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& AQUACULTURE
PIRSA

Policy for the release of aquatic resources

APRIL 2015

PREMIUM
FOOD AND WINE FROM OUR
CLEAN
ENVIRONMENT



Policy for the Release of Aquatic Resources

Information current as of April 2015

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1. INTRODUCTION

The role of the South Australian Government, as custodian of the State's aquatic resources, on behalf of the broader community and future generations, is to ensure that they are protected, managed and used in a manner that is consistent with the principles of ecologically sustainable development, in pursuit of the objects of the *Fisheries Management Act 2007* (the Act). This includes authority for regulating translocations of live aquatic resources under the Act, i.e. the movement and release of living aquatic resources from one area to another.

A diverse range of factors may affect the productivity of fish stocks in the marine, freshwater and estuarine environments. This includes natural changes in environmental conditions that influence breeding success, larval survival, recruitment, manmade habitat modifications, pollution, climate change, fishing pressure, coastal/urban development and the introduction of disease or exotic species.

One way to address declines in productivity of fish stocks is the translocation of aquatic resources. Translocating aquatic resources can be used to help increase abundance of recruitment limited stocks, to restore depleted populations, to provide protection for endangered species or to enhance catch rates of important commercial, recreational and Aboriginal traditional fisheries. An increase in fish stocks, as a result of releasing aquatic resources can provide many benefits environmentally, socially and economically to the community and to the various fishing sectors. This can include creating 'put and take' fisheries and augmenting existing fish stocks providing improved fishing opportunities, conservation outcomes, employment and subsequent economic benefits.

Three types of stocking (and then release) of aquatic resources will be considered in this policy. These are 'conservation stocking', 'stock enhancement' and 'harvest stocking'. Conservation stocking is where a fish stock is not performing against biological or environmental fisheries management objectives and requires a recovery program (e.g. protected, endangered or threatened species). Stock enhancement is where a fish stock or fishery is not performing against defined fisheries management objectives, whether they are biological, social, economic or environmental, or where a fish stock or fishery is performing satisfactorily, but production could be further improved (provided the environment can cope with the increase in fish stock without detriment to the ecosystem). Harvest stocking is where a fish stock or fishery is to be established in waters where the fish stock or fishery did not previously exist (e.g. a freshwater impoundment or dam).

Reviews of numerous programs around the world have indicated that the translocation of aquatic resources is most successful at increasing the productivity of a fish stock when it overcomes the limiting factors that impact the fish stock (Gillanders et al. 2006). Other elements for successful translocation programs require that the habitat must be in good condition and the species being translocated must be physiologically and behaviourally capable of surviving at the site of stocking.

This policy has been developed to guide applicants who wish to translocate aquatic resources into South Australian waters for the purpose of conservation stocking, stock enhancement and harvest stocking. It establishes a risk-based assessment process to evaluate and regulate such translocations. The cost effectiveness of proposals will be a consideration for the applicant.

Any future translocation of aquatic resources in the waters of South Australia, which are assessed as suitable, would be performed consistent with the principles of ecologically sustainable development, while minimising the risk of introducing disease (or exotic species) as defined in the *Livestock Act 1997*. Other relevant State and Commonwealth legislation will also be taken into account when assessing applications.

This policy has been developed with the guidance of the *National Policy for the Translocation of Live Aquatic Organisms, - Issues, Principles and Guidelines for Implementation 1999*. In the future, protocols for specific situations are likely to be developed on an as-needs-basis to support this policy.

2. SCOPE

The policy addresses the consideration of applications to translocate live aquatic resources into South Australian waters managed under the *Fisheries Management Act 2007* for the purposes of conservation stocking, stock enhancement and harvest stocking under section 78. It does not include translocations for the purpose of open water aquaculture, land-based aquaculture, research, display, live bait, live seafood and aquarium trade. This policy does not manage translocations incidental with other processes such as ship ballast water discharge or translocations for other purposes or into other waters.

3. OBJECTIVES

The objectives of this policy are to:

- Implement South Australia's commitment under the *National Policy for the Translocation of Live Aquatic Organisms - Issues, Principles and Guidelines for Implementation*;
- Provide a risk assessment process and administrative framework for proposals to translocate aquatic resources for the purposes of stock enhancement within South Australia that require approval under the *Fisheries Management Act 2007*, consistent with the principles of ecologically sustainable development;
- Provide transparency and information for stakeholders involved in the administrative process and all other users of the aquatic environment; and
- Provide guidance and clarity about the administrative process that must be completed prior to undertaking the translocation of aquatic resources.

4. POLICY AND LEGISLATIVE FRAMEWORK

National Policy for the Translocation of Live Aquatic Organisms - Issues, Principles and Guidelines for Implementation 1999

To meet the intentions of the *National Policy for the Translocation of Live Aquatic Organisms - Issues, Principles and Guidelines for Implementation* all Australian states and territories are required to develop for their jurisdiction arrangements that achieve:

- Consistency in the consideration of translocations within Australia;
- Effective coordination of administrative arrangements within jurisdictions;
- Appropriate support legislation;
- Acceptable levels of compliance;
- A nationally accepted, explicit and transparent risk assessment process;
- Regular assessment and continuous improvement of risk management strategies, including the adequacy of risk assessment, decision making and enforcement procedures; and
- Increased community and industry awareness of the potential risks associated with the translocation of live aquatic organisms.

This policy aims to meet all of these commitments.

Fisheries Management Act 2007

The *Fisheries Management Act 2007* defines ecologically sustainable development as comprising the use, conservation, development and enhancement of the aquatic resources of the State in a way, and at a rate, that will enable people and communities to provide for their economic, social and physical well-being while:

- (a) sustaining the potential of aquatic resources of the State to meet the reasonably foreseeable needs of future generations
- (b) safeguarding the life-supporting capacity of the aquatic resources of the State
- (c) avoiding, remedying or mitigating adverse effects of activities on the aquatic resources of the State,

Where resource management decisions must be made in an environment of uncertainty, the Government, in partnership with key stakeholders, will take a precautionary approach to the management of South Australia's aquatic resources. Under this approach, if there are threats of serious or irreversible damage to the aquatic resources of the State, a lack of full scientific certainty should not be used as a reason for postponing measures to prevent such damage.

The Minister, Director and other persons or bodies involved in the administration of this *Fisheries Management Act 2007*, and any other person or body required to consider the operation or application of the *Fisheries Management Act 2007* (whether acting under the *Fisheries Management Act 2007* or another Act), must:

- (a) act consistently with, and seek to further the objects of, the *Fisheries Management Act 2007*;
- (b) insofar as this *Fisheries Management Act 2007* applies to the Adelaide Dolphin Sanctuary, seek to further the objects and objectives of the *Adelaide Dolphin Sanctuary Act 2005*;
- (c) insofar as this *Fisheries Management Act 2007* applies to the River Murray, seek to further the objects of the *River Murray Act 2003* and the *Objectives for a Healthy River Murray* under that Act; and
- (d) insofar as this Act applies to areas within a marine park, seek to further the objects of the *Marine Parks Act 2007*.

Section 78 (2) of the *Fisheries Management Act 2007* specifies that it is an offence to release an exotic fish, any aquaculture fish or any fish that has been kept from their natural habitat into (unconfined) natural waters. The Minister may issue a permit authorising a person to release aquatic resources into specified waters.

Regulations may be made under section 130 of the *Fisheries Management Act 2007* to control exotic organisms and disease, including regulations for the control of exotic aquatic organisms and the prevention, control and eradication of disease in aquatic resources.

This policy guides the implementation of the provisions of the *Fisheries Management Act 2007* and regulations under this Act. It does not replace them or in any way, affect the operation or significance of the legislation and should be read subject to them. This policy replaces all previous policies or other determinations in relation to the release or translocation of aquatic organisms under the repealed *Fisheries Act 1982* or under the *Fisheries Management Act 2007*.

Environment Protection and Biodiversity Conservation Act 1991

Under the *Environment Protection and Biodiversity Conservation Act 1991* (EPBC), actions that have, or are likely to have, a significant impact on a matter of national environmental significance requires approval from the Australian Government Minister for the Environment. The Minister may exempt a person proposing to take action under certain circumstances.

Livestock Act 1997

The *Livestock Act 1997* requires any person that knows or suspects livestock or livestock products (this includes aquatic livestock) owned by, or under, his or her control, are affected with, or died from, a notifiable disease must report the incident and take all reasonable measures to control or eradicate the disease (Part 4 of the *Livestock Act 1997*).

Aquaculture Act 2001

Delineation between the release or translocation of aquatic resources and aquaculture will require a case-by-case analysis of the prescribed activities, considering the proposal and the definition of aquaculture in the *Aquaculture Act 2001*. The *Aquaculture Act 2001* defines 'aquaculture' as *farming of aquatic organisms for the purposes of trade or business or research, but does not include an activity declared by regulation not to be aquaculture and 'farming of aquatic organisms' as an organised rearing process involving propagation or regular stocking or feeding of the organisms or protection of the organisms from predators or other similar intervention in the organisms' natural life cycles.*

Where there is a private benefit for an individual or company, derived from a trade or business or research-related farming activity on private land, or leased waters from the State (as per Part 6 of the *Aquaculture Act 2001*) with a corresponding aquaculture licence, the activity falls under the regulatory management of the *Aquaculture Act 2001*. Although there are some generalisations that can be made in relation to the delineation between stock enhancement and aquaculture there will be a need to consider specific activities on a case-by-case basis to determine which category a proposal fits.

5. POLICY POSITION

The translocation of aquatic resources will be considered by PIRSA when:

- The purpose of the translocation is for conservation stocking, stock enhancement and harvest stocking;
- There are no other identified factors that would prevent stock recruitment; and
- The risk of negative impacts of the translocation of aquatic resources is determined to be within acceptable limits.

The translocations of aquatic resources will be assessed on a case-by-case basis in accordance with the following policy guidelines:

- The translocation of aquatic resources is one possible response to a decline in stock size. Addressing limiting factors and applying a suite of management tools are likely to be optimal for achieving both short and long term improvements in stocks.
- A precautionary approach must be taken in assessing applications for the release or translocation of aquatic resources consistent with the *Fisheries Management Act 2007*.

When the risk of translocating aquatic resources poses a higher risk or is not fully understood, an ecologically sustainable development risk assessment may be required.

All ecologically sustainable development risk assessments should be conducted in accordance with the Australian standards AS/NZS 4360:2004 for Risk Management or the *National ESD Reporting Framework for Australian Fisheries* of Fletcher et al. (2002), which can be found at the website: http://www.fisheries-esd.com/a/pdf/WildCaptureFisheries_V1_01.pdf, as this will facilitate outcomes that can be assessed to determine the level of risk.

6. ADMINISTRATION OF RELEASES

Applicants may identify an opportunity to translocate aquatic resources in South Australian waters. Alternatively, the Minister or a delegate may invite applications to participate in the translocation of aquatic resources. The application process outlined below and summarised in **Appendix 1** details the administrative process (including applications forms and risk assessments) to provide a transparent basis for the consideration of proposals and for PIRSA to meet its roles and responsibilities in association with other government agencies, industry and the community.

All applications must be completed by the applicant using the prescribed form and be accompanied by the fee fixed by regulation. These forms are available from the PIRSA website (www.pir.sa.gov.au/fishing) or by calling (08) 8226 0900.

PIRSA will have primary responsibility for managing the administration of release of aquatic resources applications, including administrative support to the application assessment process and advice to the applicants on the completeness or otherwise of the application. The applicant is responsible for preparing and submitting a completed application to release aquatic resources into the waters of South Australia under the *Fisheries Management Act 2007*. If further information is required, it is the responsibility of the applicant to provide this information. In instances where the information requested is not provided within 12 months of the date it was requested, PIRSA will not proceed with the application. PIRSA will also provide advice on proposed translocations and protocols during development and administrative assessments.

For more complex applications, external advice may be sought and provided to the Minister for Agriculture, Food and Fisheries or a delegate in accordance with the objects of the *Fisheries Management Act 2007* and other relevant State and Federal legislation. The people consulted for this external advice will vary depending on the nature of the application assessed, but will likely include representatives from the recreational fishing sector, as well as those with expertise in areas such as aquatic resource management, conservation, fish stocking, aquatic animal disease and disease management, fish habitat and aquatic species (and understanding of community).

To assess the merits of applications, PIRSA may, at any time, use recent research or evaluation tools that are not contained within this policy document. The application may be subject to a two stage process, dependent on the assessment at Stage 1 as explained below.

Stage 1

The first stage of the application process is for an initial assessment of the permit application (*Stage 1- Permit to Release Aquatic Resources into a Non-specific Aquaculture Site*) to ensure it complies with State and Federal legislation. This will be done by PIRSA, who will assess the permit application to identify if it aligns with current government priorities and programs (for example, an application for the release of a noxious species is unlikely to be approved). To support the assessment of permit applications, a set of internal guidelines have been developed.

Dependent on the assessed level of risk of the permit application to possible impacts on the local environment the permit application may be:

- a) approved to allow the translocation of aquatic resources when risks are determined to be low;
- b) required to proceed to Stage 2 of the application process, when risks are determined to be higher or not fully understood; and
- c) not approved when risks are determined to be too high.

Stage 2

Stage 2 of the application process requires additional information to be submitted by the applicant, as the assessment conducted at Stage 1 has determined that the application to translocate aquatic resources poses risks that are high or not fully understood.

To fully understand the extent of any risks, the applicant will need to undertake an ecologically sustainable development risk assessment in accordance with the Australian standards AS/NZS 4360:2004 for Risk Management or the *National ESD Reporting Framework for Australian Fisheries* of Fletcher et al. (2002) and submit a summary of this ecologically sustainable development risk assessment to the Minister or a delegate for a better evaluation the application.

PIRSA (with the help of external advice, where appropriate) will assess the merits of Stage 2 applications. An acceptable risk assessment is provided in the *Stage 2-Permit to Release Aquatic resources into a Non-specific Aquaculture Site* application form.

At Stage 2 the application may be:

- a) approved to allow the translocation of aquatic resources when risks are determined to be low following the ecologically sustainable development risk assessment;
- b) approved to undertake a pilot program when risks are determined to be low to medium following the ecologically sustainable development risk assessment; and
- c) not approved when risk are determined to be too high.

Some applications will need to gather additional data through a pilot program to inform the assessment (e.g. assess the impact of genetic and behaviour changes to naturally occurring stock). Once the pilot program has been completed, the applicant must complete and submit an additional application form *Stage 2- Permit to Release Aquatic resources into a Non-specific Aquaculture Site* to PIRSA, which evaluates the findings of the pilot program. This includes outlining how the environmental, social and economic risks identified in the ecologically sustainable development risk assessment were minimised.

Following the receipt of the data from the pilot program the Minister or a delegate will make a decision in respect of the application, and notify the applicant of the outcome. If an applicant is dissatisfied with the decision, an appeal may be made under Part 9 of the *Fisheries Management Act 2007*. Successful applicants may only commence the proposed activity upon receipt of an approved permit.

Monitoring program

A preliminary and/or ongoing monitoring program may be required to assess any positive and negative impacts of the translocations of aquatic resources in the stock receiving waters. Any monitoring will need to consider the risks associated with the program, including risks to the local environment and to economic and social flow-on effects.

Costs

The *Fisheries Management Act 2007* requires fisheries to be managed in a cost effective manner and that targets be set for the recovery of management costs. Consequently, there are a number of costs to applicants and permit holders associated with establishing or participating in translocating aquatic resources. An application fee is payable by applicants at the time of submitting an application at Stage 1. This fee relates to the cost of assessing the application. Costs involved in performing an ecologically sustainable development risk assessment, pre- and on-going monitoring and preparing a proposal for PIRSA will be the responsibility of the applicant. If a permit is approved for either a small scale pilot or a full scale program by the Minister or delegate, the applicant will be required to pay for all costs involved in the program.

Section 78 permit conditions

Permit conditions are necessary to ensure that the translocation of aquatic resources is carried out in an appropriate way and in accordance with the objects of the *Fisheries Management Act 2007*. All permits for the translocation of aquatic resources into waters of the State will specify the conditions which permit holders must comply with and may include specific requirements regarding the following:

- species type, number and from where they may be sourced
- the permitted location(s) for release
- the marking of stock
- disease free certification by an independent registered veterinarian
- reporting requirements
- reporting before aquatic resources are released
- monitoring and evaluation of the program

In addition to complying with permit conditions, permit holders are required to conduct their operations in accordance with the *Fisheries Management Act 2007* and any other relevant legislation such as the *Environment Protection and Biodiversity Conservation Act 1991*. Permits may be issued for up to three years, at the discretion of the Minister or his delegate. Permit holders may reapply to continue the activity.

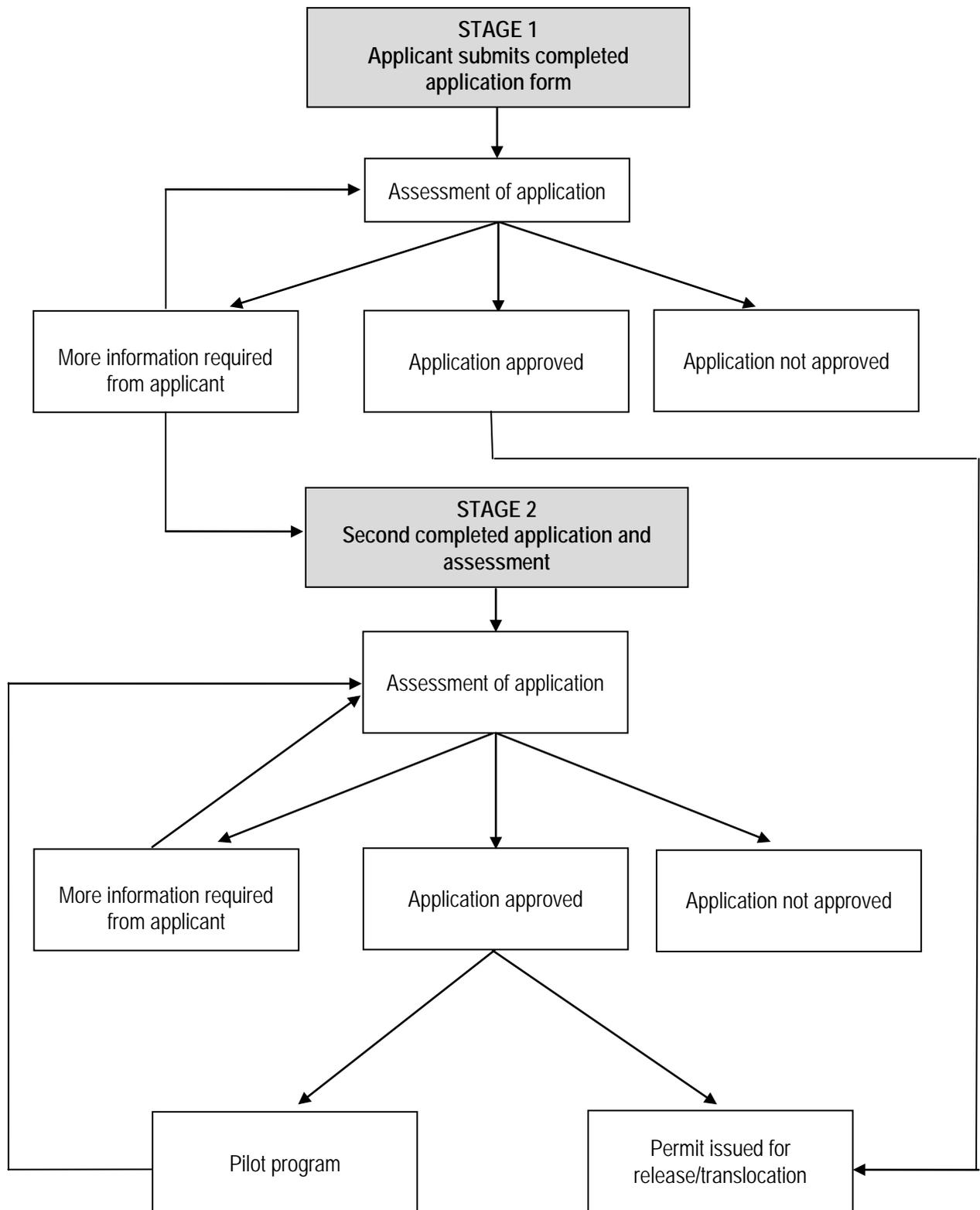
Environment Protection Authority

Water used to transport aquatic organisms may require some form of chemical treatment. As a consequence, the applicant will need to ensure that disposal of this water complies with Environment Protection Authority legislation, in particular, the *Environment Protection (Water Quality) Policy 2003* so it does not result in environmental harm.

7. REVIEW OF THE POLICY

PIRSA may review this policy at any time and as soon as practical after five years from the date of the commencement of this policy and submit a report on the outcome of a review to the Minister for Agriculture, Food and Fisheries within 12 months after the commencement of the review.

APPENDIX 1 – Application Process



APPENDIX 2 – Evaluation criteria to identify risk associated with translocation of aquatic resources

Ecological risk ratings:

Variable	Risk rating	
	Negligible or Low Risk	Moderate, High or Extreme Risk
Environmental/Ecosystem level		
Water body	Small enclosed lake or impoundment without possibly of discharge into natural water bodies	Open ocean, large river system, or area subject to flooding allowing the species or disease to spread.
Status of the current environment	Degraded or artificial habitat	Pristine natural environment
Natural occurrence of species	Natural stocks of the species to be stock enhanced already exist in the release area	The species to be stock enhanced are currently not present in the release area
Potential food chain interactions	Lower trophic level prey species amongst low biodiversity with existing high fishing pressure on the release species to be stocked. i.e. limiting factor is fishing pressure	Top order trophic level predator amongst high biodiversity. Could significantly impact predator prey interactions of wild native populations
Localised extirpation of a species	Moderate to high abundance of other species	Low abundance of other species
Exceeding carrying capacity	A 'one off' stocking of a small number of fish to be stocked into the area	A large number of fish on a number occasions are stocked into the area
Abundance/behaviour responses		
Competition between stocked and wild fish for food	Stocked fish will be unable to outcompete wild fish for food	Stocked fish will outcompete wild fish for food
Competition between stocked & wild fish for space & habitat	Minimal competition between stocked and wild fish for space and habitat	High level of competition with stocked and wild fish for space and habitat
Stocked fish behaviours	Stocked fish will have no behaviours that will cause competition with wild fish	Fish are known to have aggressive behaviour that will compete with wild fish
Stocked fish alter behaviour of wild fish	Minimal impact on behaviours of wild fish such as movement, feeding etc	High level of impact on behaviours of wild fish such as movement, feeding etc
Displacement of wild fish	Resources are abundant and some level of natural recruitment	Limited resources and stocking will exceed recruitment rates
Predation	No predation on other species	Predation on other species
Genetic		
Species reproduction	Released individuals will be unable to reproduce naturally	Individuals are capable of forming self sustaining populations.
Hybridisation with wild population	The stocked population will be unable to reproduce with wild populations	The stocked population will be able to reproduce with wild populations

Source of broodstock or translocated stock	Locally caught broodstock with only F1 progeny released	Broodstock from outside the local area with released individuals being the result of multigenerational captive breeding or selective breeding program
Local area species significance	Area has a low native abundance of the specie/s to be stocked	Area has a high native abundance of specie/s to be stocked
Disease		
Severity of known diseases that affect species	Flesh irritation the most severe symptom	Notifiable or infectious pathogenic disease
Disease risk	Notifiable or known infectious disease endemic in SA	Notifiable or known infectious disease exotic to SA
Probability of release stock carrying a disease	PIRSA approved biosecurity standards and health certification suggesting no notifiable or infectious disease	Disease status of stock unknown
History of storage and culture facility that produces stock	Good reputation and history for quality and disease control	Poor reputation and history of poor quality fingerlings and poor disease control
Mobility of species	Little or no movement or migration once released	Highly mobile and migratory
Diagnostic tests for known diseases	Epidemiology well documented. Testing provides high level of certainty	Epidemiology poorly documented. Testing not likely to provide a high level of certainty

Socio-economic risk ratings

Variable	Risk	
	Negligible or Low Risk	Moderate, High or Extreme Risk
Number of major commercial fisheries in the area	No commercial fisheries in the area	A number of significant commercial fisheries in the area
Value of commercial fisheries in the release area	Exclusively low value fisheries	A number of high value fisheries
Number of people dependent to the local environment for income	Small number of dependent people	Large number of dependent people
Other major industries in the release area dependant on the release environment	Few other industries dependent on the release environment	Many other industries dependent on the release environment

APPENDIX 3 - Definitions

TERM	MEANING
Acceptable risk	Where the benefits of an activity are determined to outweigh its costs following a transparent and robust risk assessment process.
Application	A solicited or unsolicited proposal to release live aquatic organisms for the purpose of stock enhancement. The proposal must be provided in a form specified in the policy. The 'proponent' is the entity making an application.
Aquatic resource	Fish or aquatic plants.
Aquaculture	The farming of aquatic organisms for the purposes of trade or business or research (but does not include an activity declared by regulation not to be aquaculture).
Closed system	Land-based rearing of aquatic species in raceways, tanks and ponds. Recirculation technology is implemented which cycles water through filtration processes and returns it back into the aquaculture system. This process aids in maintaining water quality whilst ensuring minimal exchange with natural waterways.
Conservation stocking	A fish stock is not performing against biological or environmental fisheries management objectives and requires a recovery program (e.g. protected, endangered or threatened species).
Disease	Any bacterium, virus, parasite, insect or other organism or agent capable of causing disease in animals or humans.
Establishment	Survival of stock released but no further propagation vs perpetuating generations from the stock released due to successful breeding.
Exotic aquatic organism or exotic fish	A fish or an aquatic plant of a species that is not endemic to any of the waters of this State.
Farming	An organised rearing process involving propagation; or regular stocking; or feeding of the organisms; or protection of the organisms from predators; or other similar intervention in the organisms' natural life cycles (as defined in the <i>Aquaculture Act 2001</i>).
Fishery	A term used to describe the collective enterprise of taking fish. A fishery is usually defined by a combination of the species caught (one or several), the gear and/or fishing methods used, and the area of operation. In any other case means a class of fishing activities declared by regulations to constitute a fishery for the purposes of the <i>Fisheries Management Act 2007</i> .
Fishing activity	The act of taking an aquatic resource, or an act preparatory to, or involved in, the taking of an aquatic resource.
Fish stocks	Functionally discrete population that is largely distinct from other populations of the same species and can be regarded as a separate entity for management or assessment purposes.

TERM	MEANING
Harvest stocking	A fishery or fish stock is to be established in waters where the fishery or fish stock did not previously exist (e.g. a freshwater impoundment or dam).
Live aquatic animal	An aquatic animal of any species, and includes the reproductive products and body parts of any aquatic animal as defined under the <i>Fisheries Management Act 2007</i> .
Noxious aquatic organism	A species of aquatic resource declared by the Minister for Agriculture, Food and Fisheries or delegate by notice in the Gazette to be a noxious species for the purposes of the <i>Fisheries Management Act 2007</i> .
Semi-closed systems	Land-based production of a species, in which water is exchanged between the farm and a natural waterway. Waste water is released from the ponds into the local waterway, whilst the farm is replenished with fresh water pumped back into the system.
State waters	Any sea or inland waters, which includes any body of water or watercourse of any kind whether occurring naturally or artificially created. However, State waters does not apply (other than the taking of aquatic resources for a commercial purpose or the introduction of exotic aquatic organisms or disease in aquatic resources) to inland waters if those waters are surrounded by land that is in the ownership, possession or control of the same person (being a person other than the Crown or an instrumentality of the Crown).
Stock receiving waters	Bodies of water into which the species to be translocated are release.
Stock enhancement	A fishery or fish stock is not performing against defined fisheries management objectives, whether they are biological, social, economic or environmental, or where a fishery or fish stock is performing satisfactorily, but production could be further improved (provided the environment can cope with the increase in fish stocks without detriment to the ecosystem).
Release of an aquatic resources	Releasing aquatic resources into an aquatic environment. Under the <i>Fisheries Management Act 2007</i> it is an offence to release live aquatic resources into South Australian waters without authorisation.
Translocation of aquatic resource	<p>A process that has been approved by the Minister for Agriculture, Food and Fisheries or delegate for the deliberate, human-assisted movement of a live aquatic resource to the waters of the State as defined in the <i>Fisheries Management Act 2007</i>. A translocation is defined by: the species of organism translocated, source of translocated organism, destination of the translocated organism and controls that manage the environmental risks of the translocation.</p> <p>Examples of controls include the size and number organisms, requirement for fish health certificates, certification of source stocks (or other certifications), biosecurity controls, monitoring requirements and the time for which the approval is valid.</p>

APPENDIX 4 - Further reading list

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