Genetic Resources Management in Commonwealth Areas

Sustainable Access Shared Benefits



Understanding the new Australian regulations for access to genetic and biochemical resources found in native species in Commonwealth areas

Acknowledgements

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Pages Contents, opposite foreword, inside back cover: Fiona Scott, Sany Molloy, David Thomas, Geraldine Nash – Australian Antarctic Division ©Commonwealth of Australia; 1: (watermark) Professor Adrian Gibbs, Director of National Parks; 2: CSIRO Plant Industry; 3: Australian National Botanic Gardens; 4: Professor Adrian Gibbs; 5: Australian Institute of Marine Science; 6: Australian Institute of Marine Science; 7: Director of National Parks, Australian Institute of Marine Science; 8: Director of National Parks; 9: Director of National Parks; 10: Professor Adrian Gibbs; 11: (watermark) Professor Adrian Gibbs; 12: Director of National Parks, Australian Institute of Marine Science; 14: Director of National Parks; 15: Director of National Parks; 17: (watermark) Professor Adrian Gibbs; 18: Director of National Parks.

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Foreword



The genetic and biochemical resources of plants, animals and microorganisms have been used by humankind for centuries. Improved food production, medical advances and greater scientific knowledge are examples of the myriad benefits derived from this use of natural resources.

Today, modern biotechnology plays a vital role in this process, enabling cutting-edge research to greatly accelerate our understanding of genetic and biochemical resources.

Australia is rich in genetic and biochemical resources. Its biodiversity represents up to 10 per cent of the total biodiversity of the planet. Moreover, over 80 per cent of that biodiversity is indigenous to Australia. As such, Australia is a megadiverse country, rich in resources for use in scientific and technological research, and with potential to be developed into new and innovative commercial products.

Australia recognises its responsibilities under the Convention on Biological Diversity (CBD) and is developing legal frameworks to facilitate access to and use of genetic and biochemical resources. In providing opportunities for the ecologically sustainable and ethical use of its biological diversity Australia also recognises the responsibility to ensure fair and equitable sharing of the benefits arising from the use of its resources.¹

Australia's national biodiversity strategy framework respects Indigenous people's special knowledge of biodiversity and ensures that Indigenous people have both the choice and means to share their knowledge on fair and equitable terms.²

Today, Australia is uniquely placed to take advantage of its natural resources, substantial research infrastructure and stable, developed economy. We welcome and support biodiscovery investment and offer a number of comparative advantages, in addition to our abundance of endemic genetic and biochemical raw materials. Australia has first class commercial and intellectual property law, stable public administration and a strong and collaborative scientific community supported by national biodiversity policy and laws. In addition it has high quality taxonomic data and is investing in making that data web-accessible.

Australia can now provide for biodiscovery the necessary framework to demonstrate legal provenance of biological discoveries, giving investors in the industry confidence and security when committing to large and sustained investment in research and development.

Australia seeks to be a leader in the dynamic field of biodiscovery and in partnership with Indigenous people, biotech companies, research scientists and managers of biodiversity, it aims to ensure practices and advances in biodiscovery are sustainable, inclusive and rewarding.

The legal framework for Commonwealth (Federal) areas described here is an essential step to ensure legal certainty for users of the resource and to provide for facilitated access while ensuring that the environment is protected.

¹ Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources, www.deh. gov.au/biodiversitv/science/access/index.html

² National Strategy for the Conservation of Australia's Biological Diversity, www.deh.gov.au/biodiversity/publication/strategy/index.html



An historical perspective

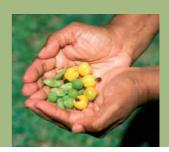
Until 1993, genetic resources were widely considered the 'common heritage of mankind'. Resources were taken from many environments in the hope of developing new products, with little thought given to the communities or countries that provided the raw materials.

In consequence, major discoveries based on natural resources, sometimes involving the use of Traditional Indigenous Knowledge, did not result in benefits returning to the country or community providing that material.

Examples of this lack of benefit-sharing include the discovery of the antibiotic Erythromycin and the development of Cyclosporin A, an anti-rejection drug. Cyclosporin A originated from a soil fungus found in a nature reserve prior to the CBD in what is now Norway's Hardangarvidda National Park. Annual sales revenue from Cyclosporin-based products in 1997 totalled US\$1.2 billion. In the absence of any legislation providing for benefit-sharing Norway was not entitled to any share. Norway subsequently introduced a regulatory framework in 2005.







Biotechnology today

The 'common heritage of mankind' doctrine ended when the CBD was ratified in 1993, affirming a nation's sovereign rights over its natural biological resources, including its genetic resources.

Under the CBD, in return for granting access to biological resources, countries are entitled to a fair and equitable share in the benefits that may result from the use of those resources.

Australia acknowledges the need for a stable and transparent system to facilitate sustainable access to biological resources while ensuring appropriate returns to those who granted permission to use the resources. Australia's broad policy response to the need to conserve its biodiversity is set out in its National Strategy for the Conservation of Australia's biological diversity.³ Following the adoption in 2002 by the Convention on Biological Diversity of world's best practice guidelines for national legislation (the Bonn Guidelines), all Australian governments have also agreed to a nationally consistent approach to implement such a system.⁴

The appropriate use of traditional knowledge is also respected and all Australian governments have agreed that use of Traditional Knowledge is to be undertaken with the cooperation and approval of the holders of that knowledge and on mutually agreed terms.⁵

³ National Strategy for the Conservation of Australia's Biological Diversity, www.deh.gov.au/biodiversity/publication/strategy/index.html

⁴ Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources,

www.deh.gov.au/biodiversity/science/access/index.html

5 Objective 1.8 of the National Strategy and Principle 7 of the NCA









A new regulatory scheme

The value of genetic resources is being increasingly acknowledged worldwide. To ensure economic, social and environmental benefits can be gained from Australia's biotechnology by future generations it is necessary to manage access to those resources.

To do this for Commonwealth areas, new regulations have been introduced under the *Environment Protection and Biodiversity Conservation Act 1999* to appropriately manage the sustainable access and equitable distribution of benefits derived from genetic and biochemical resources.

The regulations contribute to managing Australia's genetic resources to obtain benefits, while simultaneously ensuring ecologically sustainable use of those resources while protecting biodiversity and Australia's natural capital. Similar legislation has been introduced, or is being developed, by Australia's State and Territory governments.

What is regulated?

The Australian Government regulations relate only to the taking of biological resources of native species for research and development on any genetic resources, or biochemical compounds, comprising or contained in the biological resource.

The regulations do not apply to the taking of resources for any other purpose, including amongst many other things, fishing for commerce or recreation, taking essential oils from plants or taking wild animals or plants for food.

The regulations only apply in Commonwealth areas 6.

⁶ Commonwealth areas are those lands and waters owned or managed by the Australian Government and those not managed by State and Territory governments.



Building on earlier policy work

The regulatory framework gives effect to Australia's obligations under the CBD in relation to access to Australia's native biological resources. Consistency with international obligations creates certainty for investors.

The regulatory framework is consistent with a number of Australia's policies and Acts including:

- a. National Competition Policy
- b. the Trade Practices Act 1974
- c. the Native Title Act 1993
- d. the National Strategy for the Conservation of Australia's Biological Diversity
- e. the Intergovernmental Agreement on the Environment.

It is also consistent with the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation.

From 1 December 2005 any individual, organisation or institution seeking to gain or provide access to genetic resources in Commonwealth areas will be obliged to abide by these regulations.



Comparative Advantages

Research and investment in the field of biotechnology is a time and capital-intensive business. When looking to invest in this industry, advantages such as those offered by Australia, provide an additional level of security.

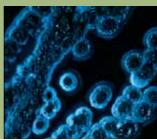
Mega Biodiversity

Australia is one of 17 megadiverse countries and it is estimated to have up to 10 per cent of the world's biodiversity, with possibly the highest rate of endemism. A significant proportion of Australia's biodiversity, particularly in the marine sphere, remains to be identified.

Established system of commercial and intellectual property law

Australia is a developed country with a well-respected and long established system of commercial and intellectual property law that offers security to investors.







Stable public administration and skilled workforce

The Australian Government delivers a sound system of public administration and is committed to excellence through the open exchange of ideas, good practices and innovation.

Australia offers the availability of a highly skilled workforce underpinned by an excellent tertiary education system. This workforce is also multilingual, with approximately 1.3 million Australians fluent in a major European language, and 900,000 in a major Asian language, of whom more than 400,000 speak a Chinese dialect⁷.

Legal framework to facilitate access

Australia's new regulatory scheme under the *Environment Protection and Biodiversity Conservation Act 1999* provides a transparent legal framework to facilitate sustainable access to genetic resources found in Commonwealth areas while ensuring an equitable share of benefits for all involved in the process.

Strong scientific and research base offering collaborative opportunities

Australia offers strong science-based and burgeoning biotechnology and health industries.

Australia has excellent health infrastructure to support our innovative science-based industries and is ranked ninth in the world for the quality of its scientific research institutions by the 2004 World Economic Forum.⁸

⁷ Australian Bureau of Statistics 2003

⁸ Networked Readiness Index Rank 2004





Supporting non-commercial scientific research

Australia recognises the importance of encouraging access for non-commercial scientific research, particularly taxonomic research.

To that end, the requirements for obtaining access to Commonwealth owned or managed genetic materials for non-commercial scientific research is more flexible and less involved than for commercial scientific research.

In place of an access and benefit-sharing agreement, the permit applicant is simply required to obtain written permission from the access provider of the resource to enter a Commonwealth area and remove samples.

A straightforward statutory declaration must also be made which includes agreeing to certain obligations. These include accepting the obligation to negotiate a full benefit-sharing agreement should the purpose of research and development change, and to obtain permission from the access provider before passing the sample on to anyone else.



Access and benefit sharing

The following objectives describe the fundamental principles of Australia's approach to facilitated access and equitable benefit-sharing regarding native genetic resources.

Reducing transaction costs

The new regulatory scheme seeks to minimise, through a number of initiatives, transaction costs involved in reaching agreement between those seeking access and those granting it through a number of initiatives.

Administrative fees to access permits are set at a minimal level - \$50 or \$0 - depending on whether undertaken commercially or non-commercially. Australia's financial interests are safeguarded through benefit-sharing agreements and encouraging the maximum amount of research and development.

Application for permits can be completed online. This avoids undue delays that can be experienced when using traditional, paper-based application processes. The Department of the Environment and Heritage website also provides links to other permit applications under the *Environment Protection and Biodiversity Conservation Act 1999* and accredited schemes. To avoid delay in decision-making and granting permit applications, specific timeframes are included in regulations.

There is also a reduction in the number of permits that an applicant may require through arrangements that allow for flexible access arrangements for lengthy, or even unlimited periods.

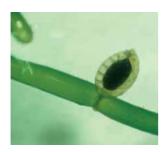
Annual and continuous review

These regulations will be reviewed after the first year of operation and the Department will liaise with key stakeholders as the regulations are implemented.

Monetary and non-monetary benefits to access providers

The Australian Government recognises that benefits for providing access to biological resources can be in both monetary and non-monetary form.

The nature and value of benefits depend on factors such as the nature of the access agreement, the circumstances of the parties and the prevailing market conditions. The sole rights of the parties to the agreement to determine the terms of the agreement are fully recognised.



Monetary benefits could include:

- up-front payments
- milestone payments
- royalties
- research funding
- licence fees in case of commercialisation
- special fees paid to trust funds supporting conservation and sustainable use of biodiversity
- salaries and preferential terms
- joint ventures
- joint ownership of relevant intellectual property rights.

Non-monetary benefits are wide-ranging and include:

- sharing in research and development results
- collaboration, cooperation and contribution in scientific R&D programmes, particularly biotechnological research activities, where possible
- · participation in product development
- collaboration, cooperation and contribution in education and training
- admittance to ex-situ facilities of genetic resources and to databases
- transfer to the provider of the genetic resources of knowledge and technology
- facilitate abilities of Indigenous and local communities to conserve and sustainably use their genetic resources
- · institutional capacity building
- · training related to genetic resources with the full participation of providing Parties
- access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies
- · contributions to the local economy
- institutional and professional relationships that can arise from an access and benefitsharing agreement and subsequent collaborative activities
- social recognition
- joint ownership of relevant intellectual property rights.

Prior Informed Consent

When determining which benefits are appropriate the Department is sensitive to the fact that biodiscovery is an uncertain process. The chances of any individual sample resulting in a commercial product are extremely low. Consequently, there will be a focus on balancing non-financial benefits against financial benefits.

In accordance with Article 15, paragraph 5 of the CBD, access to genetic resources is subject to prior informed consent given by the contracting party providing the resources, unless determined otherwise.

The basic principles of prior informed consent are as follows:

- there shall be legal certainty and clarity
- access to genetic resources should be facilitated at minimum cost
- restrictions on access to genetic resources should be transparent, based on legal grounds and not run counter to the objectives of the CBD
- the consent of the relevant competent national authority(ies) in the provider country should be obtained
- the consent of the relevant stakeholders, such as subject to domestic law, should also be obtained.

The issuing of an access permit will be evidence of prior informed consent.

Maximise certainty

All legal and administrative requirements are based in legislation and the new arrangements do not alter in any way existing property or intellectual property law.

Transparency and accountability

All criteria regarding decisions on which permits are granted will be fully disclosed and reviews of decision-making policies will be integrated into regular administrative reviews.

Simplicity, accessibility and efficiency

The Department of the Environment and Heritage administers the permit scheme and advises the Minister on the operation of the regulations. It also undertakes the bulk of benefit-sharing negotiations on behalf of the Commonwealth.

Issues affecting owners of Indigenous people's land and holders of native title

Factors specific to Indigenous people, such as ensuring adequacy of prior informed consent, are given special consideration by the Minister when deciding whether to grant or refuse an access permit involving Indigenous people's land or holders of native title.







Industry and research issues

Parameters for benefit-sharing arrangements are very flexible. They allow parties to negotiate a wide range of benefits and include appropriate or simplified terms facilitating benefit-sharing to be negotiated where research is undertaken for non-commercial purposes.

Environmental issues

Prior to granting a permit application the Minister must be satisfied that the proposed access takes into account the precautionary principle and is ecologically sustainable and consistent with the conservation of Australia's biological diversity. The Minister may also attach conditions to permits to meet certain objectives such as the requirement to lodge voucher specimens in Australian public collection institutions and provide information about the specimens.

Environmental impact assessment may be required where environmental impacts from access activities are likely. While these safeguards are important in protecting and conserving biodiversity, it is generally understood that in most cases biodiscovery is a low impact activity.

Contribution to a nationally consistent approach to access and benefit-sharing

The regulatory scheme reflects the principles of the *Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources*, endorsed by the Natural Resource Management Ministerial Council, which takes into account the diversity of access providers and ensures respect for property rights.

Ex-situ collections

The regulatory scheme enables holders of ex-situ collections to determine whether they wish to be covered or to seek exemption where existing arrangements meet the objectives of the scheme.



Indigenous-owned land in Commonwealth areas

The three significant Commonwealth areas involving Indigenous owned land, leased to the Australian Government, are found in the jointly managed Kakadu National Park, Uluru-Kata Tjuta National Park and Booderee National Park.

Use of Traditional Biological Knowledge in the scientific, commercial and public domains will only occur with the

cooperation and control of the traditional owners of that knowledge. This ensures the use and collection of that knowledge is undertaken with the cooperation and approval of the knowledge holders, and on mutually agreed terms.

One mechanism of protection is that access approval is given only when the applicant can demonstrate that they have obtained the informed consent of Indigenous owners to the benefit-sharing agreement.

The property rights of Indigenous landowners in Commonwealth areas are explicitly protected in the legislation with all benefits negotiated by the owners vesting with them, and with the Australian Government receiving no part.

The effect of native title and access to resources

Applicants entering into a benefit-sharing agreement that may claim to affect native title rights and interests in relation to land or water need to be aware of the provisions of the *Native Title Act 1993* and the availability of Indigenous land use agreements (ILUA) under Division 3 of Part 2 of that Act as a means to validate actions that may otherwise be construed to be invalid future acts by that Act.⁹

If such circumstances were to arise, the Minister may be satisfied that issuing a permit or varying the conditions attaching a permit would not be an invalid future act if the following criteria were met:

- an ILUA has been registered for the area under the Native Title Act 1993;
- the ILUA authorises the action proposed to be taken under the permit; and
- sets out the native titleholders' consent to the grant of the permit.







Environmental Impact Assessments

Uncontrolled collection of biological resources can result in potentially severe and irreversible damage to the viability or conservation status of a species or population.

Isolated international incidents of uncontrolled access to biological resources resulting in loss of populations of ecologically valuable species serve as examples of what is to be avoided. The loss of several species of the Brazilian tree Pilocarpoius, through unsustainable harvesting of their leaves for a glaucoma drug, demonstrates the risks of an irreversible outcome and short-lived benefits.

Unsustainable practices in accessing biological resources can commonly prevent the realisation of potential value in the medium to long-term in a broad range of ecosystem services. Practices that damage or destroy biodiversity in efforts to bring immediate results do so at incalculable future costs to the environment, economy, and society. Such damage occurs mainly through wild harvest rather than through the initial biodiscovery collection.

Nevertheless, the nature of biodiscovery is essentially an extractive process, and as such can be potentially damaging to some sensitive environments such as micro climes, sea vents and hot springs. This risk can be significantly reduced or eliminated, through careful management.

Australia seeks to minimise potential environmental impacts through a number of ways by requiring that:

- the Environment Minister is satisfied that the proposed access will be ecologically sustainable and consistent with the conservation of Australia's biological diversity (taking into account the precautionary principle);
- in appropriate cases, there be an environmental assessment of proposals; and
- the Minister is able to attach conditions to permits through which a range of environmental objectives can be met.



The permit system

The Minister for the Environment and Heritage issues permits to access biological resources in Commonwealth areas.

Applying for a permit

From 1 December 2005, applications for permits can be made via the website at www.deh. gov.au/biodiversity/science/access/index.html. Once the application has been submitted, the Department of the Environment and Heritage will assess the application, in consultation with the relevant Commonwealth agency or landowner, and will make a recommendation to the Minister as to whether the access permit should be granted or refused.

Before the permit can be granted, the applicant is required to negotiate an equitable benefit-sharing agreement/contract with the provider of the biological resources.

A model contract is being developed as a guide to assist parties when developing a benefit-sharing agreement. The model contract will not be mandatory, but will aim to provide assistance and incorporate best practice examples from similar agreements worldwide. The development of the model contract is taking place in consultation with State and Territory governments, industry, Indigenous interests, the scientific community and biotechnology representatives.

It is a requirement that the Minister be satisfied that negotiations regarding the benefitsharing agreement involving the owners of Indigenously owned land were conducted on a fair and equitable basis, with informed consent given by the access providers, and in terms that were mutually agreed.

Additionally, the Minister must be satisfied of the following:

- environmental assessment (if required) was undertaken and the process is completed and
- proposed access is ecologically sustainable and consistent with the conservation of Australia's biodiversity;



- · submissions from interested parties (if required) have been taken into account; and
- there is a benefit-sharing agreement between the parties addressing the following major issues:
 - informed consent of any Indigenous owners of biological resources (when applicable);
 - mutually agreed terms; and
 - adequate benefit-sharing arrangements, including protection for and valuing of Indigenous Knowledge and, if practicable, some benefits are used for biodiversity conservation in the area from which the resources were obtained.

To maintain transparency all permit approvals are published on the Web and all Ministerial declarations are published in the Gazette.

There is a permit application fee of \$50 – or \$0 for non-commercial access.

Note: The benefit-sharing agreement would only have effect if the Minister issued an access permit.

Exemptions

In order to avoid overlap between this and already existing systems, the Minister can decide to exempt certain biological resources if existing arrangements meet the objectives of the scheme. Exemptions can also be granted if resources are held and managed by the Commonwealth or under a Commonwealth or other law, or where another international agreement controls access.

Varying, transferring or revoking a permit

The permit application process provides the flexibility to vary, transfer or revoke a permit, by either the Minister or the permit holder, by written notice.

In the case of transfer, the Minister must be assured that the proposed transferee, in addition to other criteria, will meet the conditions of the permit.

Penalties for non-compliance

The regulations provide for the penalty of \$5,500.

Applicants should note that the issue of a nationally consistent approach to broader deterrent-level penalties is under consideration by representatives of all Commonwealth, State and Territory governments.

Records and samples

Keeping records

Appropriate sample records must be kept. Records must include:

- A unique identifier for each sample, marked either on a label attached to the sample, or the container holding the sample.
- The date the sample was taken.
- The place from which the sample was taken.
- An appropriate indication of the quantity or size of the sample.
- The scientific name of, or given to, the sample.
- The location of the sample when first entered in the record.
- The details about any subsequent transfer of the sample, including the names and addresses of others having possession of the sample, or a part of the sample.

Disposal of samples

If a permit holder decides not to keep a biological resource sample that has been officially recorded, they must offer the sample and record to the access provider of that sample prior to considering disposal.

If the access provider of the sample does not want the sample and accompanying record, the permit holder may then dispose of the sample, and must send the accompanying record and details of the disposal of the sample to the Department.

Transparency

Every permit granted by the Minister will be kept on a register of information. Along with the reporting requirements established under the regulations, this means that every sample that has been legally obtained from Commonwealth areas can be tracked back to its source. Any conditions attached to that sample, agreed to by parties to the benefit-sharing agreement, can also be easily identified.

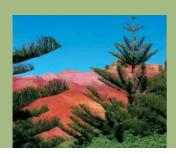
This register is available for public inspection and may be viewed on the Department's website at www.deh.gov.au/biodiversity/science/access/index.html.

Any information however, that is deemed culturally sensitive, or if disclosed could damage a commercial interest, result in a risk to the environment or harm the national interest, will not be disclosed.

Many members of the public have a genuine concern for, and interest in, the effective and sustainable management of Australia's genetic resources. To accommodate this important component of effective, accountable and transparent governance, the Minister will annually invite applications from interested parties wishing to be included on a consultation register.

Each notice of invitation will be published in both the Gazette and major daily newspapers available in each State and Territory. The Minister will register any person who applies in writing and registrations will last for a minimum of 12 months.





Australia - open for business

Genetic resources are a vital ecosystem service, underpinning biotechnology innovation around the globe. The Australia Government understands this and accepts its responsibility to facilitate access to genetic resources.

Australia is positioned to both offer and obtain substantial economic, social and environmental benefits from the ecologically sustainable use of its genetic and biochemical resources while protecting biodiversity and its natural capital.

Australia provides many advantages to those seeking to invest in biotechnology. Domestic and international investment in biodiscovery in Commonwealth areas is both welcomed and encouraged through a streamlined access scheme and a strong supporting legal framework. Australia offers certainty to genetic resource users and providers and is committed to contributing to and building a workable international system.

Persons and organisations interested in taking advantage of this opportunity are encouraged to contact the Genetic Resources Management Policy Section of the Department of the Environment and Heritage.

Contact may be made by any of the following methods:

Email: grm@deh.gov.au Tel: +61 2 6274 1936 Fax: +61 2 6274 2735

Mail: Director, Genetic Resources Management

Department of the Environment and Heritage GPO Box 787 CANBERRA ACT 2601 Australia

For a concise explanatory statement of the new scheme, including a clause by clause explanation of the regulations, visit www.deh.gov.au/biodiversity/science/access/index.html.

Contacts

For more information about genetic resources management in Commonwealth areas in Australia: http://www.deh.gov.au/biodiversity/science/access/index.html

Or contact the Director of Genetic Resources Management Policy:

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