



Bioresecurity Act 2015 –Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016

Cover Sheet

Please complete and submit this form with your submission:

By email: newbiosecuritylegislation@agriculture.gov.au
Or by post: Biosecurity Legislation Implementation Office
Biosecurity Implementation Branch
Australian Government Department of Agriculture
and Water Resources
GPO Box 858
CANBERRA ACT 2601

Contact Name: Dr Adam Main

Position: CEO

Organisation: Tasmanian Salmonid Growers Association

Address: PO BOX 321

Suburb/City: Sandy Bay

State: TAS

Postcode: 7006

Phone: 03 6214 0555

Mobile: 0459 065 595

Email: adam.main@tsga.com.au

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Submission to the Australian Government Department of Agriculture and Water Resources (DAWR) with respect to the Exposure Draft- *Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016.*

Our Industry

The industry is comprised of four marine farming companies Tassal Group Ltd, Huon Aquaculture Group, Petuna Pty Ltd, and Van Diemen Aquaculture Pty Ltd. Marine farms are supplied with juvenile stock from several freshwater hatcheries, most of which are individually owned by one or other of the farming companies. In addition, there are numerous independent companies that directly support the industry, such as the Saltas hatchery, Snowy range hatchery and Targa hatchery. There is also a growing number of service companies that are part of the successful development of salmonid farming in Tasmania, including but limited to, Skretting, Ridleys, Mitchells Plastic Welding, De Bruyn, Plastic Fabrications, SeaFarm.

The industry is fully vertically integrated. It both produces and purchases smolt (young salmon) for its diversified marine sites situated around Tasmania (geographic distribution mitigates environmental and disease risk). Fish are harvested in the main at Dover, in the lower Huon River and Macquarie Harbour prior to packaging and/or further processing at the specialist sites, Huonville, Margate, Devonport, and Parramatta Creek.

From an initial 56 tonne harvest in 1986-87, in 2015, the Tasmanian salmonid farming industry:

- produced in excess of 55,000 HOG (head on, gutted) tonnes of Atlantic salmon & ocean trout with a GVP of approximately \$650M;
- provided direct employment for 2,092, and indirect employment for a further 3,850, largely in rural areas;
- the industry's fish growing and processing operations are spread across most regions around the state, from south to north; and
- exported almost \$80M worth of premium salmon and ocean trout to countries all around the world.

The Tasmanian salmonid industry is now:

- the largest single "fishery" sector in Australia by GVP;
- by far the largest aquaculture sector in Australia;
- the largest primary production sector in Tasmania;
- larger than all other aquaculture and fishery sectors in Tasmania combined; and
- a significant contributor to the Australian "food bowl" concept.

The Tasmanian Salmonid Growers Association (TSGA) is a not for profit organisation established by its grower members almost 30 years ago to represent the Industry by working with Federal and State Governments and their regulatory agencies.

TSGA is charged by its members with ensuring that reasonable and viable operating standards and conditions are established for the industry by an industry/government partnership within an appropriate regulatory framework.

Executive Summary

Priority One

The number one priority for the TSGA is the maintenance of freedom of disease and pest status in Tasmania as it relates to salmonids. Many of the serious diseases and pests of concern are exotic to Australia and will potentially have major implications for aquaculture and fisheries across Australia. However, wherever the Commonwealth can't justify quarantine measures on a national basis it is critical that formal recognition of Tasmania as a region of differentiation in relation to biosecurity and quarantine matters is enforced due to its special circumstances and geographic isolation. Tasmania's unique pest and disease status should be recognised and maintained to ensure the ongoing viability of primary industry in Tasmania. As a region heavily reliant on primary industries and its clean green image, which not only underpins primary production, but other significant sectors such as tourism, the consequences of an exotic pest or disease incursion would have a far greater effect on the Tasmanian economy than in most other states.

Our regional freedom from certain pests and diseases has many important implications for Tasmania including:

- Viability of the salmonid sector – certain exotic diseases and pests are likely to render the industry unviable. Increased market access in overseas markets.
- Significantly reduced antibiotic usage (currently negligible relative to comparable overseas salmonid farming regions such as Chile where antibiotic use is considerable).
- Reduced WHS risk due to reduced chemical usage.
- Brand enhancement for the “clean and green” image.
- Downstream branding – hospitality and tourism.

Key points regarding the risks associated with losing regional differentiation for salmon aquaculture

- The crisis caused in the Chilean industry by the trio of Infectious Salmon Anaemia (ISA), Salmon Rickettsial Syndrome (SRS), and sea-lice, is now acknowledged to have halved production and cost 25,000 jobs in rural Chile. There is now evidence that the ISA virus was introduced into Chile in 1996/97 via **imported material**, before emerging as a disease in 2006 and exploding as a disease catastrophe in 2008/09. Following this collapse, considerable restructuring of the industry occurred. Despite this, ISA has re-emerged in the last couple of years as a serious problem. SRS continues to be a major cause of economic loss in the Chilean

salmon industry which still incurs large mortalities despite the large amounts of antibiotic used to try and control this disease. See **Appendix 1** for more information on ISA.

- Pancreas Disease is another serious disease found in Norway and Scotland requiring stringent management practices to control its spread. Norway was divided into two regions on the basis of Pancreas Disease status, but a couple of years ago a new strain of Pancreas Disease not previously known in Norway (but present in Scotland) was found in Norway, necessitating a review of the regional boundary.
- Spring Viraemia and Koi Herpes virus of cyprinids is on the increase in the UK. Viral Haemorrhagic Septicaemia (VHS) virus is spreading in the United States. The common thread is pathogens inadvertently transferred from one environment to another, then finding a suitable host to become established. Once new pathogens or pests become established in the aquatic environment it is virtually impossible to eradicate them - unlike in a terrestrial situation where there is at least some opportunity for isolation and control.
- In addition to Infectious Salmon Anaemia Virus (ISAV), Pancreas Disease Virus (PD), Salmon Piscirickettsia (PRS) and Viral Haemorrhagic Septicaemia Virus (VHSV), the list of serious infectious salmonid diseases found overseas but not present in Australia includes but is not limited to : Infectious Pancreatic Necrosis Virus (IPNV), Infectious Haematopoietic Necrosis Virus (IHNV), Cardiomyopathy Syndrome Virus (CMS), Heart and Skeletal Muscle Inflammation Virus (HSMI), *Vibrio ordalii*, *Myxobolus cerebralis* (brain parasite), Bacterial Kidney Disease (BKD), and *Lepthiotherius salmonis* louse.
- Import risk assessments should be focused on the science of the issue, examining the potential for imported product to carry exotic disease pathogens and pests, the risk of introduction to the aquatic environment and ultimately the consequences of the disease or pest becoming established. Many of these considerations rely on the availability of sensitive and specific diagnostic testing capability. There is often also a political component which is heavily biased in favour of national rather than regional interests, particularly given the pressures of international trade, trading away one industry sector against others.
- In 2009 TSGA members, representing 98% of the salmonid farming industry in Australia, implemented a strategic plan aimed at growing the industry 80% by 2020, and doing so in a sustainable fashion. As consistently demonstrated over many years of advocacy we remain extremely concerned about the disease and pest risk posed by imported material, a factor largely determined by the federal government and out of our control. We consider it very fortunate that the Tasmanian Government, with the support of many Tasmanian senators in the Federal Parliament, resolved to implement additional measures to restrict the movement of imported salmonid product into Tasmania thereby reducing the biosecurity risk from exotic salmonid diseases and pests.
- Even with this added level of protection, salmonid product biosecurity breaches still occur in Tasmania. Earlier this year, on three different occasions, non-approved imported salmonid products were found on Tasmanian supermarket shelves and reported to the regulators by concerned consumers. As an industry we will not accept ignorance as an excuse for non-compliance by the importers of these products.
- While such regional restrictions are easily justifiable on a scientific basis, the Tasmanian salmonid industry has been committed to the Tasmanian Salmonid Health Surveillance Program (TSHSP) which underpins demonstration of specific exotic disease and pest freedom. The TSHSP is a joint initiative between the Tasmanian Department of Primary Industries,

Parks, Water and Environment (DPIPWE) and the Tasmanian Salmonid Growers Association that has been in operation since 1993. One of the key objectives of the TSHSP is demonstration of freedom for those salmonid diseases and pests considered exotic to Tasmania, but not necessarily Australia, in order to provide support for maintaining state border biosecurity regulations.

Priority Two

The TSGA strongly asserts that the wording of the “**alternative conditions**” for bringing or importing dead fish and fish products of the family Salmonidae or Plecoglossidae into Australian territory is critically reviewed in relation to the previous conditions stated in the *Quarantine Proclamation 1998 made under section 13 of the Quarantine Act 1908*.

The TSGA believes that the wording in the new ‘alternative conditions’ is too ambiguous, specifically Section 13, sub section 17 and 24 (pp12-13). It is our opinion that ambiguous wording frequently shifts greater application and interpretation power to the agencies and the courts. As a result, it is highly likely that this policy will be decided by largely unelected, less directly accountable, and less scientifically robust decision makers.

The TSGA seeks **immediate** clarification of what is meant by the statements at 24(b)(i) and 24(b)(ii):

b) the goods:

(i) have been processed in a way that ensures that biosecurity risks associated with the goods have been appropriately managed; and

(ii) have been commercially prepared and packaged; and

Point (ii) seems to have absolutely **no relevance** to biosecurity matters.

These statements are also similar to 17(a):

“the goods have been processed to the extent needed to manage biosecurity risks associated with the goods to an acceptable level”

It is our very strong view that these statements are highly subject to interpretation and clarification is required.

The TSGA is also seeking clarification on statement 17(3(c)(ii):

"accompanied by a certificate from a body that the Director of Biosecurity has recognised as being competent to certify that biosecurity risks associated with the goods can be managed to an acceptable level and that is specified in a list published on the Agriculture Department's website, as existing on 16 June 2016",

Again the TSGA seeks clarification on exactly what the Department considers ‘an acceptable level’ and how competency will be assessed, maintained and audited.

Introduction

National considerations must include consideration of, and **not be to the detriment** of, a specific state(s) economy or capacity to generate income.

Social and environmental consequences of maintaining regional differentiation are important drivers of biosecurity. In regions such as Tasmania, preservation of World Heritage Areas and other environmentally sensitive areas is essential as it is also financially significant to the state's economy both now and into the future.

It is important that the subordinate legislation, which is currently focussed on trade risks, captures the gamut of biosecurity risks which affect a jurisdiction. When does an Appropriate Level of Protection (ALOP) take into consideration brand image, tourism, hospitality or regional economies of scale? When an ALOP is profiled against a specific disease or pest threat it almost certainly does not take into consideration the broader consequences of a biosecurity breach. In Tasmania, a primary industry can be the mainstay of a regional community. It can be the item on every single menu across the state and even nationally, it can be the iconic image on tourism advertisements, and it can sometimes provide the only remaining impetus to keep local schools and shops open.

Tasmania must be able to exercise its rights in relation to protecting its borders to ensure that the Tasmanian economy and well-being of the state are maintained.

Whilst it has been argued that having one single national approach makes market access easier and reduces confusion, Australia deals with a number of countries that continue to maintain regional differentiation due to pest and disease risk; two examples being USA and China. Australia respects the rights of foreign countries to set regional zones based on quarantine status and therefore Australia should recognise within its own federation the rights of states to have their own quarantine zones and restrictions as well.

The Tasmanian Perspective

Tasmania has several unique characteristics which reinforce the potential for risks to be assessed at a regional level. With Bass Strait acting as a natural barrier and strong quarantine protection through entry points, the ability for Tasmania to maintain a separate quarantine zone is feasible and demonstrable by resource allocation. Tasmania, through the strength of its quarantine measures, has successfully maintained area freedom from several mainland pests such as fruit fly

Furthermore, the consequences of serious exotic disease incursions or pest establishment in Tasmania can have immediate and considerable consequences on the regional economy of Tasmania. One in five people are directly or indirectly employed in primary industry in Tasmania and the income generated from the sector underpins the survival of our regional areas and towns.

Dealing with exotic disease or pest incursion

The new measures to be introduced through the proposed legislation cause concern for state sovereignty, as the rights of states to maintain their own laws could be threatened. Whilst the intent of the new *Biosecurity Act 2015* is to work co-operatively with the states, the state legislation can potentially be overridden by the Director of Biosecurity where it is deemed the state is undermining the Commonwealth.

Enabling the Commonwealth with the power to intervene and manage exotic pest and disease incursions across all state jurisdictions could be advantageous to ensure a quick and co-ordinated response. However, the decision pathway to implement the control measures appears to be left again to the discretion of the Director of Biosecurity. Will this sole person be responsible for making the call whether to eradicate the pest or disease or simply act to control the pest or disease? There are many technical and scientific considerations to be made when assessing an incursion and these considerations need to be more clearly articulated in the legislation. The complexity and importance of dealing with pest and disease incursions in an appropriate manner is highlighted by the extensive National AquaVetPlan documents which have been developed as a series of manuals under the Aquaplan to provide detailed information in the event of an emergency response being required. A considerable amount of relevant scientific and veterinary expertise resides within specific States and must be included in specific responses, particularly where certain States are more greatly impacted

Alternative Conditions

The TSGA find it extremely difficult to comprehend that the Director of Biosecurity, or delegate, will have the confidence or ability to accurately and appropriately apply the legislation with respect to the alternative conditions, unless the wording is amended. The TSGA has worked with the Commonwealth Government for almost 30 years in regard to setting appropriate levels of protection for the salmonid industry, and we view the open statements in the 'alternative conditions' as a blatant attempt at undermining and dismissing all that effort.

The TSGA seeks **immediate** clarification of what is meant by the statements at 24(b)(i) and 24(b)(ii):

b) the goods:

(i) have been processed in a way that ensures that biosecurity risks associated with the goods have been appropriately managed; and

(ii) have been commercially prepared and packaged; and

These statements are also similar to 17(a):

“the goods have been processed to the extent needed to manage biosecurity risks associated with the goods to an acceptable level”

It is our very strong view that these statements are subject to considerable interpretation which exposes Tasmania and the salmonid industry to open discrimination - clarification is required.

The TSGA is also seeking clarification on statement 17(3(c)(ii):

"accompanied by a certificate from a body that the Director of Biosecurity has recognised as being competent to certify that biosecurity risks associated with the goods can be managed to an acceptable level and that is specified in a list published on the Agriculture Department's website, as existing on 16 June 2016",

Again the TSGA seeks clarification on exactly what the Department considers 'an acceptable level' and how competency will be assessed, maintained and audited.

Furthermore, the TSGA requires that the following detail is added to *Section 13 Alternative conditions—dead fish, crustaceans and related goods for human consumption, subsection 24:*

Either:

- a. the goods are retorted; or
- b. the goods:
 - i. have been eviscerated and the head and gills have been removed or processed further than evisceration in a way that ensures that biosecurity risks associated with the consumer ready goods have been appropriately managed; and
 - ii. have been commercially prepared and packaged and are accompanied by a certificate from a body that the Director of Biosecurity has recognised as being competent to certify that biosecurity risks associated with the goods can be managed to an acceptable level and that is specified in a list published on the Agriculture Department's website; and
 - iii. are brought in as baggage or mail; and
 - iv. are in a quantity of not more than 5 kilograms if brought in as baggage, or are in a quantity of not more than 450 grams if brought in as mail

Note 1: In deciding if the biosecurity risks have been 'appropriately managed' the Director of Biosecurity:

- a. must consider the level of quarantine risk if the goods were brought or imported into Australian territory – noting that the level of risk can be changing on an ongoing basis (i.e. level of disease in a source country is changing) and the scientific information on risk factors and diagnostic capability is continuously evolving; and
- b. must consider whether, if the goods were brought or imported into Australian territory, what additional conditions on it would be necessary to limit the level of quarantine risk to one that is acceptably low; and
- c. must consider the findings and policies in the *AQIS Import Risk Analysis on Non-viable Salmonids and Non-salmonid Marine Finfish, 1999*; and
- d. must take into account anything else that he or she knows that is relevant; and
- e. must consider the economic, social and environmental consequences of disease or pest establishment.

Note 2: The following are examples of potentially significant risk consumer ready products of fish of the family Salmonidae and Plecoglossidae:

- f. cutlets, including the central bone and external skin but excluding fins, each cutlet weighing no more than 450 grams;
- g. skinless fillets, excluding the belly flap and all bones except the pin bones;

- h. skin-on fillets, excluding the belly flap and all bones except the pin bones, each fillet weighing no more than 450 grams;
- i. eviscerated, headless, 'pan-size' fish, each fish weighing at least 200 grams but not more than 450 grams;
- j. a product that is processed further than a stage described in paragraphs (f) to (j).

Approved Arrangements- Verification

Approved Arrangements are, in principal, a cost effective and resource friendly option however they are only as good as the rigour and integrity built into the auditing and monitoring process.

The Australian government needs to ensure primary industry that the systems implemented and managed by the exporting country meet the requirements of Australia and that an appropriate audit and monitoring system is in place. This establishment of trust is critical if bilateral trade is to occur. At the same time DAWR should ensure that such systems are also available to Australian producers seeking market access.

To test this point, the TSGA would like to **formally request** information from DAWR regarding their activity in regard to managing the importation of salmonid goods from Infectious Salmon Anaemia (ISA), sea lice, Pancreas Disease (PD), Infectious Haematopoeitic Necrosis (IHN) and Salmon Rickettsial Syndrome (SRS) affected regions.

In 1999 AQIS published an import risk analysis report, in partnership with the salmonid industry, titled *Import Risk Analysis on Non-viable Salmonids and Non-salmonid Marine Finfish*. In that report it states that:

“to mitigate risks associated with the importation of eviscerated salmonids in relation to the establishment in Australia of ISAV, AQIS will permit the importation of eviscerated Atlantic salmon subject to the conditions shown below:

Risk management measures for infectious salmon anaemia virus for Atlantic salmon

PRE-EXPORT REQUIREMENTS

- *The fish must be derived from a population for which there is a documented system of health surveillance and monitoring administered by a competent authority.*
- *The Atlantic salmon must not come from a farm known or officially suspected of being affected by an outbreak of ISA.*
- *The head and gills must be removed and internal and external surfaces thoroughly washed.*
- *The fish must be inspected and graded under the supervision of a competent authority.*
- *The product for export must be free from visible lesions associated with infectious disease and fit for human consumption.*
- *The fish must be processed in a premises approved by and under the control of a competent authority.*
- *Consignments exported to Australia must be accompanied by official certification confirming that the exported fish meet Australia’s import conditions in full.*

POST-IMPORT MEASURES

- *Only premises approved by AQIS will be permitted to commercially process imported salmonids in Australia.*
- *Only consumer-ready product will be released from quarantine.”*

The TSGA are **seeking confirmation** that DAWR has an historical audit record of all accompanying official certifications that confirm that the exported fish meet Australia's import conditions in full (as stated above). The TSGA are also **seeking confirmation** that no exported fish meat has come from a farm known or officially suspected of being affected by an outbreak of ISA. Biosecurity requirements are of little real value if they are not monitored and verified. Please see attached information on ISA at **Appendix 1**.

In Summary

Although biosecurity can be a complex and challenging activity for federal, state and territory governments, the Tasmanian salmonid industry is poised to lose our reputation for being a world leader. Tasmania's advantage of being relatively free of pests and diseases, in the face of increasing global trade and visitors is under threat—putting primary producers, regional economies, the environment and Tasmania's clean green image at risk.

The omissions of the regulations are easily rectified. Where possible we have identified the simple changes necessary to correct these omissions. While we accept that these simple changes will not be incorporated verbatim, they clearly articulate our proposed solution in the spirit of being helpful to the Committee.

Finally, the TSGA strongly believe that there is desire by both industry and government to '*get this right*'. The last thing we want to see is the regulations and guidelines '*rushed*' and an inferior outcome achieved early. We strongly urge the Department to:

- Maintain purposeful engagement and consultation with stakeholders.
- Set appropriate time frames for review and consideration.
- Eliminate inconsistencies that exist with other legislation that is being simultaneously developed.

We have waited 104 years to replace the Quarantine Act 1908; it is imperative that the time is taken to ensure that critical omissions are properly addressed in the regulations and guidelines, in an atmosphere of good governance.

The TSGA and its members are available to provide professional, informed advice and testimony to the Committee; and we respectfully request the opportunity to do so.

I thank you for the opportunity to comment on the proposed *Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016* and I look forward to your reply.

Yours sincerely,



Dr Adam Main
Chief Executive Officer
Tasmanian Salmonid Growers Association Ltd (TSGA)
adam.main@tsga.com.au

Appendix 1

Information Sheet

Infectious salmon anaemia virus (ISAV) and other Orthomyxoviruses

Steve Percival (Sep 20th 2012)

1. Introduction

Note - ISA refers to the disease and ISAV refers to the virus

Infectious salmon anaemia (ISA) is a disease of sea-farmed Atlantic salmon. This highly contagious disease can be insidious, with an initial low mortality rate leading to cumulative mortality that can sometimes exceed 90%.

ISA (originally known as Haemorrhagic Kidney Disease) was first described in Norway in 1984. However, it was not until early 1990s that the cause was confirmed as infectious salmon anaemia virus (ISAV) when a cell culture of salmon head kidney (SHK-1) was developed. Since the late 1990s, outbreaks have also been reported in Atlantic salmon in Canada, UK, Faroe Islands, USA and Chile.

ISA continues to occur in Norway, Canada and Chile, however seems to have been eradicated from farmed salmon in both Scotland and Faroe Islands.

2. Causative Organism

The morphological, physiochemical and genetic properties of ISAV are consistent with those of the *Orthomyxovirus* family (includes the influenza viruses). ISAV has recently been classified as the type species of the new genus *Isavirus* within the *Orthomyxovirus* family.

ISAV is now well characterised and the genome has been fully sequenced. ISAV is an enveloped virus, 100-130 nm in diameter and with 10-12 nm surface projections. The ISAV genome consists of 8 RNA segments which encodes at least ten proteins including two main surface glycoproteins:

- Hemagglutinin-esterase (HE) responsible for receptor-binding and receptor-destroying activities and
- A fusion protein (F)

A small highly polymorphic region (HPR) of the viral hemagglutinin-esterase (a surface glycoprotein encoded by genetic segment 6) can be used to classify ISAV isolates into numbered groups. HPR0 and HPR00 consist of the viruses that can be detected in fish but are not culturable on currently used tissue cell lines. These viruses seem to be non-pathogenic for Atlantic salmon and other salmonids. Viruses with deletions in the HPR (e.g. those viruses classified as HPR1, HPR2, HPR3 etc.) appear to be more virulent and can be isolated in tissue cell cultures. A number of HPR genotypes have been detected.

All pathogenic variants of ISAV associated with disease outbreaks are characterised by the occurrence of a sequence deletion within the highly polymorphic region (HPR), compared to the reputed ancestral form of the HE gene designated HPR0.

Sequence analysis of various gene segments has revealed differences between isolates both within and between geographical areas where salmon farming occurs. According to differences in the 5'-terminal end of the HE gene, ISAV isolates have been divided into 2 major groups:

- European group and
- North American group

North American and European lineages of ISAV appear to have been present and diverged long before the development of commercial Atlantic salmon aquaculture. Both European and North American groups contain a number of sub-groups.

Molecular detection methodologies have been developed to cover the broad range of ISAV viruses in global circulation, providing confidence that the pathogen can be accurately detected. Information on the existence of the ISAV-HPR0 variant has been invaluable in interpreting the results of molecular diagnostic tests which currently do not differentiate between this and other variants of the virus. The fact that the ISAV-HPR0 variant has been shown to be present, even in areas with freedom of ISA disease, suggests a clear distinction in risk associated with the presence of ISAV-HPR0 cf. other disease causing variants.

All orthomyxoviruses found in Atlantic salmon in Norway have been identified as ISAV. 90 % of Atlantic salmon in Norway are positive for the HPR0 variant of ISAV, but mostly found in the gills – very few in the kidney and heart.

3. Species Affected

The non-pathogenic form of the ISAV (HPR0 or HPR00) has been detected in healthy farmed and wild fish in all the major regions of Atlantic salmon production worldwide, including: Norway, Scotland, Canada, Chile and Faroes.

Outbreaks of ISA occur in farmed Atlantic salmon. Wild Atlantic salmon might also be susceptible but this is not known. Rarely, isolates have been reported to cause disease in other salmonids.

One ISAV isolate was linked to illness in Coho salmon in Chile in 1999, by both virus isolation and serology, however ISAV has not been reported from any disease outbreaks in coho salmon since then. A different ISAV isolate caused clinical signs in experimentally infected Rainbow trout. This isolate was highly virulent in Atlantic salmon but only infected coho salmon sub-clinically.

The reservoir hosts for ISAV are unknown. In experiments, isolates that are virulent for Atlantic salmon usually infect other fish species without causing any disease. Sub-clinical infections with these isolates have been reported in brown trout, sea trout, rainbow trout, steehead trout, coho salmon and arctic char, as well as some non-salmonids such as herring, cod, and pollock.

Other fish species are susceptible to infection with ISAV, but only Atlantic salmon develop disease following infection with ISAV. Therefore, these other species can be considered as potential carriers/reservoirs for ISAV.

4. Geographic Distribution

ISA outbreaks occur periodically in Norway and Chile, as well as a limited region of North America shared by the US and Canada. Outbreaks have been reported occasionally in other countries including Scotland and Faroe Islands.

The non-culturable, apparently non-pathogenic (HPR0 and HPR00) isolates of ISAV have been reported in wild salmonids in several areas, including Norway, Scotland, Ireland, New Brunswick, Maine, Nova Scotia and Chile. These non-culturable isolates probably also occur in at least some other areas where fish have not been tested.

The North American and European genotypes are not confined to their respective geographic areas. In Chile and USA, viruses of the European genotype have caused ISA in Atlantic salmon, but virus isolated from coho salmon in Chile in 1999 was from the North American group. Most of the ISA viruses that have been detected in Canada and the US belong to the North American genotype, but non-virulent (HPR0) viruses from the European genotype have been found in both countries.

5. Epidemiology

Understanding the epidemiology of ISA is still incomplete, which complicates its control. The reservoirs for the virus are not known, but experiments have shown that several species of salmonids can carry virulent ISA viruses without showing symptoms of disease. These viruses might cause outbreaks if they are transmitted to farmed Atlantic salmon. Non-culturable, apparently non-pathogenic, isolates have also been detected in wild salmonids. Small changes in these viruses, analogous to the mutations that allow low pathogenicity avian influenza viruses to become highly pathogenic, may allow them to become more virulent.

Orthomyxoviruses such as Influenza virus and ISAV are characterised by a high potential for adaptation via several mechanisms for genetic change, including:

- Mutation
- Reassortment and
- Recombination

Molecular epidemiological evidence suggests that pathogenic ISAV which causes disease in fish farms likely originates from a reservoir of the ISAV-HPR0 variant within the local fish populations.

The mechanisms governing adaptation of the ISAV-HPR0 variant in aquaculture are however, poorly understood. The fact that new cases of ISA which have emerged in countries previously free of the disease, however, does suggest that a lack of synchronous fallowing or susceptible stressed populations and thus provision of opportunity for pathogens to persist over long time periods may contribute to the risk of emergence of disease.

6. Transmission and Survival Outside of Host

The main infection route is most likely through the gills but infection via the intestine cannot be excluded. ISAV is shed in skin/gill mucus, urine, faeces and gonadal fluids. ISAV also occurs in blood and tissues.

ISAV is transmitted from infected sources horizontally via contaminated water, and sharing of staff and equipment between sites. Horizontal transmission occurs readily within a tank or net pen. However, transmission occurs more slowly between salmon in different nets at a site as well as between farms.

The prompt disinfection of affected and contaminated sites is likely to mitigate the risk of transmission.

ISAV replicates best at 5-15 °C. Optimal growth in tissue cell lines is 10-15 °C. ISAV does not replicate at 25 °C.

Fish that survive illness can shed virus for more than a month.

In sea trout ISAV RNA can still be found 135 days after infection. Blood from brown trout, taken 7 months after infection caused disease when it was injected into Atlantic salmon.

ISAV can be transmitted from trout to salmon and salmon to trout when these fish are in the same population.

Sea lice can transmit ISAV.

It is probable that virulent ISAV strains are generated from non-virulent strains that circulate in wild salmonids and other species.

Molecular evidence suggests the ISAV found in Chile came from Norway, with vertical or trans-generational transmission being plausible based on the significant historical import of fertilised eggs into the region. This has led to biosecurity measures aimed at guarding against such import of ISAV. This includes broodstock testing regimes based on molecular detection, accompanied by destruction of ova originating from ISAV-positive tested parents and development of protocols for the disinfection of imported eggs. Whether true vertical transmission of ISAV (ie. the internal transmission of virus within the gametes) occurs with ISAV remains somewhat controversial. It seems likely from evidence in Chile that trans-generational transmission is highly likely to have occurred. Whether this represents true vertical transmission or resulted from inadequate disinfection of eggs remains uncertain.

Once present at a location, horizontal transmission remains the main mechanism for dissemination of ISAV.

Exposure of cell culture-propagated ISAV to 15°C for 10 days or to 4°C for 14 days had no effect on virus infectivity so has potential to survive for prolonged period in the right environmental conditions.

7. Clinical Signs

ISA is highly contagious and causes a systemic disease and mortality characterised by severe anaemia and variable haemorrhages and necrosis in several organs.

Mortality rates are highly variable. Few fish may be affected at the beginning of an outbreak: initial daily mortality is often 0.5 – 1.0%. If the spread of the virus remains unchecked, mortality can increase either gradually or suddenly. Cumulative mortality varies from insignificant to moderate or severe. Highly virulent ISAV may kill > 90% of fish over a few months.

As with many infectious diseases of fish, ISAV-infected fish may not necessarily exhibit clinical signs but the onset of disease may be precipitated by adverse environmental conditions or stress such as increased water temperature or poor water quality. Stress factors (eg. rising or falling temperature) appear to play an important role in precipitating disease outbreaks in sub-clinical carrier fish.

Clinical signs are reported to occur in 2-4 weeks in experimentally infected fish. In Atlantic salmon the clinical signs may include: lethargy, anaemia, low white blood cell count, abdominal fluid, protruding eyes, darkened skin and increased mortality. In some cases, haematocrit can be normal, while in others it can be as low as 2-3% resulting in gills to be pale. Haemorrhages may be found in the eye and jaundice can occur on the ventral surface of the body.

In morts there can be extensive petechial haemorrhages in various organs and tissues, including: the eye, internal organs, visceral fat and skeletal muscle. Spleen may be enlarged and congested. Congestion, enlargement and necrosis may be apparent in the liver and in some

cases the liver may be dark brown or black and covered in a layer of fibrin. The kidney may be swollen and dark. The gastrointestinal tract may also be congested.

Subclinical infections may be common among salmonids in some locations. A recent study in Norway detected ISAV in 22 of 24 Atlantic salmon smolt production sites using RT-PCR. In this study more than one isolate was found in some smolt populations and at one marine site. In Norwegian rivers, the prevalence of apparently non-pathogenic strains in wild salmonids was highly variable; in some cases, the virus was detected in only a single fish, while in others, it was found in 100% of the fish tested. Similarly, the distribution of the virus was not homogeneous among wild fish in Scotland.

Disease usually occurs in salmon in the marine stage, outbreaks have rarely been reported in fish in freshwater. Although outbreaks are possible any time of the year, mortality is reported to peak in early summer and in winter.

The disease often begins in one or two pens and it may not spread to other pens for months. The onset of disease can be precipitated by management factors such as water temperature, the amount of time the fish have been in seawater, nutrition, infestation by sea lice and other stressors. Outbreaks can be brought on by handling fish on infected sites.

Disease presentation - ISA variants

In Norway they see 3 variants of the disease:

- Liver variant – classical disease
- Kidney variant -
- Gut variant – bleeding in gut, damage to capillaries in endothelial cells in lamina propria. Typically get anaemia, red fingers of pyloric caecae in between fat in area. Also see reddening in hind gut.

In Norway – ISA initially seen as the liver variant. If look back at historical histology they do see changes consistent with the kidney variant, but to lesser degree. In Canada – ISA initially seen as the kidney variant.

Clinically ISA tends to be either the liver or kidney variant. In cases of the gut variant, the gut changes tend to be associated with liver variant changes but the changes in the gut predominate.

8. Control

Good management and biosecurity can decrease the risk of infection. Boat traffic and the movements of fish, supplies and people must be controlled. Boats and equipment should be cleaned and disinfected before and after visiting sites. Personnel must also clean and disinfect themselves and their gear. Whenever possible, dedicated equipment and personnel should be used for each site. Divers should disinfect their gear before and after diving, and between cages. It is recommended that cages with the youngest fish be dived first, and cages with the highest mortality dived last. Dead fish should be removed regularly from cages, as ISAV can be transmitted in blood and tissues. Decontaminating wastes, including waste water, from slaughter facilities and fish processing plants prevents infections from this source.

Salmon farms should be separated by a distance that will not allow the virus to spread readily (ideally > 5km). This distance may vary with the location. To reduce the transmission of ISAV from older fish to younger fish, sites should be stocked with a single year class. Nets should be

disinfected between uses. Following between year classes should occur. Sea lice which can be involved in transmission should be controlled and stress should be minimised.

If ISA is detected, aggressive depopulation of the affected cages can decrease losses. Early detection by regular surveillance can improve the effectiveness of this technique, as fish can shed ISAV before the mortality increases.

Disinfection

ISAV can be inactivated by a variety of disinfectants including: sodium hypochlorite, chloramine-T, chlorine dioxide, iodophors, sodium hydroxide, and Virkon. Virkon should be used at 2% solution for 10 mins.

Non-culturable ISAV isolates

Non-pathogenic ISAV isolates (eg. HPR0) that can be detected only by RT-PCR do not necessarily trigger automatic disease control efforts. The prevalence of these viruses in salmonid and non-salmonid fish, and their potential to generate virulent ISAV isolates, is still poorly understood. Their existence could mean however, that the complete elimination of ISA might be impossible.

Immune Response and Vaccines

Atlantic salmon survivors of an ISAV infection appear to be less susceptible to re-infection indicating the presence of a protective immune response. In addition, anti-serum from convalescing fish has ISAV-neutralising activity.

For the development of vaccines the existence of different ISAV strains needs to be taken into consideration. However, Oystein Evenson says commercial vaccines seem to provide degree of cross-protection. Chilean isolates work in Norway and vice versa. However, Canadian isolates do not provide cross-protection with European strains. Canadian isolate seems to work OK in Faroe Islands.

Inactivated viral and DNA vaccines have been investigated and shown not to be 100% effective. Nevertheless, commercial vaccines are available and have been used in North America, Faroe Islands and Norway. These vaccines do not give virus clearance in immunised fish so vaccinated fish may become carriers.

The genotype of the fish may affect their susceptibility. Differences in susceptibility among different family groups of Atlantic salmon in freshwater have been observed in challenge experiments and in field tests, indicating the potential for breeding resistance.

In Norway – a positive finding of HPR0 is OK – no control required. Criteria for culling of the site include:

- Clinical outbreak consistent with ISA and
- Typical pathology and
- Confirmation of ISAV by IFAT/RT-PCR in cell line culture of samples from infected fish

Some flexibility, but if average daily mortality > 0.2% then must cull. Oystein Evenson thinks culling strategy is very important in controlling escalation of ISA. In UK the average response time between disease and culling was only 40 days (now free of ISA). In Norway the average response time was 80-90 days (can't control – keeps popping up as a problem). In Chile the average response time was in between, although slow was extensive culling.

9. Diagnosis and Diagnostic Tests

Clinical

ISA should be considered in Atlantic salmon with increased mortality and signs of anaemia, or lesions consistent with ISA disease. It should always be investigated if the haematocrit is less than 10%.

Laboratory Tests

Outbreaks of ISA can be diagnosed by isolating live virus from salmon organ samples on tissue cell cultures, the detection of ISAV antigens and using RT-PCR tests.

A few ISAV isolates from sick salmon have been difficult to culture and non-virulent isolates carried subclinically in wild salmonids can usually only be detected by RT-PCR.

ISAV can be isolated in SHK-1 (Atlantic salmon head kidney) or ASK (Atlantic salmon head kidney leukocyte) tissue cell cultures, or in other susceptible cell cultures such as CHSE-214 (Chinook salmon embryo) or TO (Atlantic salmon head kidney leukocytes) cells. Not all ISAV isolates grow in all cell lines; if possible more than one type of cell lines should be inoculated with fish samples. Cytopathic effects (CPE) are more apparent in some cell lines than others. The identity of the virus grown on cell lines can then be confirmed to be ISAV by using subsequent tests such as RT-PCR, immunofluorescence, hemadsorption or other assays to detect viral antigens and nucleic acids.

Viral antigens can be detected using an indirect fluorescent antibody test (IFAT) in infected salmon tissues or virus grown on cell cultures. Antigens can also be detected in infected salmon tissues using immunohistochemistry. Rapid tests based on immunochromatography are also available in some countries. RT-PCR is usually used to detect nucleic acids in infected salmon tissues.

Fish, including Atlantic salmon and rainbow trout can have humoral antibodies to ISAV. Enzyme-linked immunosorbent assays (ELISAs) have been developed to detect these antibodies. ELISAs have not been standardised for use in surveillance or the diagnosis of clinical cases.

Histopathology consistent with ISA can also aid in reaching a diagnosis.

Suspect and Confirmed Cases

The occurrence of non-culturable, apparently non-virulent ISA viruses in fish complicates the diagnosis of ISA. There is no gold standard test for ISAV and the confirmation of infection depends on a combination of test results. The World Organisation OIE currently defines a suspect case as one that meets any of the following criteria:

- Either clinical signs or lesions are consistent with ISA disease
- ISAV has been isolated in cell culture from one sample from a fish
- Two independent tests (e.g. RT-PCR and IFAT on tissues) suggest that the ISAV is present
- Antibodies to ISAV have been found.

ISA is confirmed if:

- The illness is consistent with ISA and
- Viral antigens have been detected in tissues with specific antibodies (e.g. by IFAT) and
- ISAV has either been cultured or nucleic acids have been detected by RT-PCR from at least one fish.

Samples to Collect

Samples should be from net pens that contain diseased fish: ISAV may be difficult to detect in adjacent pens, even if very sensitive techniques are used. Because outbreaks are confirmed by using different tests in individual fish (as described above), the OIE does not recommend that these samples are pooled. However, pooled samples may be collected for surveillance by RT-PCR or culture. The number of samples taken for surveillance varies with the prevalence of the virus in the population and the test used.

Blood should be taken for non-lethal sampling. RT-PCR testing of gill mucus has also been suggested for screening live fish. Samples of heart and mid-kidney should be collected for virus isolation and/or RT-PCR. The gills can also be included for surveillance if the RT-PCR test is used, however microbial contamination prevents the gills from being used for virus isolation on tissue culture. The detection of ISAV in the gills or gill mucus by RT-PCR could also be attributed to contamination by viruses in the water rather than necessarily to infection in the fish.

Antigens can be found in the kidney, heart and liver using the IFAT test. The OIE recommends mid-kidney smears for immunocytochemistry, and the mid-kidney and heart, including the valves and bulbus arteriosus for immunohistochemistry.

Histopathology

Tissue samples of the mid-kidney, liver, heart, pancreas/intestine, spleen, gills and skin/muscle should be taken for histopathology.

Histological changes in clinically diseased Atlantic salmon are variable, but can include the following:

- Numerous erythrocytes in the central venous sinus and gill lamellar capillaries where erythrocyte thrombi also form in the gills.
- Multifocal to confluent haemorrhages and/or hepatocyte necrosis at some distance from larger vessels in the liver. Focal accumulations of erythrocytes in dilated hepatic sinusoids.
- Accumulation of erythrocytes in blood vessels of the intestinal lamina propria and eventually haemorrhage into the lamina propria.
- Spleen stroma distended by erythrocyte accumulation.
- Slight multifocal to extensive diffuse interstitial haemorrhage with tubular necrosis in the haemorrhagic areas, erythrocyte accumulation in the glomeruli in the kidney.
- Erythrophagocytosis in the spleen and secondary haemorrhages in liver and kidney.