Biodiscovery in Queensland



Prepared by: Strategy, Policy and Evaluation, Department of Environment and Science

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Overview

In Queensland, the *Biodiscovery Act 2004* (the Act) regulates biodiscovery activities. Biodiscovery involves the collection and analysis of native biological material to use for commercial purposes. The Act establishes access and benefit sharing requirements for native biological material and for traditional knowledge associated with the material. For material collected from State land or Queensland waters, consent and benefit sharing must be agreed with the State. Where traditional knowledge is used, consent and benefit sharing must be agreed with the custodians of that knowledge, regardless of where in Queensland the native biological material was collected from.

The primary purposes of the Act are to: ensure biodiscovery entities act appropriately when accessing or using traditional knowledge; assist biodiscovery entities to access and use sustainable quantities of native biological material from State land or Queensland waters; encourage the development of value added biodiscovery; ensure that the State obtains a fair and equitable share in the benefits of biodiscovery; and ensure biodiscovery enhances knowledge of the State's biological diversity.

An example of biodiscovery could be using native fruit collected from State land to test for bioactive pharmaceutical compounds. Biodiscovery also includes ex-situ collections, such as propagating plants from parent stock collected on State land.

Further information on the types of activity that are considered biodiscovery can be found within the Determination of Biodiscovery operational policy, accessible via the library catalogue.

It is an offence under the Act for a biodiscovery entity to commence biodiscovery activities without first obtaining the necessary approvals. This includes a benefit sharing agreement (BSA) and collection authority, where applicable. It is also an offence to use traditional knowledge in biodiscovery without taking all reasonable and practical measures to seek the agreement of the custodian of that knowledge.

The decision tree in Figure 1, on the next page, will help you determine whether the Act applies to your proposed activities.

Much of the terminology used in this guideline is defined in the Act. This document does not purport to state the law. All applicants should be guided by their own legal advice and be familiar with the Act.

It is highly recommended that you first attend a pre-lodgement meeting with Science Strategy and Partnerships within the Department of Environment and Science to assist with preparing any applications relating to biodiscovery. To arrange a meeting, or for general inquiries, please contact the team on qldscience@des.gld.gov.au or 13 QGOV (13 74 68).

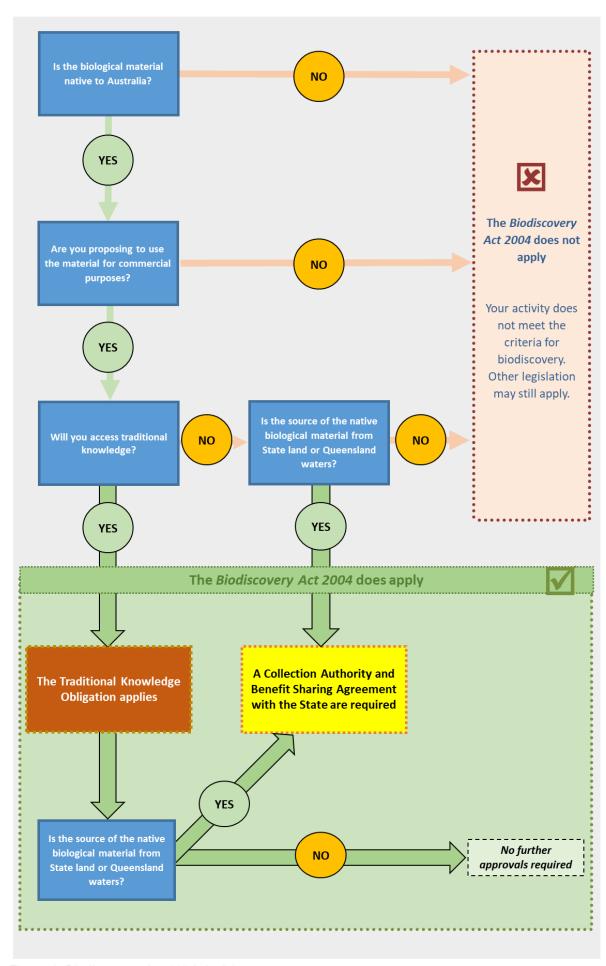


Figure 1: Biodiscovery Act 2004 decision tree

Definitions

Commercialisation

For an activity to be considered biodiscovery, the use of the material must be for the purpose of commercialisation.

Under the Act, commercialisation of native biological material means using the material in any way for gain. This excludes using the material to obtain financial assistance from the State or the Commonwealth, such as through a government grant.

Using the material for gain extends beyond just making profit. However, there must be some commercial aspect to the gain for the activity to be subject to the Act. For example, 'gain' arising from a better scientific understanding of an endangered plant does not have a commercial aspect and is thus not subject to the Act.

Another key component of this definition is the purpose of the entity in doing the activities. An activity is *not* biodiscovery if the entity only intends to conduct research with no intent to use the material for gain. However, if there is an intention to commercially gain from a product that is derived from research using native biological material, then the Act will apply.

This means that your activity may be subject to the Act even if at the time of seeking approvals:

- you are not actually receiving a commercial gain
- you have an intent to commercialise your research but are not sure if a commercial outcome is certain or what the final product may be
- you are only conducting research but intend to pass the research on to another entity to commercialise.

State land and Queensland waters

Under the Act, State land means all land in Queensland other than freehold land, land contracted to be granted in fee-simple to the State, or land subject to a native title determination granting exclusive possession rights. It includes national parks, road reserves and state forests. Freehold land that is owned by the State or an entity representing the State is still considered State land.

Queensland waters is water for which Queensland has jurisdictional powers. It includes waters within the limits of the State and coastal waters within three nautical miles of the territorial sea baseline, including water reserves and marine parks.

You may require additional authority to collect native biological material in locations that are under Commonwealth jurisdiction (such as areas of the Torres Strait, the Great Barrier Reef Marine Park and the Wet Tropics World Heritage Area). This means that your collection may be subject to additional or alternative conditions to those imposed by the state.

To help determine whether the area you are collecting from is State land or Queensland waters, you can use the Queensland Globe or Australian Marine Spatial Information System.

Traditional Knowledge Obligation

The Act regulates the access and use of traditional knowledge in biodiscovery. An example of using traditional knowledge could be learning about the traditional medicinal uses of a plant from First Nations peoples, then using that knowledge to conduct research with a view to producing an anti-inflammatory cream.

Section 9B of the Act establishes a Traditional Knowledge Obligation, which requires that a person take all reasonable and practical measures to only use traditional knowledge in biodiscovery with the agreement of the custodian of the knowledge. In general, this means only using traditional knowledge with the free, prior and informed consent of custodians and once benefit sharing has been negotiated on mutually agreed terms.

The Traditional Knowledge Obligation applies to native biological material irrespective of where in Queensland it is collected. This means that you are required to seek custodians' agreement to use their knowledge, even if the material you are collecting is not sourced from State land or Queensland waters. If you are using traditional knowledge and using material from State land, you are required to enter into an agreement with the custodians of the knowledge as well as obtaining the necessary approvals from the State (see the 'approvals' section below).

The Department of Environment and Science is not involved in negotiating agreements with First Nations peoples for the use of traditional knowledge in biodiscovery. These agreements are only between the biodiscovery entity and custodian(s) of the knowledge.

The following materials are available to support biodiscovery entities and First Nations peoples to understand and comply with the Traditional Knowledge Obligation:

- The Traditional Knowledge Code of Practice outlines the minimum requirements for biodiscovery entities to meet the traditional knowledge obligation under the Act.
- The Traditional Knowledge Guidelines provide practical information and best practice advice for biodiscovery entities to meet the code requirements and engage in a culturally appropriate way with First Nations peoples when seeking permission to use their traditional knowledge.
- A Capacity Strengthening Toolkit provides information in plain English to assist First Nations
 peoples to decide whether to participate in and/or initiate biodiscovery projects, and support
 collaboration between industry and First Nations peoples.

Approvals

If the Act applies to your proposed activities, the Department of Environment and Science can assist applicants in applying for the relevant approvals. Figure 2 details the biodiscovery approvals process. It also indicates which area of the Department of Environment and Science you should contact for each step in the approvals process.

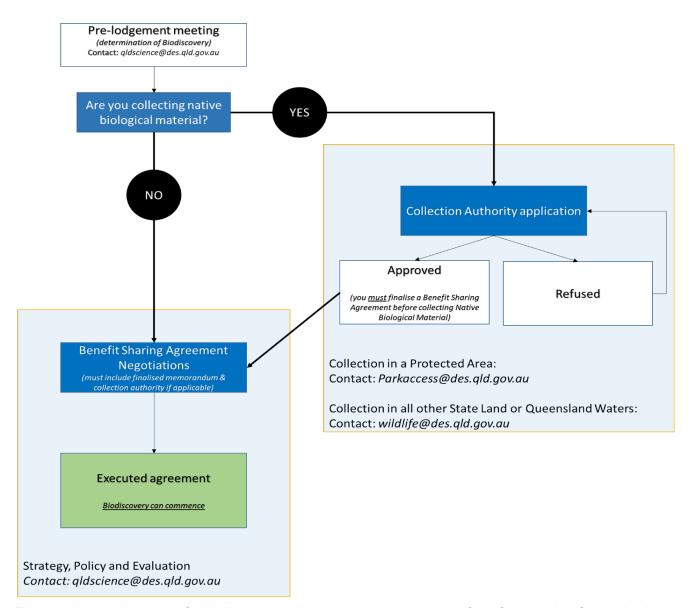


Figure 3: Approvals process for biodiscovery using native biological material from State land or Queensland waters Note: Prior to September 2020, biodiscovery entities were required to prepare, and obtain approval of, a Biodiscovery Plan prior to entering into a BSA. This requirement was removed through the *Biodiscovery and Other Legislation Amendment Act 2020*.

Collection authority

What is it?

A collection authority allows the take and keep of sustainable quantities of native biological material from State land or Queensland waters. You must have a collection authority to do biodiscovery unless you are utilising ex-situ native biological material for biodiscovery activities.

When applying for a collection authority, you must allow up to 40 business days for its assessment.

Before you collect and use the native biological material, you will also need to negotiate a BSA with the Department of Environment and Science.

Further information is available at: https://environment.des.qld.gov.au/licences-permits/plants-animals/biodiscovery

Who is involved?

Entities are responsible for submitting a collection authority application to the Department of

Environment and Science.

If you are collecting outside of a Protected Area, Forestry Reserve or Marine Park but on State Lands, submit your application to the Wildlife Assessments team at: wildlife@des.gld.gov.au

If you are collecting within a Protected Area, submit your application to the Queensland Parks and Wildlife Service at: Parkacess@des.qld.gov.au

Benefit sharing agreement

What is it?

A BSA provides the mechanism for the State and a biodiscovery entity to negotiate the right to use native biological material and share in the benefits of biodiscovery - including royalties if applicable. A BSA is a legally binding agreement with the State. Each BSA contains mandatory contractual clauses, as well as project-specific description of biodiscovery activities covered by the agreement within a memorandum. A single BSA can have multiple memoranda to cover different projects.

A BSA must be executed prior to the collection of native biological material or any biodiscovery activities commencing. As a formal legal agreement, BSAs can take time to negotiate. It is strongly recommended that you review the model BSA, which provides a starting point for negotiations, and contact qldscience@des.qld.gov.au well in advance of when you intend to commence biodiscovery.

If you are collecting native biological material, you must obtain a collection authority before a BSA can be executed. Note, that if a BSA is not executed within one year of a collection authority being granted, the authority will lapse, and you will need to reapply. The State will not enter into a BSA unless satisfied that you are compliant with the Traditional Knowledge Obligation, if applicable.

Further information regarding preparation of a BSA is available in the Guideline for preparing a Benefit Sharing Agreement.

Downstream biodiscovery and subsequent use agreements

In the course of biodiscovery you may engage other downstream entities who may be part of the research or commercialisation process. If a downstream entity is using native biological material for biodiscovery, their activities are also subject to the Act and they will either need to:

- enter into a separate BSA with the State OR
- enter into a subsequent use agreement with the entity who already holds a BSA.

If you are planning to use subsequent user agreements, your BSA will outline the prescribed minimum terms that must be included in any subsequent use agreement. Any agreement, including a material transfer agreement, can be a subsequent use agreement under the Act if it includes the prescribed minimum terms.

Subsequent use agreements are not required for situations where assistance with biodiscovery is provided on a fee for service basis. For example, where a biotechnology company conducts a toxicology test on a product derived from native biological material for a fixed fee.

Who is involved?

Entities wishing to undertake biodiscovery should contact the Science Strategy and Partnerships division within the Department of Environment and Science by emailing: qldscience@des.qld.gov.au

Prior to meeting with the Department of Environment and Science, you may wish to review the Guideline for Preparing a Benefit Sharing Agreement.

Upon approval, the responsible Minister will enter into the BSA on the State's behalf.