freshwater-farmed adult salmonids) to N (wild-caught salmonids).
- significance of consequences = L–M
- importation risk for *P. salmonis* = acceptable ('yes' in Figure 1.1).

That is:

- the risk associated with the unrestricted importation of eviscerated salmonid fish, wild and marine and freshwater farmed, including juveniles, meets Australia's ALOP; and
- risk management measures are not warranted.

In Box 4.8 the release assessments (R) are given in terms of four probabilities which are given values of 'very low', 'low', 'very low' and 'negligible' and there appear to be no scientifically sound explanations for these values. Admittedly, it is difficult to give concrete reasons for something vaguely or imprecisely defined as the qualitative values of the probabilities are only described in descriptive terms and not in numerical or

quantitative terms. However, what is written in the section 'Release assessment' on pages 105-106 of the IRA (AQIS, 1999) does not lead one to conclude that the appropriate values of the probabilities are those given in Box 4.8 (AQIS, 1999).

The exposure assessment (E) is given as 'extremely low'. It is difficult to infer from the discussion on the 'Exposure assessment' given on pages 106-107 of the IRA as to whether the assessment 'Extremely low' is appropriate because of the difficulty of interpretation alluded to in the previous paragraph.

The probability of disease establishment is then found by combining the release (R) and exposure (E) assessments in some unexplained method.

Similar remarks apply to the consequence assessment which is assessed as 'moderate'. In view of the remarks on page 107 of the IRA given below

> In Chile, economic losses due to piscirickettsiosis are highest in spring and autumn. Mortality rates of 30% in coho salmon, 20% in rainbow trout and 10% in Atlantic salmon have been recorded and piscirickettsiosis was estimated to have caused losses greater than US$50 million in 1994.

It would be of value to know what might be the expected monetary value losses which were assessed by AQIS in order to derive a 'moderate' level of loss. Did these losses correspond to one year's expected trade or were the consequences of say ten years' trade?

The risk evaluations result as a combination of values of probabilities and consequences of establishment using Figure 1.1 of the IRA (AQIS, 1999). The risks given in Box 4.4 would be largely arbitrary in their values and leading to unsound decisions about importation of salmonids concerning the disease *P. salmonis*.

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APPENDIX 2a

Risk of Piscirickettsiosis from imported salmon
Recalculation of probable risk estimated in 1999 Salmonid IRA.
(Tasmanian Salmonid Growers Association Ltd – July 2006)

Overview

While the Biosecurity Australia (BA) methodology for Import Risk Analysis (IRA) has been used several times over the past few years for making a determination of the risk posed by import of several agricultural products, this methodology is under considerable challenge by risk management experts on biological, mathematical and legal grounds. Indeed a ruling in Federal Court has rejected the validity of BA's IRA methodology.

Over and above the objectively debatable biological, mathematical, and legal arguments, there is a high degree of political subjectivity in relation to Consequence assessment[2], which in turn drives the determination of the Appropriate Level Of Protection (ALOP) adopted by Australia.

The risk assessment performed for the fish disease Piscirickettsiosis (caused by the pathogen *P. salmonis*) in the 1999 Salmonid IRA[3] is re-examined here in light of the latest published information, and the risk of importing head-off and eviscerated salmon[4] from Chile is recalculated.

Conclusions

The calculations below return a finding that head-off and eviscerated salmon from Chile would fail to meet Australia's ALOP; additional risk management measures would therefore be required.

Liquid CO2 tunnel freezing, while expensive, would be an acceptable treatment.

Recalculation of risk assessment.

The basic "formula" for the IRA is:-

$$^{\text{probability}}\text{Release} \times {}^{\text{probability}}\text{Exposure} = {}^{\text{probability}}\text{Disease Establishment}$$

and

Matrix [$^{\text{probability}}$Disease Establishment vs Consequence Assessment]

determines

Whether (unrestricted) Risk Estimate meets Australia's ALOP.

1. **Release (= entry) assessment (R)** (i.e. any disease organisms entering Australia irrespective of the level of pathogen titre).

   The unrestricted probability of P. Salmonis entering Australia as a consequence of importing head off and eviscerated adult salmon would be **high**[5] (70 to 100%, average say 85%) because:-

   - Most Chilean salmon are infected at a chronic level and generally go through more than one phase of clinical infection (seasonally related).
   - Harvested fish may have both clinical and subclinical infection.
   - Sub-clinically infected and clinically infected fish showing low level signs will not be graded out on production lines.

[2] See "Describing Impacts", pages 7 & 8 of this document.

[3] "Import Risk Analysis of Non-viable Salmonids & Non-salmonid Marine Finfish" AQIS, July 1999, p 105-109

[4] As per Australian Quarantine Policy Memorandum 2000/26.

[5] See Table 1, "Nomenclature for Qualitative Likelihoods", page 4 of this document.

- It is very likely that P. salmonis will be in the skin, somatic musculature, and any residual kidney tissue of eviscerated Chilean salmon imported into Australia.
- Probability of introduction occurring in a shipment of *just one container* may in fact be close to 100%.

*This recalculated probability is in contrast to the finding of the 1999 IRA which was listed as **very low**.*

2. Exposure assessment (E)

- Pathway to marine environment would be via inadequate waste disposal controls (Sydney Fish market) or raw product being used for fish bait / thrown overboard from a boat or from a beach picnic.
- On entering the marine environment infection is possible through multiple routes. This pathogen is reported to remain viable for up to two weeks in the marine environment without a host.
- In Tasmania the water temperatures that are ideal for *P. Salmonis* would be prevailing when smolts are going to sea and AGD infection is getting more severe. These are highly vulnerable conditions for infection to take hold.
- Tasmanian experience with a similar but less virulent strain of rickettsia-like organism demonstrates that salmon have become infected through exposure to low doses.
- Taking a conservative approach probability of E is assessed as being **low** (5 to 30%, average say 17.5%) for juvenile adult or market size stocks of salmon.

*This recalculated probability is in contrast to the finding of the 1999 IRA which was listed as **very low**.*

3. Probability of Disease Establishment (R x E)

- R = 0.7 to 1.0, average say 0.85
- E = 0.05 to 0.3, average say 0.175
    - Average R x E = 0.15 = **low**
    - At high end of probability range R x E = 1.0 x 0.3 = 0.3 = **moderate**
- This demonstrates the fickleness and inadequacy of nomenclature of likelihood[6].

*This recalculated probability is in contrast to the finding of the 1999 IRA which was listed as **very low**.*

4. Consequence Assessment

- There are no adequate control measures at this point for the Chilean strain of *P. salmonis* strain.
- Industry would be commercially wiped out by disease establishment. (Though not at the same GVP level as beef, wheat etc, the Industry is of national importance, with a GVP of some $170M and supplying over 80% of the domestic market for fresh, frozen, and value added salmonid product.)
- There is no way of eradicating the disease from the environment.

[6] See Table 1, "Nomenclature for Qualitative Likelihoods", page 4 of this document.

- Recreational salmonid based industries and native species could also be impacted.
- Hence the consequence is defined as **high**.

*This recalculated probability is in contrast to the finding of the 1999 IRA which was listed as **low to moderate**.*

5. Unrestricted Risk Estimate

Risk Evaluation Matrix Figure 1.1, from p14 of the 1999 IRA

Figure 1.1

Risk evaluation matrix

PROBABILITY OF ESTABLISHMENT	N	L	M	H	C
H	yes	no	no	no	no
M	yes	no	no	no	no
L	yes	yes	no	no	no
VL	yes	yes	yes	no	no
EL	yes	yes	yes	yes	no
N	yes	yes	yes	yes	yes

SIGNIFICANCE OF CONSEQUENCES

'Yes' = the risk is acceptable and importation can be permitted.
'No' = the risk is unacceptable and importation cannot be permitted without further risk management.
Level of probability: H=high, M=moderate, L=low, VL=very low, EL=extremely low, N=negligible.
Level of significance: C=catastrophic, H=high, M=moderate, L=low, N=negligible.
Source: AQIS (prepared for this IRA, 1999).

- A **high** significance of consequence and **low** probability of establishment **does not meet Australia's ALOP**.
- Hence from the recalculation presented in this paper a higher level of risk management is required.

If the case for high consequence is agreed, then probability of establishment has to drop to extremely low before head-off & eviscerated becomes an accepted risk management measure. Even if consequence was rated at medium, a low probability of establishment would still require risk management measures greater than head off and eviscerated.

*This recalculated probability is in contrast to the finding of the 1999 IRA which was listed as **meeting Australia's ALOP**.*

APPENDIX 2b

CONSEQUENCE ASSESSMENT (Extract from Pilchards IRA 2003)

Table 4 - Nomenclature for qualitative likelihoods

Likelihood	Descriptive definition	Probability (P)
High	The event would be very likely to occur[7]	Range= 0.7 → 1
Moderate	The event would occur with an even probability	Range= 0.3 → 0.7
Low	The event would be unlikely to occur	Range= 0.05 → 0.3
Very low	The event would be very unlikely to occur	Range= 0.001 → 0.05
Extremely low	The event would be extremely unlikely to occur	Range= 10^{-6} → 0.001
Negligible	The event would almost certainly not occur[3]	Range= 0 → 10^{-6}

Criteria for assessing the consequences associated with a pest or disease incursion are outlined in the relevant Australian legislation and international agreements, and in the standards prepared by the OIE. In particular:

The Quarantine Act requires decision-makers to take into account the likelihood of harm being caused (to humans, animals, plants, other aspects of the environment, or economic activities) and the probable extent of the harm (Section 5D).

The SPS Agreement states that:

> *Members shall take into account as relevant economic factors; the potential damage in terms of loss of production or sales in the event of entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.*

The OIE expand the 'relevant economic factors' described in the SPS Agreement and provide examples of factors that typically will be relevant to an import risk analysis. In each case, consequence assessments do not extend to considering the benefits or otherwise of trade in a given commodity, nor to the impact of import competition on industries or consumers in the importing country.

The *OIE Code* also states that a consequence assessment should '*describe the potential consequences of a given exposure, and estimate the probability of them occurring*'. This approach is reflected in the Quarantine Proclamation 1998, which requires that the '*probable extent of the harm'* is considered in making quarantine decisions.

Estimation of likely consequences are addressed in terms of direct and indirect impacts on animal and plant life and health *on a national scale*, including economic, environmental and social effects (as detailed below); and separately in terms of consequences to human life or health.

[7] A probability of 1 means the event will occur and a probability of 0 means the event will never occur. A probability of 10^{-6} corresponds to a one in a million chance of an event occurring.

The latter is dealt with separately because responsibility for trade on matters of human life or health does not rest with Biosecurity Australia. It is also relevant that under the SPS Agreement, matters of human life or health are assessed against the separate ALOP that applies to human health. Because there is no known report of VHSV infecting humans, no further consideration is given in this assessment to impacts to human health or life.

The following sequences of steps were taken in assessing the consequences associated with VHSV entry and exposure:

1. Identify the major outbreak scenarios that may occur as a result of the occurrence of an index case of VHS
2. Determine the likelihood of each outbreak scenario occurring – to obtain a partial likelihood of establishment and spread (PLES) for each outbreak scenario
3. Determine the level of adverse (economic, social and environmental) impacts resulting from each outbreak scenario
4. Combine the partial likelihood of occurrence of each potential outbreak scenario with the corresponding estimation of adverse impacts to obtain an estimation of the 'likely consequences' – or partial risk of establishment and spread (PRES) – associated with each outbreak scenario
5. Combine these outbreak scenario-specific consequences to obtain an overall estimation of 'likely consequences' resulting from the infection of a susceptible host fish in Australia.

Despite the fact that three main exposure scenarios (tuna feed, rock lobster fishing bait and line fishing bait) have been identified, this assessment considered there to be only a single exposure group, namely, susceptible populations of free-ranging (wild) marine finfish. It is assumed that virus spread from free ranging marine fish into local salmonid populations (both captive and wild) would eventually occur, should VHSV establish in a local wild fish population, anywhere in Australia. *As such, the level of adverse impacts (item 3 above) associated with disease establishment through any of the three exposure scenarios is the same and is not calculated separately for each of the three exposure scenarios.*

Consequence assessment also requires estimating the likelihood that disease would establish and spread (item 2 above). Based on overseas experience, water temperature and seasonal changes in water temperature are considered central in this regard. As such, climatic differences (and therefore the geography) associated with each of the three end-uses (exposure scenarios) would be a critical factor influencing the likelihood that disease would establish and spread within a local wild fish population. *The consequence assessment component of this report takes a cautious approach by assuming end-use in the most high-risk areas, namely the relatively cold waters of southern Australia, including off the coast of Tasmania.*

By adopting this approach, it was possible to determine a single estimation of likely consequences that could be applied to each end-use for calculating the risk associated with each of the three corresponding exposure scenarios.

1. Identification of outbreak scenarios

In this analysis the potential outbreak scenarios are restricted to the following two:

(i) Virus does not spread from index case and does not establish in an Australian fish population.

In this outbreak scenario the number of index cases would not be sufficient to ensure the disease established in a local population of wild fish near the tuna farms. In ecological terms, there would be insufficient "propagule pressure" (the rate of introduction of VHSV infected fish – index cases – into an environment) for the disease to establish in a susceptible population. All infected fish (there may be multiple individual index cases), would die before transmitting disease to other fish.

(ii) Virus spreads from index case/s and establishes in an Australian fish population.

In this outbreak scenario the level of propagule pressure would be sufficient to ensure establishment of disease in a local population and subsequent spread of VHSV to its natural geographical limits in all potentially susceptible fish species.

The second outbreak scenario incorporates the possible spread of marine VHSV to Australian salmonid populations with associated adverse impacts, including loss of export markets*. The likelihood of spread to salmonid populations is assumed to be high, if VHSV establishes in a non-salmonid marine finfish population.*

2. Likelihood associated with outbreak scenarios

When determining the likelihood associated with each of the two outbreak scenarios, qualitative descriptors such as *negligible*, *low*, *moderate* etc, are used as detailed previously. Factors considered in evaluating the likelihood associated with each outbreak scenario include the likely routes of transmission and environmental conditions (specifically water temperature).

3. Adverse (economic, social and environmental) impacts

The 'potential impacts of an exposure' may be direct or indirect. The direct and indirect impacts considered in this assessment are as follows:

Direct impacts

These describe direct impacts on:

- life or health (including production effects) of production, domestic or feral animals; or the life or health (including production effects) of commercially cultivated, garden or feral plants.
- the living environment, including the life or health of native animals and plants, and any impacts on the non-living environment

Indirect impacts

These describe impacts on:

- new or modified eradication, control, surveillance or monitoring and compensation strategies or programs
- domestic trade or industry, including changes in consumer demand and impacts on other industries supplying inputs to, or utilising outputs from, directly affected industries

- international trade, including loss of markets, meeting new technical requirements to enter or maintain markets and changes in international consumer demand
- indirect impacts on the environment (see below), including biodiversity, endangered species, the integrity of ecosystems
- indirect impact on communities, including reduced tourism, reduced rural and regional economic viability and loss of social amenity, and any 'side effects' of control measures.

A range of factors is relevant to the consideration of harm to the environment. This includes harm arising from the impact of the disease agent itself, as well as from any treatments or procedures used to control it. The extent of harm was evaluated taking into account the factors outlined below:

- all on-site and off-site impacts
- the geographical scope and magnitude of the impact
- the frequency and duration of the action causing the harm
- the total impact which can be attributed to that action over the entire geographic area affected, and over time (i.e. cumulative impact)
- reversibility of the impact
- the sensitivity of the receiving environment (recognised environmental features of high sensitivity)
- the degree of confidence with which the impacts of the action are known and understood.

The direct and indirect consequences described above collectively cover the *economic*, *environmental* and *social* effects of a disease. Given this, the consequences are also mutually exclusive — that is, an effect was not assessed more than once. In particular, the direct effects of a disease on a native or wild species were assessed under the criterion describing the '*the living environment, including the life or health of native animals and plants, and any impacts on the non-living environment*', whereas the indirect or 'flow-on' effects on the environment were assessed under 'indirect impacts on the environment' criterion.

Describing direct and indirect impacts

Two groups of qualitative descriptors have been adopted by Biosecurity Australia to describe the impact of a pest or disease on each of the identified direct and indirect criteria:

Level of impact — consequences accrued at a national, State or Territory, district or region and local level.

Magnitude of impact — the relative seriousness of the consequences of a pest or disease at a national, State or Territory, district or region and local level.

Level of impact

Although the consequences of a pest or disease agent will ultimately be assessed on a national scale, it will be helpful to describe it also at the 'State or Territory', 'district or region' or 'local' level. These are defined as follows:

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National: Australia-wide.
State or Territory: an Australian 'State' (New South Wales, Victoria, Queensland, Tasmania, South Australia or Western Australia) or 'Territory' (the Australian Capital Territory, the Northern Territory.
District or region: a geographically or geopolitically associated collection of local aggregates — generally a recognised section of a State or Territory, such as the 'North West Slopes and Plains', 'East Gippsland' or 'North Queensland'.
Local: an aggregate of households or enterprises — e.g. a rural community, a town or a local government area.

Magnitude of impact
The magnitude of impact on each criterion is evaluated by Biosecurity Australia using four qualitative terms. These terms can be applied to impact on a national scale, or at the State or Territory level, the district or regional level, or local level. At each level, the frame of reference should be the impact on the community at that level, which will often differ markedly from the impact of the pest or disease on directly affected parties.

Unlikely to be discernible: indistinguishable from day-to-day variation.
Minor: recognisable, but minor and reversible.
Significant: serious and substantive, but unlikely to disrupt either long-term economic viability or the intrinsic value of the criterion.
Highly significant: extremely serious and irreversible and likely to disrupt either economic viability or the intrinsic value of the criterion.

Assessing direct or indirect impacts on a national scale
A national scale implies the collective consequences of a pest or disease on the Australian economy or community. To estimate consequences on this scale, it is necessary to describe carefully the outbreak scenario upon which the consequence assessment is based. This includes the likely number and distribution of affected areas, districts or regions and States or Territories, as well as the number, distribution and characteristics of affected industries or communities, and relevant aspects of the environment.

Biosecurity Australia uses a structured qualitative framework to assess the direct or indirect consequences of a pest or disease on a national scale. This framework is described schematically in Table 5 below. Under this schema, the first step is to assess the magnitude of direct or indirect impact on the national economy or the Australian community. If, for that particular criterion, there is no discernible impact at a national level (i.e. if there would be no discernible impact on the national economy, or no threat to a thing of value to the Australian community), then, in descending order, the magnitude of impact at the State or Territory level, the district level or the local level will be investigated. This results in a left-to-right movement through the columns of the table.

Two additional points will be relevant:

- The impact of a pest or disease at a given level on more than one State or Territory, more than one district or region, or more than one local area, may represent the same magnitude of impact at the level above. For example, a pest or disease outbreak in several States or Territories, with a 'minor' direct impact on the environment in each

affected State or Territory, would be considered to have a 'minor' impact at the national level.

- At each of the lower levels, an impact more serious than 'minor' is understood to be discernible at the level above. In this situation, the magnitude of impact at the level above should be considered. For example, a pest or disease with a 'significant' indirect impact on local communities would have, at least, a 'minor' impact at the district or regional level.

Estimates of the consequences of the introduction, establishment and spread at the local, district, regional and national level were subsequently translated to an overall score (A–G) using the schema outlined in Table 5.

Assessment of direct or indirect impacts on a national scale

Impact score	National	State or Territory	District or region	Local
G	**Highly significant**[1]	–	–	–
F	**Significant**		–	–
E	**Minor**			–
D	Unlikely to be discernible	**Minor**		
C	–	Unlikely to be discernible	**Minor**	
B	–	–	Unlikely to be discernible	**Minor**
A	–	–	–	**Unlikely to be discernible**
		Level		

[1] Shaded cells with bold font are those that dictate national impact scores

After obtaining a measure of individual direct and indirect VHSV-associated consequences, these were combined to estimate the overall consequences associated with each outbreak scenario. Individual effects on each direct and indirect criterion were summed using the following rules. The rules are mutually exclusive, and were addressed in the order that they appear in the list. For example, if the first set of conditions does not apply, the second set is considered. If the second set does not apply, the third set is considered..., and so forth until one of the rules apply:

1. Where any direct or indirect effect is 'G', the overall consequences associated with the outbreak scenario were considered to be '*extreme*'.
2. Where more than one direct or indirect effect is 'F', the overall consequences associated with the outbreak scenario were considered to be '*extreme*'.
3. Where a single direct or indirect effect is 'F' and each remaining direct or indirect effect is 'E', the overall consequences associated with the outbreak scenario were considered to be '*extreme*'.

4. Where a single direct or indirect effect is 'F' and remaining direct and indirect effects are not unanimously 'E', the overall consequences associated with the outbreak scenario were considered to be '*high*'.
5. Where all direct and indirect effects are 'E', the overall consequences associated with the outbreak scenario were considered to be '*high*'.
6. Where one or more direct or indirect effect is 'E', the overall consequences associated with the outbreak scenario were considered to be '*moderate*'.
7. Where all direct and indirect effects are 'D', the overall consequences associated with the outbreak scenario were considered to be '*moderate*'.
8. Where one or more direct or indirect effect is 'D', the overall consequences associated with the outbreak scenario were considered to be '*low*'.
9. Where all direct and indirect effects are 'C', the overall consequences associated with the outbreak scenario were considered to be '*low*'.
10. Where one or more direct or indirect effect is 'C', the overall consequences associated with the outbreak scenario were considered to be '*very low*'.
11. Where all direct and indirect effects are 'B', the overall consequences associated with the outbreak scenario were considered to be '*negligible*'.
12. Where one or more direct or indirect effect is 'B', the overall consequences associated with the outbreak scenario were considered to be '*negligible*'.
13. Where all direct and indirect effects are 'A', the overall consequences associated with the outbreak scenario were considered to be '*negligible*'.

4. Combination of the partial likelihood of occurrence of each potential outbreak scenario with the estimated adverse impacts

Having obtained an estimate of the consequences associated with each outbreak scenario, this was combined with the likelihood that the scenario will occur and thus a scenario-specific measure of 'likely consequences', or 'risk', was derived.

The matrix in Table 6 was used to combine likelihood of each outbreak scenario occurring with the respective consequences of occurrence. By applying the table systematically, the 'likely consequences' were derived for each outbreak scenario.

Likely consequences: a combination of the likelihood of establishment and spread and its consequences

Probability of establishment and spread	Negligible	Very low	Low	Moderate	High	Extreme
High	Negligible	Very low	Low	Moderate	High	Extreme
Moderate	Negligible	Very low	Low	Moderate	Moderate	High
Low	Negligible	Negligible	Very low	Low	Low	Moderate
V. Low	Negligible	Negligible	Negligible	Very low	Very low	Low
E. Low	Negligible	Negligible	Negligible	Negligible	Negligible	Very low
Negligible	*Negligible*	*Very Low*	*Low*	*Moderate*	*High*	*Extreme*

Consequences of establishment and spread

APPENDIX 2b

5. Combination of outbreak scenario-specific consequences

Because the likely consequences associated with each of the outbreak scenarios have been derived qualitatively (i.e. not quantitatively), these cannot be 'summed' in the usual sense. Instead, a system of eleven rules has been developed to provide a conservative approximation. These rules are mutually exclusive, and should be addressed in the order that they appear in the list. For example, if the first set of conditions does not apply, the second set should be considered. If the second set does not apply, the third set should be considered ..., and so forth until one of the rules apply:

1. Where the likely consequences for any outbreak scenario are '*extreme*', the overall likely consequences are also considered to be '*extreme*'.
2. Where the likely consequences for more than one outbreak scenario are '*high*', the overall likely consequences are considered to be '*extreme*'.
3. Where the likely consequences for a single outbreak scenario are '*high*' and the likely consequences for each remaining scenario are '*moderate*', the overall likely consequences are considered to be '*extreme*'.
4. Where the likely consequences for a single criterion are '*high*' and the likely consequences for remaining criteria are not unanimously '*moderate*', the overall likely consequences are considered to be '*high*'.
5. Where the likely consequences for all criteria are '*moderate*', the overall likely consequences are considered to be '*high*'.
6. Where the likely consequences for one or more criteria are '*moderate*', the overall likely consequences are considered to be '*moderate*'.
7. Where the likely consequences for all criteria are '*low*', the overall likely consequences are considered to be '*moderate*'.
8. Where the likely consequences for one or more criteria are '*low*', the overall likely consequences are considered to be '*low*'.
9. Where the likely consequences for all criteria are '*very low*', the overall likely consequences are considered to be '*low*'.
10. Where the likely consequences for one or more criteria '*very low*', the overall likely consequences are considered to be '*very low*'.
11. Where the likely consequences for all criteria are '*negligible*', the overall likely consequences are considered to be '*negligible*'.

The result of the complete process is a qualitative descriptive estimate for the likely consequences associated with the introduction of VHSV into Australia.

APPENDIX 3

Written By:	Bertrand Charron
Category:	Editorial
Date Posted:	22/02/2008 11:11 AM

IS CHILE FOR REAL? Chilean salmon industry ducking its head in the sand won't help its global image!

The Chilean salmon farming industry has now - for years - been considered as the *El Dorado* of salmon farming's 21st century prospects. It has in the south of the country great fjord-like coastlines, ideal sea temperatures for salmonid on-growing, an economy geared towards liberalism and international trade, and a willing workforce as well as local capital and a good logistics infrastructure. It is also well situated for frozen exports to the Japanese and US markets; both of which are proving salmon-hungry.

However, Chile is lagging far behind other salmon producing nations in how it communicates – and wishes to accept the very principle – with local stakeholders and international environmental NGOs (Oceana, Greenpeace, WWF, etc…); some of whom relate to the broad concerns of consumer groups in other parts of the world. By "industry", we don't just mean the salmon industry's representative body, but all of the main players.

Labour conditions are a sore point; as exemplified by the various disputes of current (AquaChile-owned Aguas Claras) and past times. Addressing multi-stakeholders' and environmental concerns seems to be the last point on the agenda. Growth (and now lack of.) seems to come first.

Fine - we'd say - if the industry is sustainable from a human, economical and environmental perspective. But, is it? And is the industry willing to discuss & address those issues?

It would seem not.

Now, the transparency issue is also affecting the results of stock-exchange listed companies. This week, Marine Harvest announced the planned lay offs of a quarter if its staff (1,000+) in Chile. All of this because of the poor Q4 2007 results announced last week, revised forecast & outlook for 2008-2010 due to the ISA salmon disease.

In 2000, the Chile's salmon farming industry was going on the record (re. *interview to the present writer*) as casting doubts over the very existence of the ISA virus in farmed salmon in the country. This even though ISAv's presence in Chilean farmed coho salmon had been reported from scientists at the Atlantic Veterinary College (AVC) at the Canadian University of Prince Edwards Island (PEI) and described in scientific literature. The OIE even confirmed last summer that ISA "*had been previously detected in Chile in 1999"*. Then, we were told for years that there are & were no particular 'fish health' or 'biological' problems. No sea lice issues, no ISA problems, etc... And even if there were a few 'incidents'; by no means did these impact the industry – officially. But there were many warning lights.

Are investors truly dumb? Do they necessarily believe everything they are fed from 'official sources' – and should they?

Indeed, things can be kept in the dark when one is far away from the world's markets and media. But now that Chile's 'salmon industrialists' want to be part of the world

globalisation & trade, have FTAs left right and centre; and sell their salmon worldwide; they can't have it both ways! i.e. tell 'outsiders' not to stir things nor ask embarrassing questions; and on the other hand take the cash of foreign investors and want to be part of that global market; never mind attract the capitals of large multi-nationals, which now have to abide to published corporate ethics, and can themselves feel the full brunt of consumer & market power.

All of that even before considering the fact that stock exchange salmon farmers (Cermaq/Mainstream/Ewos, Marine Harvest) have to report their quarterly results, thus exposing *some* of the 'biological and business' facts out there. (See *SeafoodIntelligence*'s **Børs Seafood Watch**). Otherwise, we could be scrutinising the horizon for a long time through pink (salmon)-tinted glasses…

Salmon stocks have tumbled in the past months & weeks on the Oslo Børs – the most advanced in that sector. The fall in share value for the world #1 & 2 companies can be directly linked to the reduced 'performance' and 'biological situation' experienced by their Chilean operations. AquaChile, the country's #1 producer and World #3, pulled out in October 2007 from a Santiago stock exchange listing, due to an 'unfavourable' market climate & also blaming the current "uncertainty" in 'fish health situation' [see AquaChile CEO Victor Hugo Pucci's comment earlier this week in *La Tercera*: **Biz & Finance : MOTIVATION to invest in Chile's salmon farming industry? There are 'non-economic ingredients'… (20.08.2008).]**.

Meanwhile - even long after Marine Harvest revised its 2007 Chilean production forecast in October and November 2007 – the Chilean industry representatives kept to the '*Crisis? What Crisis? No Crisis!*' mantra. Didn't SalmonChile's President, César Barros, deny on November 14th the 'supposed crisis' the industry was in, though acknowledging that 2007 did not unfold 'as they had anticipated at the end of last year'… Even yesterday (February 21st) he was quoted in the Chilean press as saying that Marine Harvest's decision to lay-off 25% of its workforce in Chile "will not affect the image of the industry".

REALLY? What makes you so sure?! Are we talking about "the image" the industry wants to project of itself, or the industry's image as perceived from abroad?

Do people want to invest in Marine Harvest – thus in Marine Harvest Chile - in the light of its dismal results lately? Suffice to say that at 13.27 last Friday (Feb. 15th) - hours after releasing its 'disappointing' Q4 2007 results - the price of Marine Harvest's shares on the Oslo Børs had plunged 10.36%. Since January 1st 2008 (and @ 11.12 GMT+1 on 22.01.2008), MHG shares lost 23.77% in value; and 63.81% in the past 12 months; most of this abysmal fall came after the Chilean forecast warning of October 2007… So, is pretending that '*all is well, regardless*…' good for the industry - never mind its image?

ISA was a (very) long time coming though… Throughout the early summer 2007 (as ***SeafoodIntelligence*** readers will recall); there was plenty of warning signs that sea lice and ISA (discovered in 1999, lets remember; and some reports even claim that sea lice could be an ISA vector) were becoming an issue in Chile. But one could only read comforting 'no problem' & 'no issue' statements.

Is Chile's salmon industry to blame for all this? "*Strongly, but not solely*" would be the answer. Indeed, the Chilean establishment seems to frown upon any input from "strangers". But lets also be fair, there aren't many countries' industry that would welcome open-armed any & all type of criticisms. It is an arduous process which takes time and openness. But the sooner it starts the better…

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So who else is to blame? Well, one could look at some of the Norwegian businessmen and US investment funds - among others - who could be accused to prioritise the 'favourable' economic & investment climate over a more global perspective encompassing as well environmental sustainability before taking business decisions. Low-cost labour = lower production cost, of course. But is this all? As we've highlighted many times before, a market - still very much cyclical - such as the farmed salmon one is very much linked to veterinary, fish health and environmental issues. And the latter (and/or their mediatisation) can indeed decide the fate of both price trends and multinationals' dividends...

Thus, what is 'ethically right' from an investor's perspective? And how does one balance the pursuit of economic gain with the interest of other concerned stakeholders? Lets not forget - and many salmon farmers are truly aware of this fact - that, foremost, the salmon farming/aquaculture industry's future depends as well on the well-being of the environment which supports and nourishes it.

Intrinsically thus, the issue is NOT REALLY about ISA, sea lice or labour conditions in particular; it is about developing a sustainably industry in a sustainable fashion.

Because this industry grows salmon in great environmental surroundings, then environmental issues should be addressed. Because this industry employs people, then labour conditions issues should be addressed. Because the industry grows salmon in an environment of which it is not the sole tributary, multi-stakeholder dialogue should take place. And because this industry trades with other countries on other markets, then it should provide objective information to those markets. [Read in passing the note: **INFORMATION LACKING about impact of April earthquake… How is Chile's salmon industry affected? (13.06.2007)]**

The end word of all this is that the Chilean salmon farming industry's attitude HAS TO CHANGE and a) acknowledge that there are problems, and b) address them. Otherwise, beware the backlash!

Other countries had to follow the same learning-curve in their dealings with other stakeholders; but Chile is now certainly not leading the pack in that respect. However close to the Antarctic as they may be, Chileans cannot live in isolation and seriously believe that a one-sided relationship with their own workers, investor's perspective, NGOs and world media will 'do it'.

The more Chile's salmon industry resists the move towards better communication, the longer it will take to truly go forward. This is also the realisation made by some prominent members of the Chilean government (when it comes to labour dispute and its handling). All it takes is one 'scandal' - one 'food scare', and sometimes one article/news report in a prominent (but foreign in Chile's case) news media - and by means of a lack of transparency an entire industry/market *could* collapse; particularly in the food business.

With market access comes the need for transparency and openness. If one should only learn one thing from 2007's "biological situation" & the stock plunges; it should surely be to admit that burying one's head in the sand (and projecting that image to the world) is not the best business solution, right?! If players in Chile's salmon farming industry seriously aim to make the country the world's #1 Atlantic salmon producer; then they must work at their communication, and be pro-active in establishing multi-stakeholder dialogues as well.

And if it's any consolation… Chile is not the only country which should improve on those fronts!

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PS: A good start would *also* be to have some communications issued in English (we selfishly comment on behalf of environmental & business parties interested… ☺) as the country's main three market are Japan, the US and the EU. It could also help, in getting their word out, if they decide to…

Read also ***a few*** of the relevant articles on the ***SeafoodIntelligence***.com News Database:

- **HOT News : UNDERESTIMATED 'BILOGICAL SITUATION'! Marine Harvest will now lay off 1,000+ of Chilean workforce (22.02.2008).**
- **Biz & Finance : MOTIVATION to invest in Chile's salmon farming industry? There are 'non-economic ingredients'… (20.02.2008).**
- **Trends & Forecasts : CHALLENGE: Expanding in Chile's Region XI & XII will increase salmon production costs re. logistics (19.02.2008).**
- **Biz & Finance : CONSOLIDATION, M&As: In 1997, 117 firms produced 80% of farmed Atlantic salmon; In 2006, it was 46… (19.02.2008).**
- **Market Comment & Prices : OF ISA… World's #1 salmon producer plans 'significant downward adjustment' in Chile's Region X (15.02.2008).**
- **Veterinary & Animal Health : Mainstream Chile had two sites with ISA outbreaks + 1 site included on the 'suspected' list (14.01.2008).**
- **Veterinary & Animal Health : "Main problem in Chile is sea lice; ISA had a relatively minor direct impact" – Cermaq (25.01.2008).**
- **Veterinary & Animal Health : GROWING list of Chilean salmon sites impacted by ISA, now reaches 13; 11/13 belong to Marine Harvest (16.01.2008).**
- **HOT News : ISA 'NO FUN': Marine Harvest Chile to continue journey SOUTH; salmon giant now considers Region XII… (21.12.2008).**
- **HOT News : UPDATED! ISA virus found in Chile's most-promising (and until now ISA-free) salmon producing region (20.12.2008).**
- **Biz & Finance : Eight ISA-impacted sites in Chile & 40+ quarantined; 'Closures could lead to hundreds of lay-offs' (10.12.2008).**
- **Veterinary & Animal Health : Chile's 'biological situation' problems began long before ISA showed up; 'virus is only a symptom' (22.11.2008).**
- **HOT News : Marine Harvest plans closure of several ISA-diseased salmon farms in Chile; Shift to Region XI (22.11.2007).**
- **Biz & Finance : Santiago-listed salmon firms also feel the pinch of Chilean 'crisis': Double digit falls there too (20.11.2007).**
- **'Wild vs. Farmed' : "CRISIS LOOMS: Mismanagement, lack of information – as ISA – pose serious problems to Chile" (20.11.2007).**
- **HOT News : 'WHAT CRISIS?! Chilean salmon industry denies problems but acknowledges Norway is 'more experienced' (16.11.2007);**
- **HOT News : Marine Harvest shares lost 21.73% of their value in one week! Will the debacle continue today? (16.11.2007).**
- **Biz & Finance : BLACK THURSDAY for Marine Harvest: Share price plummets (again), ISA impacts investors' confidence? (15.11.2007).**
- **Biz & Finance : BLACK THURSDAY for Marine Harvest: Share price plummets (again), ISA impacts investors' confidence? (17.10.2007).**
- **Veterinary & Animal Health : Chilean salmon industry reeling from ISA impact & high mortalities; 'Sea lice is probably a vector'? (17.08.2007).**
- **Veterinary & Animal Health : Only a footnote, but International body says ISA was in Chile in 1999, despite dismissal at the time (13.08.2007).**
- **Veterinary & Animal Health : No ISA outbreaks at any of Mainstream Chile's sites; firm established three new sites in region XI (10.08.2007).**
- **Veterinary & Animal Health : 'Major global threat': Outbreak of infectious salmon anaemia (ISA) in Chilean salmon farms (08.08.2007).**
- **Veterinary & Animal Health : Chilean authorities acknowledge seriousness of sea lice issues; Pure Salmon warns American public (11.07.2007).**
- **Veterinary & Animal Health : 'ISA UNDER CONTROL?'… 32 Norwegian outbreaks of Infectious Salmon Anaemia in 2003-05; 4 in 2006… (25.06.2007).**
- Etc…