

***Additional Background Information: Review
of zoosanitary requirements for the import
into New Zealand of salmonids for human
consumption from specified countries
(fissalic.spe) in relation to potential import
from Chile***

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20 August 2007

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1. Executive summary

In response to requests for the import of dead salmonid fish for human consumption from Chile, MAF has been requesting information from the Chilean authorities (SERNAPESCA) about their fish health surveillance programmes; however, it has proven difficult for MAF to fully assess the equivalence of the Chilean health surveillance system from the information provided.

To address this issue, the import health standard for the importation into New Zealand of salmonids for human consumption from specified countries (fissalic.spe), and in particular the zoosanitary requirement for a health surveillance programme, has been reviewed against both the underpinning risk analysis (Stone *et al.* 1997) and new information obtained since the risk analysis was written to assess if an equivalent zoosanitary recommendation could be developed.

It is concluded that, of the seven organisms originally concluded to be of *low* risk, the causative agent of erythrocytic inclusion body syndrome (EIBS), *Henneguya salminicola* and *Kudoa* species did not need to be considered in this review as the risk management measure in question, that is the existence of a health surveillance programme, was not originally intended to cover those organisms. In addition there was new evidence that infectious pancreatic necrosis virus (IPNV) and *Aeromonas salmonicida* should be considered to be of *negligible* risk in the defined commodity and could also be excluded from the review.

The review concluded that any equivalent measure to the requirement for a health surveillance programme need only apply to two organisms, namely infectious haematopoietic necrosis virus (IHNV) and viral haemorrhagic septicaemia virus (VHSV), and that the intent of the requirement could be adequately met if the organisms were compulsorily notifiable to the Competent Authority in the exporting country.

2. Background

The import health standard [FISSALIC.SPE] for the importation into New Zealand of salmonids for human consumption from specified countries (Specified countries: Canada, Norway and the United States of America) was based on the 1997 import risk analysis for salmonids for human consumption (Stone *et al.* 1997).

The specific zoosanitary conditions required in that import health standard (IHS) are: -

- 1) The product for export is derived from fish within the genera *Oncorhynchus*, *Salmo* and *Salvelinus*.
- 2) The product for export is derived from fish that were harvested from a population for which a documented health surveillance programme exists which is administered by a competent government-authorized agency.
- 3) The product for export is derived from fish that were not slaughtered as an official disease control measure as a result of an outbreak of disease.
- 4) The product for export is derived from fish that were processed in a premise under the supervision of a competent government-authorized regulatory agency with responsibility for food safety standards during processing of fish for export. During processing the fish were:
 - i) headed, gilled and gutted;
 - ii) individually inspected and graded, ensuring the product for export is free from visible lesions associated with infectious disease and fit for human consumption; and
 - iii) found to be sexually immature, or sexually maturing, but not sexually mature.

The 1997 risk analysis considered 42 potential hazards. Of these, it was concluded that 35 posed a *negligible* risk of introduction and were not therefore actual hazards. It was also concluded that the remaining seven organisms posed a *low* risk of introduction. These seven actual hazards were determined to be:

- Infectious pancreatic necrosis virus (IPNV)
- Infectious haematopoietic necrosis virus (IHNV)
- Viral haemorrhagic septicaemia virus (VHSV)
- The causative agent of erythrocytic inclusion body syndrome (EIBS)
- *Aeromonas salmonicida*
- *Henneguya salminicola*
- *Kudoa* sp.

The risk analysis concluded that, as the consequence of introduction of salmonid diseases into New Zealand could be severe (page 7), it was appropriate that risk management measures should exceed the OIE recommendations. The risk analysis recommended that these measures should include a documented health surveillance system in the exporting countries, export certification by the exporting country's Competent Authority that the consignments meet the commodity definition and that bulk consignments are subject to further requirements. For the purposes of the import health standard, product in bulk form is defined as "*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*". Imports of product in bulk form require a permit to import for each consignment and are not eligible for biosecurity clearance at the New Zealand border, but must be directed to a transitional facility. Product not requiring further packaging and/or processing prior to retail sale e.g.

retort pouch packaged single fish or hermetically sealed packages of fish portions are classified as *commercially packaged for direct retail sale*, do not require a permit to import and are eligible to receive biosecurity clearance at the New Zealand border.

Importers have been requesting the development of an IHS for salmonids from Chile for a number of years. In response, MAF has been requesting information from the Chilean authorities (SERNAPESCA) about their fish health surveillance programmes; however, it has proven difficult for MAF to fully assess the equivalence of the Chilean health surveillance system from the information provided.

The risk analysis group has been requested to re-examine the agents listed as posing a *low* risk of introduction (i.e the actual hazards) and the zoosanitary requirement for a health surveillance programme to determine if an alternative risk management measure may be appropriate, given any available new information, to permit the import of salmonids for human consumption from Chile.

The Customs Import Prohibition (Trout) Order 2000, administered by the New Zealand Customs Service, prohibits the importation of trout and trout products in quantities exceeding 10 kilograms, or in quantities of less than 10 kilograms if the goods are intended for sale except with the consent of, and subject to such conditions as may be imposed by the Minister of Conservation. As a result of this legislation only certain species of salmonids can legally be imported.

3. Analysis of relevant documentation

3.1. STATUS OF ORGANISMS CONSIDERED AS POSING NEGLIGIBLE RISK

There is no new information to suggest that any of the organisms identified as posing a negligible risk in the commodity should be reassessed as posing a higher risk. This document will therefore only consider the organisms identified in the risk analysis as posing a low risk (i.e. actual hazards).

3.2. OIE POSITION REGARDING ORGANISMS OF INTEREST

Of the pathogens identified in the risk analysis as being of *low* risk, the OIE lists only IHNV and VHSV as reportable diseases, but still includes a short chapter on IPNV (OIE, 2006), although it has not been updated since 2003. Infection with *Aeromonas salmonicida* is no longer included in any context in the Aquatic Animal Health Code.

There are, therefore, no OIE recommendations regarding *A. salmonicida*, erythrocytic inclusion body syndrome (EIBS), *Henneguya salminicola* or *Kudoa* species.

The Aquatic Animal Health Code chapter on IPNV states “*when importing live or dead unviscerated fish of a susceptible species or their gametes or eggs, the Competent Authority of the importing country with an official control policy for infectious pancreatic necrosis may wish to require the presentation of an international aquatic animal health certificate issued by the Competent Authority in the exporting country, attesting that the country, zone or aquaculture establishment of origin has been regularly subjected to appropriate tests for infectious pancreatic necrosis with negative results.*” (OIE, 2006).

For both IHNV and VHSV the OIE position is that “*Competent Authorities should not require any IHN/VHS related conditions, regardless of the IHN/VHS status of the exporting country, zone or compartment*” for “*eviscerated fish (chilled or frozen) packaged for direct retail trade*” (OIE, 2006).

3.3. CONTENT OF THE HEALTH SURVEILLANCE REQUIREMENT SPECIFIED IN THE IHS

Page 12 of the risk analysis (Stone *et al.* 1997) provides discussion on the content of the health surveillance programme forming the zoosanitary requirement in question. This programme was expected to be “*sufficient to record the occurrence of the OIE listed diseases affecting salmonids*”.

Given that, at the time the risk analysis was conducted, the OIE listed diseases did not include the causative agent of EIBS, *H. salminicola* or *Kudoa* species, it can be concluded that the authors did not envisage the inclusion of these organisms in the surveillance programme specified within the zoosanitary recommendations.

The causative agent of EIBS, *H. salminicola* and *Kudoa* species can therefore be excluded from any further consideration, as the purpose of this document is solely to examine potential equivalence with the original health surveillance zoosanitary requirement. It is therefore only necessary to re-examine IPNV, *A. salmonicida*, IHNV and VHSV to determine if alternative risk management measures are equivalent.

4. Consideration of individual organisms

4.1. INFECTIOUS PANCREATIC NECROSIS VIRUS (IPNV)

The OIE Aquatic Animal Health Code recommends risk management measures for IPNV only for live fish and uneviscerated dead fish. MAF considered in the original risk analysis (Stone *et al.* 1997) that, because of the likely consequences of introduction of an exotic strain of IPNV into New Zealand and the conclusion that IPNV represented a *low* risk, further measures were justified.

There are a number of relevant points to consider in reviewing risk and risk management recommendations for IPNV, including information published since the original risk analysis was conducted in 1997.

- a. Exotic strains of IPNV are notifiable organisms in New Zealand;
- b. The risk analysis concluded that the likelihood of clinically infected fish being harvested is low, but that the likelihood of carrier fish being harvested is high (Stone *et al.* 1997) in IPNV enzootic areas;
- c. Average IPNV infectivity in various organs of carrier salmonids has been measured. The highest titre was found in the kidney ($10^{6.7}$ TCID₅₀/g), similar but lower titres were found in the stomach, ovary and liver ($10^{4.4} - 10^{4.6}$ TCID₅₀/g), lower titres were found in the spleen, foregut and hindgut ($10^{3.3}$ TCID₅₀/g) and the lowest titre was found in the muscle tissue ($10^{0.3}$ TCID₅₀/g = 2 TCID₅₀/g) (Wolf, 1988). The process of evisceration removes all the tissues with elevated viral titres;
- d. IPNV has been reported in Chile (OIE, 2006);
- e. An aquatic birnavirus (related to the less pathogenic Ab strain of IPNV) has been recorded from returning, sea run Quinnat salmon (*Oncorhynchus tshawytscha*) caught in the South Island of New Zealand on a number of occasions (Tisdall and Phipps 1987, Anderson 1996, Anderson 1998). The fish showed no clinical signs of infection. Aquatic birnaviruses have also been isolated from turbot and flounder following mass mortalities in aquaculture facilities in New Zealand, although these isolates were non-pathogenic to salmon (Horner 2003);
- f. The infectious dose of IPNV by immersion varies according to the strain of virus used and the salmonid species challenged. However, some useful information can be obtained from the recent challenge experiments with virulent Sp, N1 and VR-299 serotypes of IPNV: -
 - i. Challenge titres of 10^5 pfu/mL (approximately 1.4×10^5 TCID₅₀/mL) induced mortalities of up to 95% in brook trout (*Salvelinus fontinalis*) (McAllister and Owens 1995, McAllister *et al.* 2000) and 20% in Arctic char (*S. alpinus*) (McAllister *et al.* 2000);

- ii. Challenge titres of 10^4 TCID₅₀/mL induced mortalities of 20% to 76% in Atlantic salmon (*Salmo salar*) and 43% in *Salvelinus fontinalis* (Taksdal *et al.* 1997, Kjøglum *et al.* 2005); and
- iii. Challenge titres of 10^3 pfu/mL (approximately 1.4×10^3 TCID₅₀/mL) failed to induce mortalities in *S. alpinus*, but did result in $\leq 10\%$ carrier status (McAllister *et al.* 2000).

It is apparent that the viral titre required to induce infection by immersion challenge is less than 10^3 TCID₅₀/mL. Even to reach a highly conservative value of 10 TCID₅₀/mL it would be necessary to suspend the viral content of 5000g of muscle in every litre of water. The likelihood of discarded material from retail packaged, imported salmonids accumulating to this level is extremely unlikely

- g. Oral challenge of brown trout (*Salmo trutta*) with IPNV (N1 serotype) at doses of $10^{2.5}$ to $10^{3.2}$ TCID₅₀/g food failed to transmit infection to the experimental salmonids, whereas doses of 10^6 TCID₅₀/g food resulted in detectable infection in the trout (Mortensen 1993). The viral titre in the flesh of imported carrier fish is expected to be, conservatively, 150 times less than the lowest dose that failed to transmit IPNV orally.
- h. Given the information in (f) and (g) above, the likelihood of transmission of IPNV from imported eviscerated salmonids to susceptible New Zealand fish is concluded to be *negligible*.

It is apparent, therefore, that the risk of exposure and establishment of IPNV from the importation of retail packed salmonids would be *negligible* regardless of the IPNV status of the importing country. Thus, given information now available, IPNV can also be removed from the list of organisms that should be considered when reviewing the requirement for a health surveillance programme.

4.2. AEROMONAS SALMONICIDA

The risk of *A. salmonicida* (both “typical” and “atypical” strains) introduction with salmonid imports has been considered on a number of occasions by MAF utilising both qualitative and quantitative techniques (MacDiarmid 1994, Stone *et al.* 1997, Anonymous 1999). The qualitative risk analysis upon which the import health standard in question was based concluded that the risk from *A. salmonicida* was *low*, however; the quantitative analysis in the same document indicated that the risk of introduction per tonne of product from a country with *A. salmonicida* (Norway) was no greater than 5.48×10^{-7} (Stone *et al.* 1997). In conclusion the risk analysis indicated that introduction of *A. salmonicida* was unlikely. The most recent risk analysis, considering head-on, gill-in salmonids from Australia, where *A. salmonicida* strains are found, determined the risk to be negligible (Anonymous 1999). There is no evidence to suggest that the widespread movement of eviscerated salmonids has contributed to the spread of *A. salmonicida* and it is not the intent of this document to revisit the qualitative or quantitative examinations already carried out in the previous risk analyses. The findings of these analyses are consistent with the opinions of international experts and the OIE as regards the risks of introduction of *A. salmonicida* via movements of dead, eviscerated fish (Evelyn 2001, LaPatra *et al.* 2001).

It is apparent, therefore, that the risk of exposure and establishment of *A. salmonicida* from the importation of retail packed salmonid flesh would be *negligible* regardless of the *A. salmonicida* status of the importing country. Thus *A. salmonicida* can also be removed from the list of organisms that should be considered when reviewing the requirement for a health surveillance programme.

4.3. INFECTIOUS HAEMATOPOIETIC NECROSIS VIRUS (IHNV) AND VIRAL HAEMORRHAGIC SEPTICAEMIA VIRUS (VHSV)

The OIE Aquatic Animal Health Code recommends that Competent Authorities of importing countries should not require IHNV or VHSV related conditions, regardless of the IHNV or VHSV status of the exporting country, for chilled or frozen eviscerated fish packaged for direct retail trade. MAF considered in the original risk analysis (Stone *et al.* 1997) that, because of the likely consequences of introduction of these viruses into New Zealand further measures were justified.

However, the equivalence of alternative measures can be assessed against the objective of the requirement for health surveillance.

In the original risk analysis (page 12) the authors state that the surveillance should be “*sufficient to record the occurrence of the OIE listed diseases affecting salmonids, noting the category of occurrence (free, low, sporadic, endemic, high)*”. The outcome of such a health surveillance programme is indicated to be “*data on disease occurrence which may be utilised for disease control purposes*” (Stone *et al.* 1997). This is clearly of more importance to the exporting country. New Zealand, as the importing country, has no direct stake in the control of diseases affecting aquaculture production or wild fish in another country. Therefore it can be concluded that the requirement of health surveillance is not specifically for disease control reasons, but for knowledge of disease occurrence in the source populations.

Whilst there is a zoosanitary requirement that “*the product for export is free from visible lesions associated with infectious disease*”, there is also a requirement that “[*t*]he product for export is derived from fish that were not slaughtered as an official disease control measure as a result of an outbreak of disease”. The authors of the risk analysis indicate that “*ideally...fish are not harvested as a disease control measure due to a disease outbreak*”, however as is further pointed out emergency harvests are a commercial reality in aquaculture and a suitable compromise is identified, where the authors state that “[*i*]t is, however, more realistic to expect fish slaughtered as an official disease control measure under the direction of the competent government health authority to be excluded from eligibility for export as the commodity”.

It can be concluded that the ultimate objective of the requirement for a health surveillance system is to ensure that the Competent Authorities are aware of outbreaks of OIE listed salmonid diseases so that in the event of emergency de-stocking for disease control reasons the fish could be excluded from eligibility for export. This zoosanitary condition could, therefore, be equivalently met if there was a legislative requirement in the exporting country that the relevant diseases were notifiable to the competent authority.

In the case of this import health standard the equivalence condition would apply to IHNV and VHSV, as a result of having established that the health surveillance requirement need not apply to IPNV, *A. salmonicida*, EIBS, *H. salmonicola* and *Kudoa* species.

5. Recommendations

It has been concluded that the zoosanitary requirement that “[t]he product for export is derived from fish that were harvested from a population for which a documented health surveillance programme exists which is administered by a competent government-authorized agency” can be equivalently fulfilled if the diseases of interest are compulsorily notifiable to the Competent Authority in the country of export.

It has further been concluded that this condition need only apply to IHNV and VHSV, on the basis of :

- Evidence supporting the review of IPNV and *A. salmonicida* as *negligible* risk; and
- EIBS, *H. salminicola* and *Kudoa* spp. never having been on the OIE list of salmonid diseases and thus not covered by the original intent of the health surveillance requirement.

It is recommended that:

1. Clause 12.2 of the import health standard be amended to reflect that *either* a health surveillance programme covering IHNV and VHSV administered by the Competent Authority *or* the compulsory notification of IHNV and VHSV detection to the Competent Authority is acceptable.
2. Clauses 12.1, 12.3 and 12.4 do not require any changes.

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