

The Legal Regulation of Biodiscovery in Australia

Biodiscovery refers to the process of collecting biological resources (e.g., plants, animals, microorganisms) in the search of active compounds or ingredients that can be developed into useful products. Examples of commercial products derived from biological materials include Indian snakeroot (*Rauwolfia serpentine*) which is used in the drug Reserpine to treat hypertension, and the Cinchona bark (*Cinchona*) which yields the quinine used in the treatment of malaria.

Until 1992, there was no legally-binding international agreement to govern how countries should facilitate the access and use of biological resources, and the sharing of benefits derived from the use of such resources. As a result, biodiscoveries based on the access and use of biological resources did not require the return of benefits to the country or community from where the source material was extracted. The entry into force of the 1992 Convention on Biological Diversity (CBD) and the 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from the Utilization of Genetic Resources (Nagoya Protocol) changed the regulatory dynamics of biodiscovery activities, including the access and use of biological resources (see Fact Sheet 14: Access to Genetic Resources under the Convention on Biological Diversity; Fact Sheet 15: Nagoya Protocol; and Fact Sheet 12: International Treaty on Plant Genetic Resources for Food and Agriculture).

Why is biodiscovery important?

Australia has approximately 10 percent of the world's biodiversity. In addition, advances in science and technology mean that it is possible to systematically scan biological materials for chemicals and products that may have commercial values.

The Australian Government has stated that it aims to ensure that the social and economic benefits of the use of biological resources are returned to Australia. To do this, the Government has attempted to facilitate access to Australian resources, and encourage investment in biodiscovery. The rules for biodiscovery come from two main sources: international treaties and Australian domestic law

1. International treaties

The CBD aims to:

1. conserve biological diversity,
2. promote the sustainable use of the components of biological diversity, and

3. ensure the fair and equitable sharing of benefits arising from the use of genetic resources.

The CBD entered into force in 1993 and lays down the framework for access to genetic resources and the sharing of benefits for all Contracting Parties, including Australia.

Australia is also a signatory to the Nagoya Protocol to the CBD but is yet to ratify it. The ratification of the Protocol may require Australia to make amendments to the national laws that the country has developed to comply with the CBD.

2. National laws

Commonwealth areas

Commonwealth areas include all the land and water under Commonwealth control in Australia and does not include private lands and State and Territory lands.

For Commonwealth areas, the *Environmental Protection and Biodiversity Conservation Act 1999* and the *Environment Protection and Biodiversity Conservation Regulations 2000*

implement a CBD-compatible regime of access to biological resources.

The Act and Regulations for Commonwealth areas aim to ensure that Australia's genetic resources are used for research and development by fulfilling the requirements of prior informed consent and mutually agreed terms of access and benefit sharing that providers and users of genetic resources are required to conclude.

Queensland

In 2004, the Queensland Government passed the Biodiscovery Act to implement the obligation under the CBD. The Biodiscovery Act extends only to native biological resources collected from State land and Queensland waters. State land is defined as all land in Queensland except freehold land, freehold leases or lands subject to native title determination granting rights of exclusive possession. Queensland waters are all waters within the limits of the State or coastal waters.

Northern Territory

In order to comply with the CBD, the Northern Territory Government passed the *Biological Resources Act 2006*. The Act applies to the collection of native biological material throughout the Territory, including the air above, the water and the seabed or riverbed below the water. However, the Act does not apply to the collection of native biological material from Commonwealth areas in the Territory, which are governed by the *Environment Protection and Biodiversity Conservation Regulations 2000* (Cth).

Key aspects of Australian domestic laws

Obtaining a permit

In locations where biodiscovery laws apply, applicants need to apply for a permit to collect native biological material for biodiscovery. Generally, the permit for biodiscovery is granted if the collection is:

- ecologically sustainable, and
- a Benefit Sharing Agreement has been reached with the resource provider, which includes prior informed consent and mutually agreed terms.

Concluding a benefit sharing agreement

In certain Australian States and Territories, it is a condition of access to native biological material that a Benefit Sharing Agreement be entered into. The benefits may be monetary (e.g., up-front payments or royalties on future products) or non-monetary (e.g., training and jobs).

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