

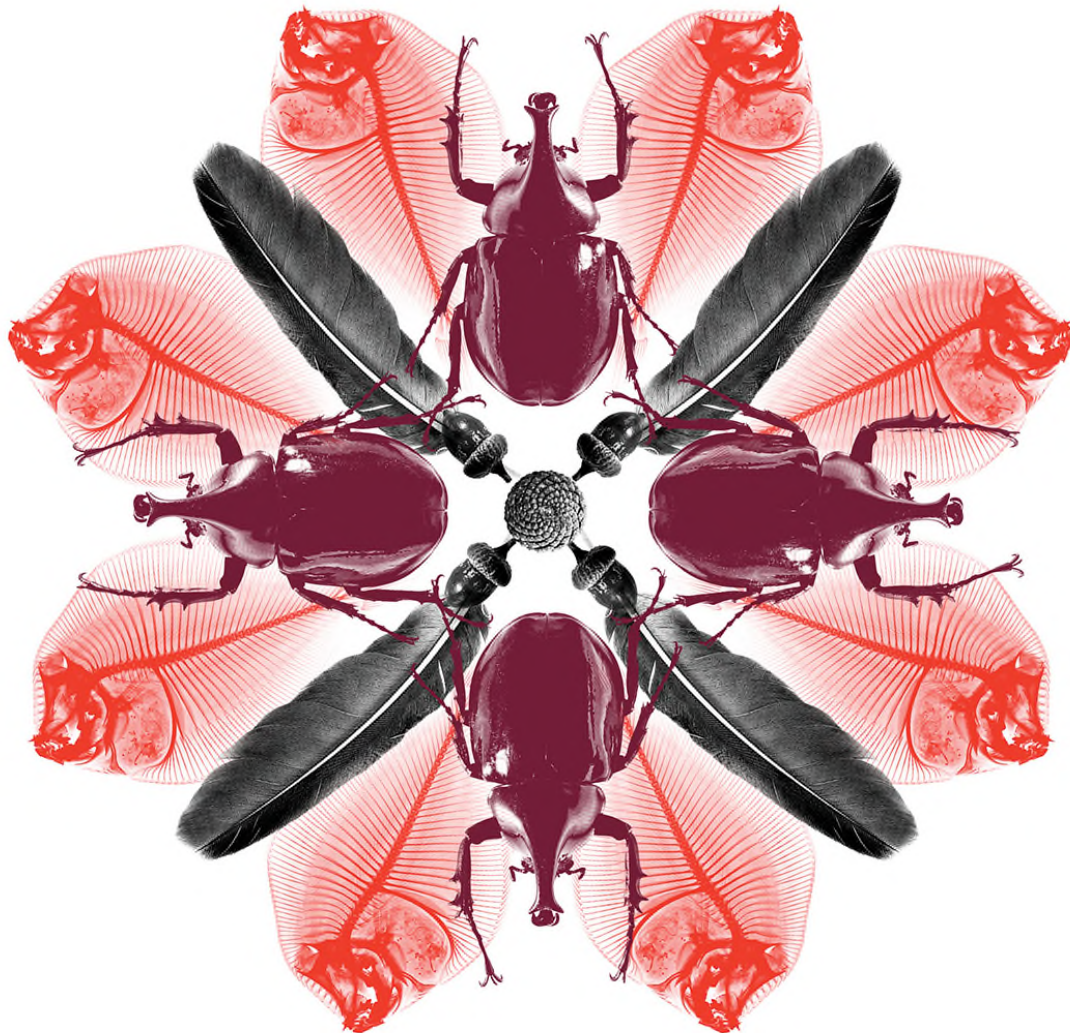


Australian Government
Department of Agriculture,
Water and the Environment

Draft assessment of a prescribed heat treatment as a risk management measure for fish and fish products for use as pet food and stockfeed

Draft report

September 2021



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Stakeholder submissions on draft reports

This draft report allows interested parties to comment on relevant technical biosecurity issues. A final report will consider any comments received.

Submissions should be sent to the Department of Agriculture, Water and the Environment and must meet the conditions specified in the relevant [Biosecurity advice notice](#).

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Summary

The Australian Government Department of Agriculture, Water and the Environment has prepared this draft report to assess an alternative biosecurity measure to the current heat treatment requirements for salmonid and non-salmonid fish products imported into Australia for use as pet food and stockfeed.

Any changes made to the import heat treatment requirements for fish products will also apply to whole non-salmonid fish imported into Australia for further processing at an approved arrangement (AA) site for the manufacture of pet food. It should be noted that whole salmonid fish are not permitted to be imported to Australia.

The alternative biosecurity measure assessed in this draft report is the European Union's processing method for category two and three material of fish origin (for definitions see, Regulation No 1069/2009 of 21 October 2009¹) in response to a request from the Norwegian Food Safety Authority (NFSA).

Australia permits the importation of fish products for use as pet food or stockfeed from any country based on import conditions. Fish products are typically a product that has been processed into a fish meal or fish oil.

This draft report proposes changes to the current biosecurity measures for fish products imported into Australia for use as pet food and stockfeed based on relevant peer-reviewed scientific information. This draft report also took advice from scientific experts into account, and considered relevant changes in industry practices, operational practicalities and international standards.

This draft report uses infectious pancreatic necrosis virus (IPNV), the most resistant of aquatic animal viruses to thermo-chemical treatments, as the minimum standard for aquatic viral inactivation to manage risks to achieve Australia's appropriate level of protection (ALOP).

This draft report proposes a combination of risk management measures and operational systems that will reduce the risk associated with the importation of fish products imported for use as pet food and stockfeed into Australia to achieve Australia's ALOP.

The proposed risk management measures applicable to fish products for use as pet food and stockfeed are:

- fish products for use as pet food and stockfeed (excluding non-salmonid fish products sourced from New Zealand) must have been treated to meet the following condition:
 - moist heated at a core temperature for at least 85°C for at least 25 minutes, or at an equivalent time and temperature agreed by the Department of Agriculture, Water and the Environment.
- must have been processed and packaged in premises approved by and under the control of the Competent Authority
- must have been manufactured from ingredients which have not been derived from terrestrial or avian animals. This includes egg products, dairy products and feathers.

¹ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:300:0001:0033:EN:PDF>

These proposed measures reduce animal biosecurity risks to a level that meets Australia's ALOP.

The proposed biosecurity measures recommended for fish products imported for use as pet food and stockfeed in this draft report differ from existing measures. The proposed changes to existing measures are:

- the current heat treatment of 100°C for no less than 30 minutes for fish products containing salmonid material will be reduced to a moist heat treatment of a core temperature of 85°C for no less than 25 minutes, or an equivalent time and temperature.
- the current heat treatment of 80°C for no less than 20 minutes, or at 85°C for no less than 15 minutes for fish products containing non-salmonid material, will be increased to a moist heat treatment of a core temperature of at least 85°C for at least 25 minutes, or at an equivalent time and temperature agreed by the Department of Agriculture, Water and the Environment.
- the current restrictions on the percentage of salmonid material contained in the fish products (no more than 2 per cent) will no longer apply.

Interested parties are requested to provide comments and submissions to the Department of Agriculture, Water and the Environment within the 60-day consultation period.

1 Introduction

1.1 Australia's biosecurity policy framework

Australia's biosecurity policies aim to protect Australia against the risks that may arise from exotic pests and diseases entering, establishing or spreading in Australia, thereby threatening Australia's unique flora and fauna, and agricultural industries that are relatively free from serious pests and diseases.

The Australian Government conducts risk analyses to formally consider the level of biosecurity risk that may be associated with proposals to import goods into Australia. If the biosecurity risks do not achieve the appropriate level of protection (ALOP) for Australia, risk management measures are proposed to reduce the risks to an acceptable level. If the risks cannot be reduced to an acceptable level, the goods will not be imported into Australia, until suitable measures are identified.

Successive Australian Governments have maintained a conservative, but not a zero risk, approach to the management of biosecurity risks. This approach is expressed in terms of Australia's ALOP, which reflects community expectations through government policy and is currently described as providing a high level of protection aimed at reducing risk to a very low level, but not to zero.

Australia's risk analyses are undertaken by the Department of Agriculture, Water and the Environment using technical and scientific experts in relevant fields and involve consultation with stakeholders at various stages during the process.

Risk analyses may take the form of a biosecurity import risk analysis (BIRA) or a non-regulated risk analysis (such as scientific review of existing policy and import conditions, or scientific advice).

Further information about Australia's biosecurity framework is provided in the [Biosecurity import risk analysis guidelines](#) 2016 located on the Department of Agriculture, Water and the Environment website.

The Department of Agriculture, Water and the Environment recognises that there might be new scientific information, technologies, or other measures that may provide an equivalent level of biosecurity protection for the disease agents identified as requiring risk management. Submissions supporting equivalence measures will be considered on a case-by-case basis.

1.2 Request to assess heat treatment

1.2.1 Background

Currently, fish products that meet the specified limits for salmonid material content, and the specific time and temperature requirements during the manufacturing process, are permitted entry into Australia. Current measures cap salmonid material content at 2%.

Australia's existing import requirements for whole fish for processing at an approved arrangement (AA) and fish products imported for use as pet food and stockfeed are specified in the relevant Australia's Biosecurity Import Conditions database (BICON) cases.

The Norwegian Food Safety Authority (NFSA) requested that Australia consider adopting the European Union's processing method for category two and three material of fish origin (Commission Regulation (EU) 2015/9 of 6 January 2015²), which includes ensilage at a pH below 4 for 24 hours before moist heat treatment at $\geq 85^{\circ}\text{C}$ for ≥ 25 minutes.

This draft report is an assessment of the European Union's processing method of ensilage at a pH below 4 for 24 hours before a moist heat treatment of 85°C for 25 minutes for managing the biosecurity risk associated with fish products for use as pet food and stockfeed in response to NFSA's request and its potential application in the Australian context.

1.2.2 Scope

The scope of this draft report is limited to an assessment of the thermal inactivation of infectious pancreatic necrosis virus (IPNV) in fish when ensilaged at a pH below 4 for 24 hours before being moist heated at 85°C for no less than 25 minutes (or at an equivalent time and temperature).

This draft report only assessed IPNV, as it is the most heat resistant aquatic pathogen (Defra 2005) and was considered the benchmark for aquatic viral inactivation to manage the biosecurity risk to achieve Australia's ALOP in imported fish products (excluding non-salmonid fish products sourced from New Zealand). The proposed heat treatment to inactivate IPNV will inactivate fish pathogens of concern to Australia. A summary of heat inactivation data for these pathogens is at Appendix 1.

Fish products are typically a product that has been processed into a fish meal or fish oil and may be imported for use as pet food and stockfeed, including aquaculture feed.

This draft report has not considered the risks posed by products that have been derived from terrestrial or avian animals and does not include an assessment of the risks associated with fish products treated to meet conditions other than those described above.

1.2.3 Existing policy

Australian Policy

Import policy exists for whole fish for further processing at an AA, and fish products from all countries for use as pet food and stockfeed.

The [import requirements](#) for these commodities can be found on BICON or on the department's website (awe.gov.au).

Currently, imports of fish products for use as pet food and stockfeed must:

- be heated at 80°C for no less than 20 minutes, or at 85°C for no less than 15 minutes, or at an equivalent time and temperature, and
- not contain any salmonid material, or
- not comprise more than 2% salmonid material, and the salmonid material has been heated at 100°C for not less than 30 minutes.

² <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:300:0001:0033:EN:PDF>

The department has considered all the diseases previously identified in the existing policies and where relevant, the information in those assessments has been taken into account in this review.

Domestic arrangements

The Australian Government is responsible for regulating the movement of animals and animal products into and out of Australia. However, the state and territory governments are responsible for animal health and environmental controls within their individual jurisdictions.

Legislation relating to resource management or animal health may be used by state and territory government agencies to control interstate movement of animals and their products. Once animals and animal products have been cleared by Australian Government biosecurity officers, they may be subject to interstate movement conditions. It is the importer's responsibility to identify and ensure compliance with all requirements.

1.2.4 Consultation

This draft report will be released for 60 days of public consultation to give stakeholders the opportunity to provide technical comment. The closing date for comments is 1 November 2021. Stakeholder submissions will be considered when finalising the draft report.

1.2.5 Next steps

This draft report gives stakeholders the opportunity to comment and draw attention to any scientific, technical or other gaps in the data, misinterpretations and errors.

The department will consider submissions received on this draft report and may consult informally with stakeholders. The department will then prepare a final report, taking into account stakeholder comments.

The final report will be published on the department's website with a notice advising stakeholders of the release. The department will also notify the proponent, registered stakeholders and the World Trade Organization (WTO) Secretariat about the release of the final report. Publication of the final report represents the end of the process. The conditions recommended in the final report will be the basis of any import permits issued.

2 The assessment

The World Organisation for Animal Health (OIE), in its Aquatic Animal Health Code (the OIE Aquatic Code), describes the components of risk analysis in Chapter 2.1.

This draft report has drawn on several sources of information (this list is not exhaustive):

- the 1999 non-viable marine finfish IRA (AQIS 1999), the full title being Australia's [Import risk analysis on non-viable salmonids and non-salmonid marine finfish](#)
- the OIE Aquatic Code (OIE 2019)
- a review of relevant scientific literature
- existing Australian Government policy.

While this report is consistent with OIE principles, it is a modified analysis, and the hazard identification is limited to the virus causing infectious pancreatic necrosis (IPN). IPN virus (IPNV) is a non-enveloped RNA virus that is the most thermo-chemical treatment resistant aquatic animal pathogen and is often used as the minimum standard for aquatic viral inactivation (Defra 2005).

IPNV can infect both salmonid and non-salmonid species and was identified as a disease of concern that requires biosecurity measures in the 1999 non-viable marine finfish IRA (AQIS 1999). Measures that inactivate this pathogen will also manage fish pathogens of concern to Australia, including but not limited to:

- infectious haematopoietic necrosis virus
- infectious salmon anaemia virus
- salmonid alphavirus
- viral haemorrhagic septicaemia
- other aquatic birnaviruses
- red sea bream iridovirus and other iridoviruses
- *Aeromonas salmonicida* typical (furunculosis) and atypical strains
- *Renibacterium salmoninarum*
- *Yersinia ruckeri* (Hagerman strain)
- *Photobacterium damsela* subsp. *piscicida*.

Therefore, in this draft report IPNV is used as the benchmark pathogen for aquatic pathogen inactivation to manage risks to achieve Australia's ALOP.

To determine viral inactivation, the desired sterility assurance level (SAL) is usually set at 10^{-6} . This SAL provides an assurance that there is less than one chance in a million of viable contamination in any one unit. Hence, a process shown to achieve a 6-log reduction (i.e. 10^{-6})

will reduce a population from a million viable pathogens (10^6) to one viable pathogenic agent (Mosley 2008).

For this assessment, if the prescribed heat treatment achieves a titre reduction of at least 6 logs (that is, 10^6) of IPNV in a fish product before export to Australia then it is considered to present a “negligible” likelihood of entry and, therefore, results in an overall risk of “very low”, achieving Australia’s ALOP.

The department has compiled its key findings, conclusions and proposed changes to biosecurity measures in this document. The report is split into two further sections, the next chapter addresses the scientific information regarding the prescribed heat treatment for inactivation of IPNV. The final section proposes changes to the biosecurity requirements for imported fish products to Australia according to the findings of this report.

3 Key findings

3.1 Infectious pancreatic necrosis virus

3.1.1 Background

Infectious pancreatic necrosis (IPN) is a particularly important disease of salmonids, but other species of non-salmonid fish are also susceptible to the disease.

IPN was originally described as a disease affecting salmonid fry and fingerlings in freshwater hatcheries in North America and subsequently northern Europe. However, since the 1980s, it has been reported in both freshwater and marine farms infecting all age groups with increasing prevalence and distribution (OIE 2009; Jensen and Kristoffersen 2015).

The mortality caused by IPNV may be as high as 70% in young salmonid fish and the virus establishes an asymptomatic carrier state in survivors, both in different species of salmonids and in other species of farmed fish, such as turbot and Atlantic cod (Curtin et al. 2005; García et al. 2006; Rodriguez et al. 2001). IPNV is also known to infect Atlantic menhaden (*Brevoortia tyrannus*), striped bass (*Morone saxatilis*) and southern flounder (*Paralichthys lethostigma*) in the United States and Japanese eel (*Anguilla japonica*) in Taiwan (McAllister and Owens 1995) and spotted wolffish (*Anarhichas minor*) (Sommer et al. 2004).

In addition, surveys and case reports have documented the occurrence of IPNV, or viruses showing serological relatedness, in a wide range of estuarine and freshwater fish species. Such as, loach (*Misgurnus anguillicaudatus*), pike (*Esox lucius*) and numerous other species in the families Anguillidae, Atherinidae, Bothidae, Carangidae, Cotostomidae, Cichlidae, Clupeidae, Cobitidae, Coregonidae, Cyprinidae, Esocidae, Moronidae, Paralichthyidae, Percidae, Poeciliidae, Sciaenidae, Soleidae and Thymallidae (Ahne et al. 1978; Chou et al. 1993; Reno 1999; OIE 2009; Jensen and Kristoffersen 2015).

IPNV is a nationally notifiable disease in Australia (Department of Agriculture 2019) and was previously listed by the OIE until 2009. The basis of delisting by the OIE is that IPNV is considered enzootic in most of the regions where salmonid fish are cultivated (Tapia et al. 2017).

Australian Status

IPNV is a nationally notifiable disease of concern and has not been reported in Australia.

3.1.2 Technical information

The virus causing IPN is a non-enveloped virus of the Birnaviridae family, which has a bisegmented genome of double-stranded RNA (Dobos 1995). There are three distinguished species of aquabirnaviruses (IPNV being the type species), categorised primarily based on host species (Delmas et al. 2019).

Aquabirnaviruses display considerable antigenic diversity and can be separated into two serogroups (A and B), with different serotypes within each group. The virus causing IPN contains a number of serotypes within group A. Different serotypes of IPNV have been isolated from a number of different geographical areas (King et al. 2011). Each serotype of IPNV has a marked difference in the degree of virulence (McAllister and Owens 1995) but any difference in thermal tolerance between serotypes, or serogroups of aquabirnaviruses, is unknown.

In experimentally infected rainbow trout (*Oncorhynchus mykiss*) control fish infected with IPNV during a vaccination trial had a viral infective titre of 10^3 to 10^8 TCID₅₀ mL⁻¹ (Heras et al. 2010). During acute IPN, viral replication in pancreatic, intestinal and kidney tissues can yield titres > 10^{10} TCID₅₀ mL⁻¹ (Smail et al., 1995, 2006), coinciding with considerable cell necrosis. While kidney titres up to 10^5 TCID₅₀ mL⁻¹ are not uncommon in apparently healthy fish (Wolf, 1988; Taksdal and Thorud, 1999).

Smail et al. (1993) reported IPNV concentrations found in fish silage from mortalities on a fish farm to be between 2-2.5 log₁₀, plaque forming units (PFU) mL⁻¹ (approximately 3-3.6 log₁₀, TCID₅₀ mL⁻¹) which was claimed to be typical for native silages.

The minimum dose for IPNV infection is unknown (Munro and Midtlyng 2011) but it has been estimated to require < 10 TCID₅₀ mL⁻¹ to infect Atlantic salmon post-smolts via the water (Urquhart et al. 2008). The observation that only very low concentrations of IPNV are needed for successful infection via water suggests that very efficient mechanisms for active uptake of the virus are present in gill, intestinal mucus and/or cutaneous tissues (Munro and Midtlyng 2011).

IPNV is also resistant to environmental conditions and may survive for days in the external environment, with loss of 99.9% of titre taking 27 days in estuarine water and 17 days in sea water at 15°C (Toranzo and Hetrick 1982).

Birnaviridae viruses are generally stable at pH 3–9 and resistant to heat at 60 °C for one hour (King et al. 2011). A review of heat inactivation information for IPNV is outlined in Table 1. It is generally accepted that IPNV inactivation is biphasic, with an initial rapid degradation phase at relatively low temperatures and a slower inactivation phase at higher temperatures. The information in Table 1 focuses on inactivation in the later phase.

Table 1 Inactivation studies of infectious pancreatic necrosis virus

Starting titre	Medium	Inactivation	pH	Time	Temperature (degrees)	Quantification method	Reference
Not reported	Not reported	99.9%	3	30 minutes	60	Not reported	OIE Animal Disease Card (2000)
Not reported	Not reported	99.9%	7-9	5 hours	60	Not reported	OIE Animal Disease Card (2000)
5.6 log ₁₀ (TCID ₅₀ mL ⁻¹)	Medium mimicking the water-soluble phase of hydrolyzed fish by-products	5 log ₁₀	4	4.1 minutes	85	Kärber method	Nygaard et al. (2012)
7.5 TCID ₅₀ mL ⁻¹ .	Citric phosphate buffer	No virus detected at end of treatment	4	5 minutes	82	endpoint dilution assay	Whipple and Rohovec (1994)

Starting titre	Medium	Inactivation	pH	Time	Temperature (degrees)	Quantification method	Reference
7.5 TCID ₅₀ mL ⁻¹ .	Fish silage	No virus detected at end of treatment	3.8-4.3	5 minutes	82	endpoint dilution assay	Whipple and Rohovec (1994)
Not reported	2 % foetal bovine material	4 log ₁₀	7.2	45 minutes	70	endpoint dilution assay	Humphery et al. (1991)

IPNV has been found to either be more resistant to thermal inactivation at lower pH when compared to neutral pH values (Nygaard et al. 2012), or pH did not have an effect on the thermal resistance (Whipple and Rohovec 1994). Fish silages are typically processed at a low pH to aid protein hydrolyzation and limit bacterial contamination.

Where the start points of the studies are stated, they are much lower than the maximum IPNV titres found in acutely infected susceptible fish (> 10¹⁰ TCID₅₀ mL⁻¹; Smail et al., 1995, 2006).

When the IPNV inactivation data of Nygaard et al. (2012) are extrapolated, the times for 6, 7, 8, 9 and 10 log₁₀ reductions at 85°C are 5.0, 6.0, 6.9, 7.9 and 8.8 minutes, respectively.

Based on the evidence outlined in Table 1, IPNV would be inactivated in a fish product when a moist heat treatment is applied at a core temperature of 85°C for 25 minutes, as per the European Union's processing method for category two and three material of fish origin.

3.1.3 Key points

- IPNV is nationally notifiable in Australia and is listed as a disease of concern in both salmonid and non-salmonid species of finfish in the 1999 non-viable marine finfish IRA
- IPNV can cause high mortality and morbidity levels with a mortality rate greater than 70 per cent in young salmonid fish
- IPNV can establish as an asymptomatic carrier state in survivors
- IPNV, or viruses showing serological relatedness, have been detected in a wide range of estuarine and freshwater fish species
- IPNV has been detected at >10¹⁰ TCID₅₀ mL⁻¹ in the target organs of heavily infected fish.
- kidney titres up to 10⁵ TCID₅₀ mL⁻¹ IPNV are not uncommon in apparently healthy fish.
- IPNV concentrations found in fish silage from mortalities on a fish farm were between 3 to 3.6 log₁₀ TCID₅₀ mL⁻¹, which was claimed to be typical for native silages from IPNV-infected fish
- Birnaviridae viruses are generally stable at pH 3–9 and there was no additional inactivation of IPNV when a heat treatment was applied at a low pH
- the proposed treatment conditions (85°C for 25 mins) for primary processing of fish product will inactivate IPNV (minimum 10⁻⁶ reduction) over the range of observed titres in individual fish or in silage of infected fish populations
- therefore, the likelihood of entry of IPNV in fish products for use as pet food and stockfeed when moist heat treated to a core temperature of at least 85°C for at least 25 minutes was estimated to be **negligible**.

3.1.4 Conclusions

Based on the above information, the processing methods as defined in the scope at section 1.2.2. of this document (moist heat treatment of at least 85°C for at least 25 minutes) will inactivate (minimum 10⁻⁶ reduction) any IPNV that may be present in fish.

Therefore, the following conclusion can be made:

- fish products that have been derived from fish that have been moist heat treated at a core temperature of at least 85°C for at least 25 minutes would inactivate any viable IPNV present in the product.
- ensilage at a pH below 4 for 24 hours prior to the heat treatment would not provide any additional inactivation of IPNV.
- to ensure that the required heat treatment has been applied, the fish products should be processed and packaged in premises approved by, and under the control of a CA.
- as the processing applied to the fish products will manage risks to achieve Australia's ALOP, the current restrictions on the percentage of salmonid material contained in imported fish products (no more than 2%) should no longer apply.
- To ensure consistency with import requirements, the proposed heat treatment should also replace the current heat treatment requirements for whole medium and high risk non-salmonid fish further processed at AA sites in Australia for the manufacture of pet food.

4 Biosecurity measures

It is proposed that the following import conditions will apply to fish products imported for use as pet food (including fish food) and stockfeed (including aquaculture feed).

4.1 Biosecurity measures for the importation of fish and fish products

Importers must obtain a permit from the Department of Agriculture, Water and the Environment to import whole fish for further processing at an AA and fish products (excluding non-salmonid products sourced from New Zealand) into Australia for use as pet food and stockfeed, before the goods are imported.

The application must include:

- the name of the importer and exporter
- a description of the goods to be imported.

The application will be assessed on the above information as well as any other criteria deemed relevant by the delegate of the Director of Biosecurity. The goods exported to Australia must be accompanied by an Official Government Certificate issued from a body listed in the List of Overseas Authorities – Aquatic Animals for Import (also known as a CA).

Non-salmonid fish and their products sourced from New Zealand do not require an import permit but will be required to meet conditions that are specified in the Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2021. These conditions specify that the goods are accompanied by a New Zealand Ministry of Primary Industries (MPI) certificate stating that the fish from which the product was derived are of New Zealand origin or were caught in New Zealand's exclusive economic zone (EEZ) or in adjacent international waters.

For further information on import requirements for the import of whole fish for further processing at an AA and non-salmonid whole fish and fish products sources from New Zealand into Australia for use as pet food and stockfeed see Australia's Biosecurity Import Conditions database (BICON): bicon.agriculture.gov.au/BiconWeb4.0

Manufactured aquatic animal feeds also require an import permit. Applications are assessed on the basis of the individual ingredients and how they have been processed.

If a fish product is present in a manufactured aquatic animal feed it must meet the same ingredient and heating requirements during the manufacturing process as for those specified fish products.

4.1.1 Import conditions

Fish products (excluding non-salmonid fish products sourced from New Zealand)

Fish products may be exported to Australia from a country with a listed CA and must be accompanied by an Official Government Certificate. The Official Government Certificate must state that the fish product:

- has been treated to meet one of the following conditions:
 - moist heated at a core temperature of at least 85°C for at least 25 minutes, or at an equivalent time and temperature agreed by the Department of Agriculture, Water and the Environment

- has been processed and packaged in premises approved by and under the control of the CA
- has been manufactured from ingredients which have not been derived from terrestrial or avian animals. This includes egg products, dairy products and feathers.

Each consignment must be packed in clean and new packaging and must be free of Biosecurity Risk Material (BRM) prior to arrival into Australian territory.

Verification of import conditions

On arrival in Australia consignments may be inspected to ensure freedom from BRM and samples may be taken to test for the presence of terrestrial animal or avian derived material.

The department will examine the certificate on arrival. If there are reasonable grounds to suspect the certificate is fraudulent, the department will conduct an investigation.

Fish and fish products may be inspected by the department to ensure compliance with biosecurity attestations.

Review of processes

The Director of Biosecurity may suspend, revoke and/or review these conditions as warranted in the light of new information and, in particular, significant changes in factors relating to biosecurity risk.

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Glossary

Term or abbreviation	Definition
ALOP	Appropriate level of protection
appropriate level of protection (ALOP) for Australia	The <i>Biosecurity Act 2015</i> defines the appropriate level of protection (or ALOP) for Australia as a high level of sanitary and phytosanitary protection aimed at reducing biosecurity risks to very low, but not to zero.
approved arrangement (AA)	Approved arrangement (AA) is defined in the <i>Biosecurity Act 2015</i> as an arrangement for which an approval is in force under paragraph 406(1)(a) (including a varied arrangement for which an approval is in force under that paragraph as it applies because of subsection 412(3)).
Australian territory	Australian territory as referenced in the <i>Biosecurity Act 2015</i> refers to Australia, Christmas Island and Cocos (Keeling) Islands.
BA	Biosecurity advice
BICON	Australia's Biosecurity Import Condition System
biosecurity	The prevention of the entry, establishment or spread of unwanted pests and infectious disease agents to protect human, animal or plant health or life, and the environment.
biosecurity import risk analysis (BIRA)	The <i>Biosecurity Act 2015</i> defines a BIRA as an evaluation of the level of biosecurity risk associated with particular goods, or a particular class of goods, that may be imported, or proposed to be imported, into Australian territory, including, if necessary, the identification of conditions that must be met to manage the level of biosecurity risk associated with the goods, or the class of goods, to a level that achieves the ALOP for Australia. The risk analysis process is regulated under legislation.
biosecurity measures	The <i>Biosecurity Act 2015</i> defines biosecurity measures as measures to manage any of the following: biosecurity risk, the risk of contagion of a listed human disease, the risk of listed human diseases entering, emerging, establishing themselves or spreading in Australian territory, and biosecurity emergencies and human biosecurity emergencies.
biosecurity risk	The <i>Biosecurity Act 2015</i> refers to biosecurity risk as the likelihood of a disease or pest entering, establishing or spreading in Australian territory, and the potential for the disease or pest causing harm to human, animal or plant health, the environment, economic or community activities.
Biosecurity Risk Material (BRM)	Material that can be found in the packaging of consignments. A definition of BRM can be found in Australia's Biosecurity Import Conditions database (BICON): bicon.agriculture.gov.au/BiconWeb4.0 .
Competent Authority	The Veterinary Authority or other Governmental Authority of a Member Country having the responsibility and competence for ensuring or supervising the implementation of aquatic animal health and welfare measures, international health certification and other standards and recommendations in the Aquatic Code in the whole territory.
the department	The Australian Government Department of Agriculture, Water and the Environment
disease agent	A biological agent that can cause disease to its host.
endemic	Belonging to, native to, or prevalent in a particular geography, area or environment.
FAO	Food and Agriculture Organization of the United Nations
Fish	Means an elasmobranch or a teleost.
Fish meal	Means a product derived from a fish that has been ground and heat processed with a low moisture content.

Term or abbreviation	Definition
Fish product	A product derived from a fish that has undergone a heat treatment as defined in the scope at section 1.2.2.
fish oil	A product that is derived from fish and is a purified fatty oil that is free of protein material for human consumption, which has destined for purposes other than human consumption
fish silage	A product that is derived from fish and is a processed protein
goods	The <i>Biosecurity Act 2015</i> defines goods as an animal, a plant (whether moveable or not), a sample or specimen of a disease agent, a pest, mail or any other article, substance or thing (including, but not limited to, any kind of moveable property).
host	An organism that harbours a parasite, mutual partner, or commensal partner, typically providing nourishment and shelter.
import permit	Official document authorising a person to bring or import particular goods into Australian territory in accordance with specified import requirements.
IRA	Import risk analysis
Low, medium and high risk non-salmonid species	Information regarding low, medium and high-risk species can be found in Australia's Biosecurity Import Conditions database (BICON): bicon.agriculture.gov.au/BiconWeb4.0 .
non-regulated risk analysis	Refers to the process for conducting a risk analysis that is not regulated under legislation (<i>Biosecurity import risk analysis guidelines 2016</i>).
OIE	World Organisation for Animal Health
OIE Code	OIE Aquatic Animal Health Code 2019
OIE Manual	OIE Manual of Diagnostic Tests for Aquatic Animals 2019
pathogen	A biological agent that can cause disease to its host.
petfood	Food for pets (including pet fish)
restricted risk	Risk estimate with phytosanitary measure(s) applied.
risk analysis	Refers to the technical or scientific process for assessing the level of biosecurity risk associated with the goods, or the class of goods, and if necessary, the identification of conditions that must be met to manage the level of biosecurity risk associated with the goods, or class of goods to a level that achieves the ALOP for Australia.
salmonid	Fish that are members of the family Salmonidae and the genus <i>Plecoglossus</i> .
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures.
stakeholders	Government agencies, individuals, community or industry groups or organisations, in Australia or overseas, including the proponent/applicant for a specific proposal, that have an interest in the policy issues.
stockfeed	Any single material, or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food producing species (including horses, poultry and for aquaculture) for the maintenance of life, normal growth, production, work and reproduction. A stockfeed comprises one or more stockfeed ingredients and may also contain one or more stockfeed additives
TCID ₅₀	50% Tissue Culture Infective Dose
unrestricted risk	Unrestricted risk estimates apply in the absence of risk mitigation measures.
WTO	World Trade Organization
viral titre	Numerical expression of the quantity of virus in a given volume.

Appendix 1

The table below outlines the evidence that the prescribed moist heat treatment (at least 85°C for at least 25 minutes) inactivates other aquatic diseases of concern.

Overview of heat inactivation for other fish viral, bacterial and myxozoan pathogens.

Pathogen	Results	Reference	Effective
ISAV	Virus infectivity is lost within 30 min of exposure at 56°C.	Falk et al. (1997)	Yes
SAV	Inactivated with no virus detected within 1 hour at 60°C.	Graham et al. (2007)	Yes
VHSV	Inactivated by heat 70°C for 1 min.	Jørgensen (1973)	Yes
IHN	Inactivated by heat 55°C for 30 sec.	Whipple & Rohovec (1994)	Yes
RSIV	RSIV is inactivated at a heat treatment of 56 °C for 30 min	Nakajima and Sorimachi (1994)	Yes
<i>Renibacterium salmonarum</i>	Was not detected after 15 min at 65°C. Undetectable after 1 min in fish silage at 55°C.	Whipple & Rohovec (1994)	Yes
<i>Aeromonas salmonicida</i>	Undetectable after 2 min at 50°C.	Whipple & Rohovec (1994)	Yes
<i>Myxobolus cerebralis</i>	Temperatures above 75°C for at least 5 min inactivated the infective stage.	Wanger et al. (2003)	Yes

ISA = infectious salmon anaemia; SAV = salmon alpha virus; VHS = viral haemorrhagic septicaemia virus; IHN = infectious haematopoietic necrosis; and RSIV = red sea bream iridovirus.