



**CONVENTION ON
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AD HOC OPEN-ENDED WORKING
GROUP ON ACCESS AND
BENEFIT-SHARING

Third meeting

Bangkok, 14 -18 February 2005

Items 3-8 of the provisional agenda*

**COMPILATION OF SUBMISSIONS PROVIDED BY PARTIES, GOVERNMENTS,
INDIGENOUS AND LOCAL COMMUNITIES AND RELEVANT STAKEHOLDERS
IN PREPARATION FOR THE THIRD MEETING OF THE AD HOC OPEN-ENDED
WORKING GROUP ON ACCESS AND BENEFIT-SHARING**

Addendum

SUBMISSION BY AUSTRALIA

Note by the Executive Secretary

1. The Executive Secretary has the honour to circulate herewith, for the information of participants in the third meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, the attached submission received from Australia in preparation for the third meeting of the Working Group.
2. The submission is being circulated in the form and the language in which it was received by the Secretariat of the Convention.

* UNEP/CBD/WG-ABS/3/1.

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Introduction

Countries with federal structures of government such as Australia face very specific challenges when introducing national access laws. Australia is a useful case study in its response to those challenges. Australia's responses and solutions may be of interest to other countries dealing with similar issues. Some issues are common whether or not a federal structure exists.

Australia has adopted a pragmatic approach to implementing the CBD's Bonn Guidelines. This approach is guided by the needs of a federal structure, existing international agreements, domestic legislation and the realities of contemporary scientific research and Australia's market-based, developed economy with a strong stakeholder voice in decision-making. This approach is encapsulated in its intergovernmental agreement: the *Nationally Consistent Approach for Access to and Utilisation of Australia's Native Genetic and Biochemical Resources (NCA)*.¹ All 9 Australian governments agreed to this overarching policy on 11 October 2002 to form the basis for Australia's implementation of the Bonn Guidelines. The agreement forms an accountable basis for all legislation and administrative action for the management of genetic resources currently underway in each Australian jurisdiction.²

Challenges:

Federalism, land management and consensus

Governance in Australia primarily consists of the national government, and the governments of 6 sovereign States and two self-governing Territories.³ Under the Australian constitution, land management responsibility largely rests with the States. Historically, achieving a common view among all sovereign jurisdictions has not always been easy and land management issues are a current source of sometimes vigorous and divisive debate on such matters as land clearing, salinity and allocation of riverine water resources. Australia has a small population (20 million) spread over a wide area: its lands and seas extend from the tropics to the Antarctic with more than 8 million square kilometers of land and a marine area of similar size. Accordingly, views on land management issues are often firmly held at the state level.

A primary tool for addressing potentially divergent views has been the creation in 2001 of the Natural Resources Management Ministerial Council. The Council's objective is to "promote the conservation and sustainable use of Australia's natural resources". Ministerial Councils facilitate, and implement nationally, plans and proposals that would not otherwise be possible because of the limitations imposed by the division of constitutional powers between Australian, State and Territory governments.

The drivers for successful coordination and co-operation between Australian governments on the Access and Benefit Sharing (ABS) issue and those that led to the adoption of a nationally consistent approach were an awareness of:

- The extent of national biodiversity
- The value of genetic resources to industry worldwide⁴ and
- Australia's obligations under the CBD⁵.

¹ See: < <http://www.deh.gov.au/biodiversity/science/access/nca> >.

² Such action was foreshadowed at Objective 2.8 of the 1996 *National Strategy for the Conservation of Australia's Biological Diversity* see: < <http://www.deh.gov.au/biodiversity/publications/strategy/> >.

³ In each Australian jurisdiction government consists of the interaction of its Parliament, Judiciary and Executive.

⁴ For example, Laird and Ten Kate quote the 1998 annual sales value of pharmaceutical products derived from genetic resources as being US\$75 billion - p247 *Biodiversity and Traditional Knowledge*, Edited by Sarah Laird and published by Earthscan Publications Ltd 2002

⁵ Acknowledged and set out at in the *National Strategy for the Conservation of Australia's Biological Diversity* see: < <http://www.deh.gov.au/biodiversity/publications/strategy/> >.

Australia is one of 17 megadiverse countries. It is estimated to have up to 7-10% of the world's biodiversity, perhaps less than Indonesia or Brazil but comparable to Mexico.⁶ It has perhaps the world's highest rate of endemism.⁷ Much of its biodiversity is also unusual, ancient, rare or inadequately known to science.

Australia is a developed country with a good science base and a burgeoning biotechnology and health care sector with a market capitalization of A\$24 billion.⁸ Of its 378 biotechnology firms, most are small and are constrained by a conservative capital market. Australian biotechnology research and development has its foundations in medical research, agriculture and natural product discovery.

The mechanism chosen by the federal government to increase awareness and to begin to build a consensus was to hold a national inquiry⁹ involving extensive stakeholder consultation. This involved all governments, indigenous peoples, industry, the science community and environment groups. The process identified key problems and suggested solutions. By clarifying thinking within government on ABS, Australia was able to give informed consideration to the draft Bonn Guidelines and was thereby encouraged to strongly support their adoption.

Bonn Guidelines implementation - national consistency

In a federal structure, a coherent legal framework requires either a single national law, (not always possible), "mirror" or "model" legislation - where each jurisdiction passes essentially the same law - or a law based on an agreed nationally consistent approach. In Australia the complexities of ABS and of existing State or Territory laws and State constitutions led to the adoption of the third option. This is the *Nationally Consistent Approach for Access to and Utilisation of Australia's Native Genetic and Biochemical Resources* or NCA.

The NCA identifies key problems and agreed solutions. Its common goal is "to position Australia to obtain the maximum economic, social and environmental benefits from the ecologically sustainable use of its genetic and biochemical resources whilst protecting our biodiversity and natural capital."¹⁰ At the time of writing, most Australian governments have begun policy reviews, passed legislation or commenced preparation of new legislation under the aegis of the NCA.¹¹

Benefit-Sharing

Realistic expectations - the success rate

Stakeholders repeatedly emphasize the chance of a new product based on natural genetic resources reaching the market is very low: about 1 in 10,000 to 1 in 100,000 samples. Furthermore many discoveries are serendipitous and the development process is often cumulative, expensive and lengthy.

6. Mittermeier, RA. *Megadiversity: earth's biologically wealthiest nations*, CEMEX [Mexico, DF] 1997, pp 26-29, 179-180.

7. Laird and Ten Kate *op. cit.* Estimates of biodiversity within national jurisdictions however vary depending on the assumptions used and the proportion of the nation's biodiversity taxonomically identified and mapped. In Australia's case a significant proportion of its biodiversity, particularly in its marine sphere, remains to be identified. A further complication is that fact that from a biodiscovery point of view the degree of polymorphism within a species can be as important as the number of species evident.

⁸ Australian Government Department of Industry Tourism and Regional Services-figures for 2004.

⁹ Commonwealth Public Inquiry into *Access to Biological Resources in Commonwealth Areas 2000 (the Voumard Inquiry)* see: < <http://www.deh.gov.au/biodiversity/science/access/inquiry/pubs/abrca.pdf> >.

¹⁰ See: < <http://www.deh.gov.au/biodiversity/science/access/nca/#goal> >.

¹¹ The federal government has drafted legislation for areas under its control. The Queensland Biodiscovery Bill was passed in August 2004. In September 2004 Northern Territory released its ABS policy for public comment while South Australia is preparing legislation and Western Australia has announced its intention to draft legislation.

While some products may be very valuable in the end, they are the exception.¹² Even at the final stages of the development process there are no guarantees. For example it is estimated that only 20% of new pharmaceutical drugs that undergo Phase 1 clinical trials will survive to be approved by the USFDA.¹³ Policy, legislation and public education activities must take this reality into account when considering access and benefit-sharing.

The immediate implication of such low success rates for development from biodiscovery is that bioprospecting as an activity, is sensitive to transaction costs - both financial and temporal (delay). This sensitivity is exacerbated where research is undertaken by small organizations (often the Australian case) or is originally undertaken as non-commercial research but leads to serendipitous discovery. In such circumstances, burdensome regulatory impediments reduce research thus further reducing the likelihood of success. Regulatory impediments include:

- cost
- delay
- uncertainty
- duplication
- complexity

The lesson Australia learned from observing the effectiveness of early ABS legislation elsewhere is that such impediments are to be avoided. The appropriate response is to balance safeguarding the public interest with arrangements facilitating access through the following:

Simplicity

Keep the underlying organizing principle simple: for example the proposed system to be used on federal land will be as follows: for access to be granted, an applicant must apply for a permit, the permit in turn will be granted if the collection does no harm to the environment and a benefit-sharing agreement has been reached with the manager of the area from which the resources are to be taken. If the collection is for non-commercial purposes the benefit-sharing agreement may be replaced with simplified arrangements.

Reducing costs and delay

The NCA provides for:

- processing of applications for access to be timely (eg federal and state legislation includes statutory time limits for decision making);
- transaction costs to be minimised (eg draft federal legislation fixes fees at nominal levels);
- model contracts and dictionaries of contractual terms for benefit-sharing agreements to be developed;
- information to be provided in a clear, readily-accessible and reliable manner;
- reassurance to be provided that arrangements do not alter existing property or intellectual property law (this is reflected in federal and state law);
- access permissions to allow flexibility in their scope and duration; and
- online application processing and information provision be used where possible.¹⁴

¹² E.g. 1997 sales revenue for Cyclosporin based products amounted to US\$1.2 billion. These products were developed from a soil fungus found in a sample taken from a nature reserve in what is now Norway's Hardangervidda National Park, but the process took 14 years and very considerable cost to the developers. - Pp 163-4, Biodiversity and Traditional Knowledge, Edited by Sarah Laird and published by Earthscan Publications Ltd 2002.

¹³ Journal Of Commercial Biotechnology Sept 2003 Vol 10 Number 1, page 55.

¹⁴ See NCA Common Element 3

Ownership of resources

Generally, genetic resources found on public lands or waters are either owned or managed by government bodies. Nevertheless the NCA identifies this issue as a matter requiring further collaboration, particularly the possible application of frameworks to private land. The new Queensland Act does not regulate the use of genetic resources on private land (including indigenously owned land) while both federal and Northern Territory governments have made it clear that they will respect the property rights of private land holders. The property rights of the owners of indigenous owned land in federal areas is explicitly protected in the draft legislation.¹⁵ All benefits negotiated by them will be theirs. The federal government will take none. Also influencing this debate is the realisation that a significant portion of Australia's biodiversity is found on publicly owned lands or managed waters, and is often represented within its extensive protected areas system.

Avoiding duplication of existing systems

Under the NCA, regulatory frameworks would allow for possible exemption of biological resources held in public collections administered consistently with its Principles. This might include, for example, institutions such as botanic gardens or herbaria that are participating institutions in the international Common Policy Guidelines for implementation of the "Principles on Access to Genetic Resources and Benefit Sharing for Participating Institutions"¹⁶. In the microbial sector, the MOSAICC initiative established a similar code of conduct for collections¹⁷. The goal here is not to duplicate or unduly complicate existing arrangements if they are consistent with the intent of the policy.

Such, or similar provisions, are also necessary to avoid disturbing administrative systems that are in place to discharge obligations under other international legal obligations or where a State or Territory may have been granted control over resources under another federal law. In the latter instance Australian Government policy is that the domestic arrangement should remain undisturbed, as any benefit received by a State is a benefit to the broader Australian community. The Commonwealth State Offshore Constitutional Settlement is an example of such an arrangement.

Certainty

The Australian experience has been that stakeholders place great value on certainty. To build this into legislation and administration the NCA provides transparency and accountability is to be supported by:

- legislation;
- disclosure of all criteria against which access is granted;
- appropriate integration of decision making into administrative review systems; and
- making information about the grant of access permits and benefit-sharing agreements public, where doing so is consistent with commercial, privacy and cultural confidentiality.

Ease of access and administrative consistency across all jurisdictions

National consistency is supported by the undertaking in the NCA to collaborate on:

- the use of common terms wherever possible;
- agreement on appropriate deterrent penalty levels for similar offences;
- the development of model contracts and contractual terms;
- establishing links between web based on-line information sites;
- developing consistent public information material;

¹⁵ This is done, in part by requiring that access approval to be given only when the applicant demonstrates that he has obtained the informed consent of indigenous owners to the benefit-sharing agreement.

¹⁶ Principles on Access to Genetic Resources and Benefit Sharing for Participating Institutions: < www.kew.org/conservation/principles.html >.

¹⁷ MOSAICC: Micro-Organisms Sustainable use and Access regulation International Code of Conduct. Available at: < <http://www.belspo.be/bccm/> >.

- the use of joint benefit-sharing contracts where intended biodiscovery collection involves crossing jurisdictional borders;
- the adoption of common collection protocols where possible;
- the sharing of common experience;
- the development of whole of government policy positions in relevant international fora;
- common issues such as the ownership of resources and the possible application of frameworks to private land; and
- the development of contract monitoring and access compliance procedures.

Fair treatment

Industry representative bodies have emphasized the concern of members, particularly those from outside Australia, that Australia's system not discriminates against their members. This concern is already addressed by existing Australian legislation which makes such discriminatory action unlawful and which binds the States and Territories. Accordingly the NCA makes reference to Australia's National Competition Policy and to the *Trade Practices Act 1974*.

Unintended regulatory consequences

The scientific community has sought to draw governments' attention to the risk that non-commercial research may be adversely affected by arrangements intended to regulate commercial research. To address this, the NCA requires that all jurisdictions facilitate continued access for non-commercial scientific research, particularly taxonomic research.

In the case of the forthcoming federal legislation, a clear distinction would be made between commercial and non-commercial research. The principle difference in the treatment of commercial and non-commercial research will be that the obligation to enter into a benefit-sharing agreement would not be required for non-commercial research in favour of an obligation to share research outcomes, address third party obligations and to negotiate a benefit-sharing agreement should they later wish to commercialise their research.

Respecting Indigenous Knowledge

While the NCA requires that all governments "recognise the need to ensure the use of traditional knowledge is undertaken with the cooperation and approval of the holders of that knowledge and on mutually agreed terms" it leaves the method to individual Australian Governments. The federal government employs the use of transparency to assist in meeting this objective. It will require that a benefit-sharing agreement include protection for, the recognition of and the valuing of, any indigenous people's knowledge used. The agreement will also require a statement regarding the use of indigenous people's knowledge and provide details of the source of the knowledge, the terms on which it was obtained and benefits to be provided or any agreed commitments given in return for its use.

Disparity in negotiation capability

To the extent that benefit-sharing agreements are negotiated between government entities and research organisations or companies there may be no significant disparity between their respective abilities to negotiate. Where the managers or owners of the genetic resources are Indigenous peoples, however, there may be a disparity in their capability to negotiate a benefit-sharing agreement reflecting mutually agreed terms. Accordingly federal legislation will provide a safeguard whereby an access permit will be granted when the Minister is satisfied, according to explicit criteria, that the applicant has obtained the informed consent of the Indigenous owners and their benefit-sharing agreement is on mutually agreed terms. The legislation will also recognise and require the involvement of relevant statutory bodies established to provide indigenous communities with legal representation. As the government will not be a party to the agreement or its benefits, there can be no apprehension of bias.

Unauthorized commercialisation of resources

To date there have been few reported and verified examples of attempted unauthorised commercialisation in Australia. The last significant example was the unsuccessful and unauthorised attempt take examples of the “Smokebush” from Western Australia in the early 1990s. To date this issue does not appear to be a problem for Australia. Researchers appear to be honoring their contractual obligations. This perception, while at odds with popular perceptions, is shared by OECD researchers who concluded recently that, for at least the short term, unauthorized commercialization does not appear to be significant.¹⁸

Monitoring and Enforcement Considerations

At present, existing government contract management arrangements appear to be working well. The aggregate cost and administrative burden of such arrangements will, however, grow rapidly as levels of biodiscovery increase and new administrative arrangements are put in place to better reflect best practice as set out in the Bonn Guidelines. The Australian government has responded to this need. Over the next four years it is providing guaranteed additional funding to enhance collaboration and efficiency among jurisdictions in their implementation of the Nationally Consistent Approach. On November 4 2004 the Commonwealth, States and Territories established a body under the National Biotechnology Strategy to undertake that coordination. This is the Biotechnology Liaison Committee Biodiscovery Working Group.

Disclosure of Information

In addition, there are two areas relevant to the cost and effectiveness of monitoring and enforcement. The first of these lies in the area of improved transaction transparency. Public registers of permits with associated internet publication enables resource managers, the scientific community, business, and venture capital to verify and monitor activity occurring within a given jurisdiction. For example Australia’s *Environment Protection Biodiversity Conservation Act 1999* at section 515A requires the weekly publication on the Internet of all permits issued or granted during the preceding week together with all matters to be made available to the public in that week.¹⁹ Australia is currently considering the extent to which it is desirable to use this mechanism to provide evidence of prior informed consent and mutually agreed terms.

In relation to disclosure of information in patent applications, discussion of measures for the disclosure of information related to the source of genetic resources is underway in a wide range of fora and covers a wide range of possible options. At this stage, Australia is still considering what options would best suit our circumstances and consequently we have no experience to report on this issue. However, we will continue to participate actively in discussions of these issues in all the relevant international fora and we would also be very interested in the experiences of Parties who have implemented disclosure regimes.

Certificates of Origin

The second area of improved genetic resources management lies in establishing, as appropriate, cost effective methods of tracking downstream use of genetic resources both within a country and globally. The general introduction of registers of permits recording basic details of what is being collected and by whom opens the way for the consideration of verification systems sometimes referred to as certificates of origin or source. Under some proposals for a certificate of origin scheme, samples of indigenous biological material may be allocated a unique identifier that then travels with each transfer of the sample or its essential components through the value development chain. Australia is actively considering the practicality and feasibility of such systems but has drawn no final conclusions.

¹⁸ OECD Working Group on Economic Aspects of Biodiversity paper Economic issues in Access and Benefit sharing of Genetic Resources: a Framework for Analysis (ENV/EPOC/GSP/BIO(2001)2/FINAL 04.11.2003

¹⁹ See <<http://scaleplus.law.gov.au/html/pasteact/3/3295/top.htm>>

Included in its consideration is that information about the original sample's origins, including evidence of prior informed consent and mutually agreed terms, as determined by the access approving body could be placed in a publicly searchable database. This might then allow a party acquiring the sample or acquiring an interest in the sample or something created from it, to verify its source and provenance simply by reference to the identifier. If practicable and cost effective, such systems have the potential to support due diligence searches, increase legal certainty, promote the effectiveness of contractual 'reach through' provisions, and encourage investment and research and support contract compliance and monitoring of genetic resources. If developed into a common standard such identifiers might add value to the associated materials. A possible outcome of such a system would be that it adds a degree of transparency and confidence to each party engaged in otherwise private dealings, that the subject matter of the transaction has a verifiable origin and traceable history.

As part of its development and implementation of ABS arrangements for federal (Commonwealth) areas under Australia's Environment *Protection Biodiversity Conservation Act 1999*, a software based application and assessment tool is being developed and tested. Specifications for this tool also allow it to be trialed as a possible verification mechanism for prior informed consent and mutually agreed terms for native genetic material obtained from federal areas.
