ACCESS AND BENEFIT SHARING: ABS LAW AND ADMINISTRATION IN AUSTRALIA

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RESUMO: Esse trabalho explica a implementação, na Austrália, das *Diretrizes de Bonn sobre Acesso aos Recursos Genéticos e Repartição Equitativa de Benefícios Derivados de Sua Utilização* (as Diretrizes de Bonn). O trabalho examinará as soluções legais que a Austrália desenvolveu para encaminhar políticas que vão além das Diretrizes de Bonn e que podem ser do interesse de países que estejam desenvolvendo ou revendo suas abordagens a esses assuntos. O trabalho é extraído da pesquisa do autor publicada agora em detalhe no capítulo 14 de *Recursos Genéticos, Conhecimento Tradicional e a Lei*, editado por Gerd Winter e publicado pela Earthscan em agosto de 2009.

ABSTRACT:This paper explains Australia's implementation of the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization* (the Bonn Guidelines). The paper will also examine legal solutions Australia developed to address policy issues going beyond the Bonn Guidelines and which may be of interest to countries developing or reviewing their own approaches to those issues. The paper draws on the author's research now published in detail at Chapter 14 of *Genetic Resources Traditional Knowledge and the Law,* edited by Gerd Winter and published by Earthscan August 2009.

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Relevance to Rapidly Developing Countries

At first glance Australia might seem to be an unlikely source of ideas for rapidly developing countries. It has a fully developed economy. It is economically and politically aligned with the United States and the 'West'. Geographically, it sits in a quiet part of the South Western Pacific Rim. It is distant to Africa, South America, South and North Asia and is twelve thousand miles from Western Europe. Socially and culturally, it is part of the Anglo-Saxon heritage of the United Kingdom shared by Canada, New Zealand and to a lesser extent, by the United States and India.

This view is misleading. Consider, like Brazil, China, India, Mexico and many developing countries Australia has a rich biodiversity. It also shares with India, Mexico and Brazil the experience of being a post-colonial society - with a federal system of constitutional government and an inherited language and political institutions. Like Brazil, and Mexico, Australia is no monoculture. Post-war immigration has drawn migrants from 140 countries and contributed to a tripling of Australia's population. This tide of immigration includes significant contributions from India, China and South America as well as from the UK and New Zealand. There are thriving Brazilian, Mexican and Chilean communities in the larger cities. Chinese and South East Asian immigrants make significant contributions to business, the professions and to Australian community life. At the same time, Australia has a growing population of Indigenous people with some 23% of Australia's landmass having reverted to Indigenous ownership.

Economically, much of Australia's wealth is dependent on access to markets for its agricultural and natural resources exports. Accordingly, it has a continuing interest in the removal of trade distorting subsidies and other market access obstacles. It therefore has common cause with rapidly developing economies facing similar barriers.

Like many mega-biodiverse countries, Australia also faces significant challenges. These include a sparsely settled and arid interior, severe, and early impact of climate change and increasing biodiversity losses. Moreover, successive governments have had only mixed success in supporting Australia's Indigenous peoples and their traditional knowledge and culture. There have been marked policy failures in this area. The current government is committed to reducing Indigenous disadvantage.

Like China, India and Brazil, Australia also has a burgeoning biotechnology sector. It includes 470 biotechnology companies with 73 publicly listed companies worth AU$22.7 billion in 2008[1]. This sector is in strong competition with North American and European biotechnology and has to seek and attract foreign investment capital to grow. Many biotechnology companies were developed from Australia's universities and publically funded research institutions.

These challenges impact on the development of ABS policy and require innovative solutions.

Background – Australia and the Convention on Biological Diversity

Australia ratified the Convention on Biological Diversity (CBD) on 18 June 1993. In 1996 it released its *National Strategy for the Conservation of Australia's Biological Diversity* (*National Biodiversity Strategy*). This strategy defines Australia's access to genetic resources policy goal in the following terms:

> Ensure that the social and economic benefits of the use of genetic material and products derived from Australia's biological diversity accrue to Australia.[2]

[1] Australian Department of Innovation, Industry Science and Research 2009. See: <http://www.innovation.gov.au/Section/AboutDIISR/FactSheets/Pages/AustralianBio technologySectorFactSheet.aspx> accessed 29 May 2009.

[2] Objective 2.8 of the National Strategy for the Conservation of Australia's Biological Diversity: see <http://www.environment.gov.au/biodiversity/index.html>

To work out how this might be achieved the government held a national inquiry into access to genetic resources in Commonwealth (federal) areas in 1999-2000 (The Voumard Inquiry)[3]. This involved comprehensive public consultation including with industry, environment interests and Indigenous communities. The resulting Inquiry Report made over 70 recommendations for the establishment of a practical ABS regime for Australia.[4] In a related development, the issue of enhanced access to biological resources was integrated into Australia's *National Biotechnology Strategy* in 2000[5]. The development of draft legislation in the form of amendments to the *Environment Protection Biodiversity Conservation Regulations 2000* (EPBC Regulations) then followed with final legislation coming into force in December 2005.

During this policy development period, Australia was active in its support for the evolution and later adoption of the Bonn Guidelines by the Convention on Biological Diversity in 2002. Within six months, Australia's international support for the Guidelines was reflected domestically when in October 2002 all nine Australian governments adopted a common framework to implement the Bonn Guidelines.[6] This intergovernmental agreement is the: *Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* (the *Nationally Consistent Approach*). It is a policy framework consisting of 14 general binding policy principles and a further 11 agreed common elements to be considered before taking action to implement the Guidelines. The purpose of the Agreement is to ensure consistency of approach and legal clarity and certainty across all Federal, State and Territory Government jurisdictions.

ABS Operating Environment

Australia is a constitutional federation of six sovereign states, two self-governing territories and a national government. It has a 'common law' legal system derived from Britain. Australia is a developed country with an annual per capita income of US$50,150 (2008)[7]. Physically, Australia is large, with a landmass of 7.692 million square kilometers and an administered marine jurisdiction of over 10 million square kilometers.[8] Its size and geological isolation has resulted in rich biodiversity with 10% of the world's species found within its borders and high levels of endemism.[9] It is a mega-diverse country. As a developed biodiverse country, Australia is both a user and a provider of genetic resources. This latter fact has had a profound effect on its understanding and approach to ABS issues, as we will see. One consequence was its early commitment to adopting and implementing the Bonn Guidelines in great detail.[10]

National ABS Law by Regulation

Australia's ABS law is found at *Part 8A Access to biological resources in Commonwealth areas* of the EPBC Regulations.[11] Authority for making ABS regulations lies in section 301 of the

[3] Commonwealth Public Inquiry into Access to Biological Resources in Commonwealth Areas: see http://www.environment.gov.au/biodiversity/publications/inquiry/index.html

[4] Ibid

[5] See: http://www.biotechnology.gov.au/ index.cfm?event=object.showContent&objectID=0B674DD3-BCD6-81AC-1871247366BECE18

[6] The Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources was adopted by the Australian Council of Governments in October 2002. See: http://www.environment.gov.au/biodiversity/publications/access/nca/index.html

[7] Australian Department of Foreign Affairs and Trade see: http://www.dfat.gov.au/geo/fs/aust.pdf

[8] Australian Government, Geoscience Australia; see http://www.ga.gov.au/oceans/mc_LawSea.jsp, accessed 29 May 2009.

[9] Number of Living Species in Australia and the World. Arthur D Chapman 2005, Australian Biological Resources Survey.

[10] The author has tested the level of congruence between the Australian ABS system and the Guidelines and this examination is published in Chapter 14 of Genetic Resources Traditional Knowledge and the Law Edited by Gerd Winter and published by Earthscan.

[11] This can be downloaded at: http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrumentCompilation1.nsf/0/ FAA515B854C46E02CA2570C900200F31?OpenDocument. The regulations deal with many other aspects of environmental management so care should be taken to download only those parts of interest.

(a) the equitable sharing of the benefits arising from the use of biological resources in Commonwealth areas;
(b) the facilitation of access to such resources;
(c) the right to deny access to such resources;
(d) the granting of access to such resources and the terms and conditions of such access."

supervening *Environment Protection Biodiversity Conservation Act 1999*.[12] This section is broad in its scope and allows for the ABS system to be established by regulation. In Australia national regulations override State and Territory law to the extent of any conflict. In this case, the regulations operate to avoid any such inconsistency by applying only to biological resources held, owned or managed by the national government. This federal jurisdiction includes defence lands, certain national parks, Australia's external territories and Australia's 10 million square kilometres of ocean resources. It includes about 5% of the world's biodiversity.

Objectives

The six objectives of the federal access to biological resources law are set out in EPBC regulation 8A.01. This states:

> *For section 301 of the Act, the purpose of this Part is to provide for the control of access to biological resources in Commonwealth areas to which this Part applies by:*
>
> (a) promoting the conservation of biological resources in those Commonwealth areas, including the ecologically sustainable use of those biological resources; and
>
> (b) ensuring the equitable sharing of the benefits arising from the use of biological resources in those Commonwealth areas; and
>
> (c) recognising the special knowledge held by Indigenous persons about biological resources; and
>
> (d) establishing an access regime designed to provide certainty, and minimise administrative cost, for people seeking access to biological resources; and
>
> (e) seeking to ensure that the social, economic and environmental benefits arising from the use of biological resources in those Commonwealth areas accrue to Australia; and
>
> (f) contributing to a nationally consistent approach to access to Australia's biological resources.

These objectives are self-evidently consistent with both the CBD and its Bonn Guidelines. For example, purposes (a) and (b) reflect the 3 objectives in Article 1 of the Convention while (c) foreshadows responsibilities to indigenous and local communities under Articles 8J and 10(c) and purposes (d) and (e) address Article 15.

How the Australian system Works

Conceptually, Australia has taken the view that research and development on genetic resources is a significant ecosystem service. Accordingly its ABS system must foster that ecosystem service to produce economic outcomes that value biodiversity and contribute to its conservation. Thus the federal ABS system is to be as clear and practical as possible with low transaction costs and high levels of transparency. It is intended to encourage research and development and protect the interests of Indigenous and non-indigenous providers and users.

Anyone wishing to access native biological resources for the purpose of research and development on its genetic or biochemical makeup and to be taken from lands or waters administered by the Australian federal government must apply for a permit from the Competent National Authority[13]. This may be done online or in writing.

If access sought is for a commercial purpose, then the permit fee is a nominal AUD $50. Access for non-commercial purposes such as taxonomy is free.

[12] "301 Control of access to biological resources
(1) The regulations may provide for the control of access to biological resources in Commonwealth areas.
(2) Without limiting subsection (1), the regulations may contain provisions about all or any of the following:
(a) the equitable sharing of the benefits arising from the use of biological resources in Commonwealth areas;
(b) the facilitation of access to such resources;
(c) the right to deny access to such resources;
(d) the granting of access to such resources and the terms and conditions of such access."

[13] In practice this is the Director of Genetic Resources Management Policy within the Australian Department of Environment, Water, Heritage and the Arts.

The Competent National Authority (delegate of the Minister) will approve the permit for a commercial purpose if the collection causes no environmental harm and the applicant has entered into a benefit-sharing agreement.

Access for non-commercial purposes does not require a benefit-sharing agreement -only satisfaction that that no environmental harm is done and that the permission of the manager of the area where the collection is made has been given. The applicant provides this information in the form of a Statutory Declaration[14]. In the Declaration the applicant also undertakes to negotiate a benefit-sharing agreement if he later wishes to commercialise. This provision is important for both biodiversity managers and applicants. It ensures serendipitous scientific discoveries can be commercialised without any penalty for the researcher having obtained the "wrong" permit.

He must also provide a taxonomic copy of any new species collected, provide a copy of his research outcomes and seek permission before transferring the material to any third party.

To encourage scientific research, Access Permits may be issued in as little as two working days.

Protecting the Rights of Indigenous Peoples

The Australian ABS system entrenches and protects the rights of Indigenous peoples in federal land and waters.

If an applicant wishes to obtain genetic material from Indigenously owned land or use any associated Traditional Indigenous Knowledge (TK) then the applicant must go to the Indigenous community and negotiate a benefit-sharing agreement with the landowners. Any benefits that flow from the resulting agreement must go to the Indigenous community. This is consistent with their property rights as owners of the land. Similarly, benefit distribution within the community is a matter for the Indigenous owners to determine. The government does not seek to interfere in such decisions or secure benefits for itself.

The role of government in such situations is to support the Indigenous owners. It recognizes that not all Indigenous owners have the resources to negotiate with applicants on equal terms. To address this, the Competent National Authority is obliged to be satisfied that the conditions for prior informed consent and mutually agreed terms in a benefit-sharing agreement with Indigenous owners have been met. Only then can the Competent National Authority issue the permit.

To assist applicants and owners these conditions are set out in law at *Environment Protection Biodiversity Conservation Regulations 2000,* regulation 8A.10. It provides:

> 8A. 10 Informed consent
>
> (1) If the biological resources to which access is sought are in an area that is indigenous people's land and an access provider for the resources is the owner of the land or a native title holder for the land, the owner or native title holder must give informed consent to a benefit-sharing agreement concerning access to the biological resources.
>
> (2) In considering whether an access provider has given informed consent to a benefit-sharing agreement, the Minister must consider the following matters:
>
> (a) whether the access provider had adequate knowledge of these Regulations and was able to engage in reasonable negotiations with the applicant for the permit about the benefit-sharing agreement;
>
> (b) whether the access provider was given adequate time:
>
> (i) to consider the application for the permit, including time to consult with relevant people; and
>
> (ii) if the biological resources are in an area that is indigenous people's land and an access provider for the resources is the owner of the land, to consult with the traditional owners of the land; and

[14] This is a legal document with penalties for dishonesty.

(iii) to negotiate the benefit-sharing agreement;

(c) if the biological resources are in an area that is indigenous people's land and an access provider for the resources is an owner of the land and is represented by a land council — whether the views of the land council about the matters mentioned in paragraphs (a) and (b) have been sought;

(d) if access is sought to the biological resources of an area in relation to which native title exists — the views of any representative Aboriginal/Torres Strait Islander body or any body performing the functions of a representative body, within the meaning of the *Native Title Act 1993*, for the area about the matters mentioned in paragraphs (a) and (b);

(e) whether the access provider has received independent legal advice about the application and the requirements of these Regulations.

(3) The Minister may be satisfied that informed consent has been given by any native title holders who may be affected by the issue of a permit if the benefit-sharing agreement:

(a) is a registered indigenous land use agreement, under the *Native Title Act 1993,* for the area; and

(b) authorises the action proposed to be taken under the permit; and

(c) sets out the native title holders' consent to the issue of the permit.

Note The requirements relating to indigenous land use agreements are set out in Part 2, Division 3 of the *Native Title Act 1993*.

A second protection in regard to the use of TK is at regulation 8A.08 setting out the requirements for a benefit-sharing agreement. The following safeguards, must be disclosed or included in the agreement:

- The existence of reasonable benefit-sharing arrangements, including protection for, recognition of and valuing of any indigenous people's knowledge to be used
- Any use of Indigenous people's knowledge, including details of the source of the knowledge, such as, for example, whether the knowledge was obtained from scientific or other public documents, from the access provider or from another group of Indigenous persons
- A statement regarding benefits to be provided or any agreed commitments given in return for the use of the Indigenous people's knowledge
- A copy of the agreement regarding the use of any Indigenous people's traditional knowledge (if there is a written document), or the terms of any oral agreement, regarding the use of the knowledge
- Details of any proposals of the applicant to benefit biodiversity conservation in the area if access is granted and
- Details of the benefits that the access provider will receive for having granted access.

The use of the Competent National Authority as a disinterested party (ie having no beneficial interest at stake in an Indigenous peoples' benefit-sharing agreement) to confirm PIC and MAT by an Indigenous community provides an important safeguard for the Indigenous community. It also protects the applicant against future accusations of biopiracy or other acts of bad faith. To some critics, any use of genetic resources and associated Traditional Knowledge constitutes biopiracy.

Reliance on safeguard provisions supporting Indigenous peoples' benefit-sharing agreements also reflects an important distinction between traditional Indigenous knowledge in Australia and that of other cultures. That is, Australian Indigenous peoples' traditional knowledge is based on an oral tradition - not a written one. It is held within Indigenous communities on terms and conditions integral to each Indigenous Community. Accordingly, any decision about the release of that knowledge is properly a matter to be determined by the community involved and in accordance with its customs and culture. In intellectual property terms, Australian traditional knowledge is analogous to trade secrets

and the option of defensive protection given to traditional knowledge in countries with a written traditional knowledge system is not available unless the holders of the knowledge choose to make such a disclosure.

To further assist applicants and the owners and managers of federal lands and waters, the government has published two model benefit-sharing agreements, one is for publicly owned areas and the other one is for Indigenous peoples' privately owned lands. These can be downloaded at: http://www.environment.gov.au/biodiversity/science/access/model-agreements/index.html

It should be noted that these model agreements are a guide only. Parties are free to find their own format if they wish. Nevertheless, each agreement is comprehensive and represents the sort of detailed and robust contract available under the common law legal tradition in Australia.

Adoption of Virtual Certificates of Source, Origin and PIC

All permits are entered into a public register which is viewable online.[15]

This creates a fully transparent system of virtual certificates of origin and legal provenance. It allows instant electronic verification of evidence of prior informed consent and mutually agreed terms at no cost. Commercial, cultural or environmentally sensitive information is not included on the viewable register. This transparency also mitigates against accusations of misappropriation of resources or biopiracy. Importantly, it allows any user of resources to meet any disclosure requirement in foreign intellectual property systems and reduces legal uncertainty over the origins and circumstances of the material collected. Australia's preparedness to do so indicates it recognizes that securing value from products derived from genetic resources is maximised if the intellectual property contained in products is protected in all markets.

In 2008/09, applications for access to biological resources in federal areas are being made and granted at the rate of more than one a week.

Innovations and Responses to Issues in Current Debate

The Australian regulations address some of the policy difficulties identified in current debates about the nature and scope of an international regime as they impinge on its domestic system.

Derivatives

This concern arises out of the perception that the CBD definition of 'genetic resources' does not allow for control of extracts or components of organisms of value but which do not have elements of heredity. In this scenario a biochemical may be taken and commercialised with no benefit-sharing with the owner or manager of the plant or animal from which it was derived. A common criticism of attempts to expand the ambit of genetic resources to cover derivatives of organisms is that it will have unintended consequences - such as affecting the ordinary trade in products made from nature such as wood or honey or commodities such as fish or wild plants. The Australian response has not been to redefine genetic resources but to identify the purpose for which the biological material is being collected. This is undertaken through a definition of 'access to biological resources', a term not defined in the CBD.

Access is defined at EPBC regulation 8A.03 as:

> **access to biological resources** means 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 resources...

This definition ensures that all elements of an organism are covered. By linking the biological object to the intended purpose of its collection and use this definition avoids any

[15] This is the Genetic Resources Information Data Base or GRID. See: https://apps5a.ris.environment.gov.au/grid/public/perrep.jsp accessed 20 August 2009.

possible confusion with wild harvest, forestry, commodity trade or other more conventional uses. Defining 'access' also avoids having to alter the meaning of the CBD definition of genetic resources. Moreover, it is within the spirit of the CBD and the intent of Article 15 and is within the scope of Article 3, which affirms countries' national sovereignty over their resources.

Finally, this approach has another advantage. In the marine jurisdiction countries control the use of living resources in their excusive economic zone but to do not generally claim ownership over those resources. A focus on regulating access avoids any need to assert ownership. Such an approach may also have positive implications for the eventual management of living resources in waters beyond national control.

Respect for National Sovereignty

The Australian system is only applied to species naturally found in Australia. Species from other countries are not covered. Australia does not seek to take advantage of its possession, accidental or otherwise, of foreign species. This accords with the spirit of Article 3 of the CBD. Driven by its high degree of endemism and conscious of its high reliance on imported genetic resources for agriculture, Australia seeks to set a model example in respecting the national interests of other countries.

Accreditation of ex-situ collections

Objective (l) of the Bonn Guidelines identifies the importance of taxonomy and avoiding action that would damage its conduct. Sub-paragraph 16 (a) (viii) provides that special terms and conditions should be established under MAT to facilitate taxonomic research for non-commercial purposes.

The EPBC regulations go beyond protecting the conduct of taxonomy to cover all non-commercial scientific research – subject to certain safeguards. In response to concerns from the scientific research community it created a special exemption for ex situ collections. The basis on which this is done is innovative. Regulation 8A.05 sets a test for the grant of an exemption from the operation of the regulations: This is whether or not the operation of the collection is administered in a manner consistent with the stated purposes of the regulations. For example, if an ex-situ collection operates in accordance with an existing international and sectoral scheme for CBD compliance then it may be exempted. This avoids dealing with the regulatory and procedural burden of two CBD compliance schemes or systems. Moreover, it is able to maintain its existing collaborative systems with similar institutions while demonstrating that they meet the accreditation requirements of the national law of Australia: a double benefit.

National accreditation of institutions meeting international ABS compliance standards is an innovation warranting further study, particularly for those countries for which the introduction and administration of comprehensive domestic ABS systems would be an administrative burden.

Compliance: Legal Certainty and Verification

Providing legal certainty for any party considering investing in research and development of genetic resources is important in maximising the amount of research undertaken and in maximising the economic value of genetic resources as a vital ecosystem service. A low cost system of 'virtual' certificates of origin and evidence of legal provenance is one way to do this.

Australia implemented such a mechanism with the introduction of the Genetic Resources Information Data Base (GRID). This is accessible online to anyone undertaking legal 'due diligence' testing before investing in research.[16] It demonstrates, at no cost, where the source material was obtained, from whom and upon what terms. Moreover GRID also progressively lists the identity of the resulting samples collected and gives each sample its own unique identity. GRID has the capacity to contain details of thousands of samples.[17]

[16] Op Cit

[17] See: https://apps5a.ris.environment.gov.au/grid/public/cerrep.jsp, (accessed 29 May 2009) and follow the same procedure as for viewing permits.

By verifying compliance with Australian ABS law the value of any biological discovery is increased compared to any similar discovery based on unverifiable sources with its attendant risks of litigation, damage to shareholder value or even criminal association. Open verification means that no credible accusations of misappropriation or biopiracy can be made. Such measures encourage and support compliance.

Disclose of source, origin and provenance

A number of countries have introduced, or are in the process of introducing disclosure requirements in intellectual property applications. These vary in complexity and in their mandatory application. By providing transparency about what material has been collected and on what terms, the GRID system supports domestic and foreign researchers to meet the requirements of any existing or future national intellectual property system. Such action facilitates the commercialisation process by informing the market about the value of the intellectual property concerned.

In addition, transparency provides an important innovation signal to governments responsible for protecting ecosystem services. If governments are clear about which areas are giving rise to the development of new and valuable bio-derived products then they have a better basis for allocating scarce conservation dollars. This is especially important for micro-organisms, as they commonly have minimal status within the public community and have difficulty attracting conservation support.

Conclusion

The Australian federal ABS system at its highest level seeks to support conservation, innovation and economic development by sustaining and nurturing the use of genetic resources as a vital ecosystem service. Its experience in doing so, provides some interesting examples for countries introducing or reviewing their own ABS systems.