COMMONWEALTH PUBLIC INQUIRY

Access to Biological Resources in Commonwealth Areas

John Voumard
Inquiry Chair

Commonwealth Public Enquiry

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ACKNOWLEDGEMENTS

In conducting the Inquiry to advise on a scheme capable of implementation through Regulations under Section 301 of the Environment Protection and Bio-Diversity Conservation Act 1999 (Cwth) to provide for the control of access to biological resources in Commonwealth areas I received invaluable assistance from the members appointed to the Inquiry's Expert Reference Group.

I am greatly indebted to them for the open minded and diligent approach they each took to the task of advising me upon the many complex issues with which the Inquiry dealt.

The members of the Expert Reference Group were Mr Sandy Donaldson, Senior Partner, Donaldson Walsh Lawyers, Adelaide, Intellectual Property Lawyer; Ms Elizabeth Evans-Illidge, Research Scientist, Australian Institute of Marine Science, Townsville; Ms Henrietta Fourmile, former Associate Professor Centre of Indigenous History and the Arts, University of Western Australia who returned to Montreal to work with the Secretariat on the Convention on Biological Diversity during the course of the Inquiry; Professor Ron Quinn, Director AstraZeneca R&D, Griffith University, Queensland; Ms Katherine Wells, Environmental Lawyer formerly of the Environment Defenders' Office, Sydney.

Dr Susan Reye, General Counsel to the Department of Environment and Heritage and Mr Paul Minogue, Counsel Bio-Diversity Group, Environment Australia provided me with comprehensive legal advice on complex issues within tight timeframes and I am most appreciative of their work.

I am deeply indebted to the staff of Environment Australia and in particular to the members of the Access Task Force, Mr Geoff Burton, Ms Sally Petherbridge, Mr Chris Mobbs and towards the end of the Inquiry Ms Sue O'Brien without whose dedicated professionalism the Inquiry's work and the provision of my report could not have occurred.

I am most grateful to all of those who took the time to make formal submissions to the Inquiry and to engage in consultations with me in the course of the Inquiry.

EXECUTIVE SUMMARY

The inquiry's terms of reference

The terms of reference required the Inquiry to advise on a scheme that could be implemented through regulations under s301 of the Environment Protection and Biodiversity Conservation Act 1999 to 'provide for the control of access to biological resources in Commonwealth areas'.

The proposed access scheme

The Inquiry's proposed scheme provides for an access permit and a benefit-sharing contract.

Under the scheme, a party seeking access to biological resources in Commonwealth areas is required to apply for an access permit. As the regulatory agency under the scheme, Environment Australia would assess the application, in consultation with any other relevant Commonwealth agency, and make a recommendation to the Minister for the Environment and Heritage to grant or refuse the permit.

While the assessment is underway, the applicant would be required to negotiate, with the holder (or owner) of the biological resources, a benefit-sharing contract which covers the commercial and other aspects of the agreement. The contract would be based on a model contract developed and agreed by Governments, industry, Indigenous organisations and other stakeholders.

The Minister may issue the permit on being satisfied, among other things, that:

* environmental assessment (if required) was undertaken and the process is completed;

* submissions from persons and bodies registered under s266A of the EPBC have been taken into account; and

* there is a benefit-sharing contract between the parties which addresses prior informed consent, mutually agreed terms, and adequate benefit-sharing arrangements, including protection for and valuing of Indigenous knowledge and environmental benefits in the area from which the resource was obtained.

The contract would only have effect if the Minister issues an access permit.

Environmental issues

The scheme takes environmental concerns into account through recommendations which recognise the need for collections of biological resources to be undertaken in accordance with the principles of ecologically sustainable development, including the precautionary principle and, where the impact of access is likely to be 'significant', following environmental assessment.

Issues affecting traditional owners

The scheme takes into account the concerns of Indigenous organisations and communities by recommending that the regulations include:

* the requirement that the Minister take certain factors into account, when deciding whether to grant or refuse an access permit; and

* provision that the decision of the owners of biological resources to deny access to their resources is not reviewable.

Industry and research issues

The scheme takes into account the major concerns of industry and research interests by including:

* proposals for benefit sharing which would allow the parties to negotiate a wide range of benefits;

* provisions which would ensure industry's interest in environmentally sensitive access to biological resources; and

* freedom for the parties to negotiate contracts which would meet their own interests and, through clear and agreed terms, promote certainty.

Nationally consistent approach

The Inquiry was the primary consultative tool of Environment Australia's Access Work Program under Biotechnology Australia. As one of the objectives of the Access Work Program is to establish a nationally consistent system the Inquiry sought the views of Commonwealth agencies and State and Territory Governments on the issue.

State and Territory Governments which have considered access issues support the development of a nationally-consistent approach. The report recommends that further consultations be held to achieve this objective.

RECOMMENDATIONS

Chapter 1

1. That this report be printed and circulated widely to stakeholders and interested parties.

Chapter 2

2. That the Department of the Environment and Heritage be the central administering agency for the access scheme.

3. That the Minister for the Environment and Heritage be given responsibility under the EPBC Act to make decisions whether to grant or refuse applications for access permits.

4. That applications for access permits be handled through the Department of the Environment and Heritage's permits web site which should be linked to the Access to Biological Resources in Commonwealth Areas page on the Department's web site.

5. That the Department of the Environment and Heritage's standard permit application be amended to include the information that applicants must provide when seeking access to biological resources under s301.

6. That the regulations include timeframes (consistent with comparable decisions under the EPBC Act) within which:

    a) after receiving the benefit-sharing contract, the Department of the Environment and Heritage is required to make a recommendation to the Minister about the permit, and

    b) after receiving the recommendation, the Minister is required to make a decision to grant or refuse the permit.

7. That the Department of the Environment and Heritage maintain a register of contracts under s301 of the EPBC Act and the permits which relate to them. To the extent possible, allowing for reasonable concerns of the parties about confidentiality (for example, for commercial, cultural or other reasons) information about the agreements should be made public.

8. That the proposed scheme be implemented through regulations under s301 of the EPBC Act.

9. That the decision of traditional owners of biological resources to deny access to their resources (ie not to enter into a contract) not be reviewable.

4 That the parties to the contract be able to seek merits review of the Minister's decision not to grant an access permit.

11. That third parties only be able to seek merits review of that part of the Minister's decision which relates to the conditions in the access permit itself, but not the conditions in the contract.

12. That civil and criminal penalties in the EPBC Act for unlawfully accessing biological resources be sufficient to deter such activities, having regard to the potential profits from biopiracy.

13. That terms in the proposed model contract anticipate that most contracts will be for commercial purposes but that in some cases, terms which reflect non-commercially motivated research purposes may need to be drafted, and benefit sharing negotiated accordingly.

14. That the Department of the Environment and Heritage develop a model contract to guide and assist the parties in their negotiations over possible benefit-sharing arrangements.

15. That the model contract be endorsed by stakeholders including Biotechnology Australia, the Australian Biotechnology Association, the Indigenous Advisory Committee, key land councils and peak environment organisations and subsequently submitted for endorsement by the Minister for the Environment and Heritage.

16. That the regulations and model contract be used in discussions with State and Territory Governments as the basis of a proposed nationally consistent scheme.

Chapter 3

17. That the Department of the Environment and Heritage, as the national focal point for the Convention on Biological Diversity and other international environmental agreements, consider means of promoting the full and effective participation of Indigenous peoples in Australia in such agreements, including by disseminating to Indigenous organisations relevant information from the secretariats of these agreements.

18. That the Department of the Environment and Heritage, in cooperation with other relevant Commonwealth agencies, monitor developments in other countries and in international fora to ensure the access scheme established by regulations under s301 of the EPBC Act meets Australia's international obligations.

Chapter 5

19. That the possibility that bioprospecting may be a matter of significance under s23 and s26 of the EPBC Act be considered in assessing permit applications for access to biodiversity on Commonwealth land or in Commonwealth marine areas.

20. That the Administrative guidelines for determining whether an action has, will have, or is likely to have a significant impact on a matter of national environmental significance under the Environment Protection and Biodiversity Conservation Act 1999 (the Administrative Guidelines) be amended to include guidelines to determine whether an action has, or will have a significant environmental impact, on Commonwealth lands.

21. That the Administrative Guidelines be amended to indicate that bioprospecting may be a matter of significance under the Act and to indicate when this is likely to be the case in relation to collection and re-collection.

22. That, in drafting these criteria, the Department of the Environment and Heritage take into account the criteria for significance and the tiered approach described.

23. That State governments take the criteria for significance and the tiered approach into account as part of developing a nationally consistent approach across all jurisdictions.

24. That in deciding whether or not to issue an access permit, the Minister for the Environment and Heritage consider the precautionary principle (this will require an amendment to s391 of the EPBC Act).

25. That, as far as possible, protocols for collecting biological resources be developed and published and that, in developing protocols, guidance be sought from protocols used by, for example, the Australian Institute of Marine Studies, the Great Barrier Reef Marine Park Authority and other relevant institutions.

26. That the adoption of the appropriate collection protocols be a mandatory condition for each permit, whether or not environmental assessment has been required.

27. That regulations under s301 and the model contract include a requirement that at least some benefits (whether of a non-monetary or monetary nature) under the contract should promote biodiversity conservation in the area covered by the contract.

28. That the Minister for the Environment and Heritage consider whether the regulations should require that a percentage of any monetary benefits (such as royalties) under the contract be allocated to a fund for environmental purposes (for example, to fund conservation projects around Australia).

29. That regulations under s301 require the parties to the contract (in practice, this would usually be the collecting body) to lodge voucher specimens and information about the collection with a CITES-approved authority in Australia which has facilities for preservation (and further dissemination, when appropriate) of this material.

Chapter 6

30. That the Department of the Environment and Heritage ensure that traditional owners and their representatives are further consulted on, and given adequate opportunities to contribute to, development of the regulations under s301 of the EPBC Act.

31. That funds from the Department of the Environment and Heritage's Access Work Program be provided to hold educative workshops or other activities with traditional owners and their representatives in all Commonwealth areas to implement the regulations.

32. That the Indigenous Advisory Committee (formed under s505A of the EPBC Act) be consulted on development of the regulations.

33. That the Indigenous Advisory Committee continue to play an advisory role in relation to operation of the regulations, in accordance with its function under s505B(1) of the Act, ie 'to advise the Minister on the operation of the Act, taking into account the significance of Indigenous peoples' knowledge of the management of land and the conservation and sustainable use of biodiversity'.

34. That, in making appointments to the Indigenous Advisory Committee, the Minister for the Environment and Heritage include a member with expertise in access and benefit-sharing issues.

35. That the trust and community register proposals, including (but not limited to) issues such as possible bioregional coverage and beneficiaries of any agreements under s301 of the EPBC Act, be discussed further in consultations on the development of the regulations and in the workshops proposed in Recommendations 30 and 31 above.

36. That the regulations ensure the distribution of benefits derived from a benefit-sharing contract is for traditional owners to determine.

37. That the Director of National Parks, as part of the responsibility for administering Commonwealth reserves and conservation zones under s514B(1)(a) of the EPBC Act, provide traditional owners with resources to enable them, if they choose, to seek independent legal or other advice in negotiations over possible access and benefit-sharing agreements.

38. That the Department of the Environment and Heritage monitor international research and debate by the World Intellectual Property Organization and the World Trade Organization (and other fora) on protection of Indigenous knowledge as well as debate and research on the issue in Australia.

39. That, in the event that stronger measures to protect such knowledge are introduced internationally or in Australia, the Department of the Environment and Heritage consider the adequacy of the regulations in protecting Indigenous intellectual property rights.

40. That the issue of protecting Indigenous knowledge be considered further in (but not necessarily limited to) discussions towards developing a nationally consistent system.

41. That IP Australia consider amending patent law to require proof of source and, where appropriate, prior informed consent, as a prerequisite for granting a patent.

42. That the regulations and the model contract stipulate that bioprospectors not collect human remains.

43. That participants in the workshops proposed in Recommendation 31 explore the possibility of innovative opportunities for Indigenous people to promote and benefit from their knowledge of biodiversity.

Chapter 8

44. That there be further discussions between the Inquiry Secretariat (the Access Taskforce) and the Great Barrier Reef Marine Park Authority regarding development of streamlined procedures under the s301 regulations to ensure access arrangements for the Great Barrier Reef Marine Park and the Commonwealth are harmonised to the greatest extent possible.

45. That, subject to any international obligations, the access scheme, as recommended by the Inquiry, apply to Australian Antarctic or SubAntarctic areas as far as practicable.

46. That the Minister for the Environment and Heritage undertake necessary legislative amendment to the Antarctic Treaty (Environment Protection) Act 1980, the Antarctic Marine Living Resources Conservation Act 1981 and such subordinate legislation as is necessary to achieve this and ensure harmonisation with the scheme established under s301 of the EPBC Act.

47. That, in applying the elements of the recommended access scheme, the Australian Science Advisory Committee continue to have a role in assessing applications for access to biological resources.

48. That, where applications are made for bioprospecting in Australian Antarctic or SubAntarctic Commonwealth areas, the Australian Antarctic Division negotiate benefit-sharing contracts.

49. That staff involved in such negotiations be independent of staff involved in considering the grant of an access permit.

50. That the principle of an integrated permits system, as introduced in the administration of the EPBC Act, apply to administrative arrangements for applications for access to biological resources in Antarctic or SubAntarctic Commonwealth areas.

51. That benefit-sharing agreements with proponents wishing to access the biological resources on lands owned, leased or otherwise controlled by both Governments on Norfolk Island be negotiated jointly.

52. That the Minister for the Environment and Heritage agree to the principle that benefits under any such agreement be for the benefit of the people of Norfolk Island and its environment.

53. That access to the marine biological resources found in the area known as the Norfolk Island Fishery be reserved for the benefit of the people of the Island with benefit agreements to be negotiated by the Norfolk Island Government.

54. That, in consequence, the regulations under s301 of the EPBC Act be framed to allow for the special circumstances of the island and that the Department of the Environment and Heritage consult with the Department of Transport and Regional Services and the Norfolk Island Government over the administrative arrangements for implementing the regulations.

55. That the Minister for the Environment and Heritage endorse the Commonwealth State Working Group principles.

56. That further consultations be held with State and Territory governments to address the broader issue of a nationally consistent approach cross jurisdictions.

57. That the Minister for the Environment and Heritage review the function of the Commonwealth State Working Group and consider steps necessary to increase the involvement of key stakeholders and ensure any future work done by that body is undertaken with defined outcomes and within agreed timeframes.

58. That the Department of Environment and Heritage, as administering agency for the EPBC Act; and Agriculture, Fisheries and Forests — Australia, as the agency with responsibility for the Fisheries Management Act 1991, together with other relevant Commonwealth agencies including the CSIRO and the Australian Institute of Marine Science, conduct discussions to establish a Commonwealth position on:

    a) the concurrent operation of s301 of the EPBC Act and the Fisheries Management Act and seek endorsement of their respective Ministers to that position, and

    b) establish a Commonwealth position in relation to exclusion of activities otherwise dealt with in regulations made under s301 of the EPBC Act from matters to be covered by future negotiated, or renegotiated arrangements with States and Territories under the Fisheries Management Act.

59. In the event that this is not possible or desirable, the Minister for the Environment and Heritage should consider amending the EPBC Act to ensure both Acts may operate concurrently and the distinction between action necessary for sustainable fisheries management and action necessary to regulate access to biological resources is clarified.

60. That the Department of the Environment and Heritage discuss with State and Territory authorities the scope for concurrent operation of regulations under s301 of the EPBC Act in Commonwealth areas where States and Territories have arrangements under the Fisheries Management Act affecting access to biological resources.

61. That, with the concurrence of the State or Territory involved, the Australian Fisheries Management Authority be invited to participate in these discussions.

62. That the Minister ask the Department of the Environment and Heritage to discuss, with holders of ex situ collections, the value of a combined request for legal advice on ownership issues.

63. That, subject to the advice subsequently obtained, the Minister consider any recommendation from the holders of ex situ collections within his portfolio for legislative amendment to resolve outstanding ownership issues.

64. That, to the extent possible, Commonwealth ex situ collections of native species be included in the access scheme to be introduced by regulations under s301 of the EPBC Act.

65. That action be taken to identify ex situ collections and that the Department of the Environment and Heritage provide advice about the introduction of the access scheme.

66. That material which is the subject of existing international agreements, such as the Food and Agricultural Organization International Undertaking on Plant Genetic Resources, be excluded from the ambit of the regulations.

67. That the Minister for the Environment and Heritage consider deferring application of the regulations to participating Botanic Gardens and other ex situ organisations if, in his view, deferral would aid progress to a common Australian position and if there was no undue delay in establishing the Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit Sharing.

68. That, in settling an Australian position in relation to the terms of the Common Guidelines for participating institutions on access to genetic resources and benefit sharing, the Council of Heads of Australian Herbaria be asked to consider the relationship between the provisions of the access scheme to be introduced under s301 of the EPBC Act and the Common Guidelines.

69. That the Department of the Environment and Heritage undertake further research to determine the extent of the export of micro-organisms and products derived from them.

70. That, in light of this information, export controls on such organisms be extended.

71. That the export provisions of the Wildlife Protection (Regulation of Exports and Imports) Act 1982 be amended to allow the s301 scheme and other similar systems, such as the tiered model being developed by Australian Institute of Marine Science and the Great Barrier Reef Marine Park Authority, to be taken into account when export approvals are sought or that this be reflected when proposed amendments to the EPBC Act incorporate the provisions of the Wildlife Protection Act.

CHAPTER 1: OUTLINE OF THE PROPOSED ACCESS SCHEME — GUIDING PRINCIPLES

An Access Scheme

Key elements of the proposed access scheme

1.1 From the outset, I have focused on developing an access scheme which is practical and fair, and which minimises transaction costs and maximises certainty for all parties. The scheme is designed to integrate with the Environment Protection and Biodiversity Conservation Act 1999 (EPBC Act) and be readily enshrined in regulations under s301 of the Act (see Appendix 1 for selected sections of the Act).

1.2 The recommended scheme reflects four key concepts:

a) contracts should be negotiated between the owner of the biological resource and the bioprospector;

b) contracts should be based on a form of model contract endorsed by key stakeholders (see 'The proposed model contract' in Chapter 2);

c) contracts only have effect when the Minister for the Environment and Heritage issues an access permit, and

d) assessment of access permit applications will ensure the Australian community's environmental and other interests are protected, and take into account Indigenous interests and consultative requirements, where applicable.

1.3 The scheme also takes into account the diversity of land tenures in Commonwealth areas and can be integrated into a nationally consistent approach for regulating access to biological resources.

A brief description of the proposed access scheme

1.4 Under the proposed scheme, either the owner or holder of resources in the particular Commonwealth area, is empowered to negotiate a benefit-sharing contract with the proponent (bioprospector). The contract will be based on a model contract to be developed and agreed by industry, Indigenous organisations and other stakeholders. The model contract will include provisions for benefit sharing through non-monetary and monetary benefits, such as fees, milestone payments and royalties, from sources including products derived from the material collected and intellectual property rights.

1.5 The contract only has effect if the Minister for the Environment and Heritage issues an access permit. The Minister may issue the permit on being satisfied that there is:

a) prior informed consent by the owners;

b) adequate benefit sharing, including protection for and acknowledgment of the custodianship of the resource by Indigenous owners;

c) proper provision for protecting traditional biodiversity related knowledge of Indigenous owners, and

d) no loss of biodiversity or other environmental damage.

1.6 The proposal that the Minister issue access permits means the community's broader interests are protected through requirements that the environment be protected and that scientific knowledge be made available to the community. The exercise of this permitting power is transparent and accountable, with the basis for Ministerial decisions set out in the s301 regulations, and review rights also specified. Linkage with the benefit-sharing contract is achieved through a requirement in the regulations that the contract include a provision that it takes effect only if an access permit has been issued.

1.7 Regulations under s301 of the EPBC Act will establish this scheme, harnessing existing legal and administrative arrangements to the benefit of the owners of biological resources, whether public or private, while ensuring the broader public interest is protected.

Role of the regulator — Environment Australia

1.8 I have concluded that Environment Australia should perform the role of the central administering agency and that, in establishing and managing the access scheme, it should:

a) assess applications for access permits as part of the administration of the integrated permit system;

b) develop and seek endorsement by stakeholders of a model contract for use by parties in Commonwealth areas and possible use in other jurisdictions;

c) consult with traditional owners and their representatives in the course of the drafting, implementation and administration of the s301 regulations;

d) work to assist traditional owners to preserve and protect their knowledge of their biological resources;

e) consult with Commonwealth agencies with an interest in the implementation of the s301 regulations;

f) negotiate benefit-sharing contracts on behalf of, or in conjunction with, other Commonwealth agencies which administer Commonwealth areas; and

g) provide leadership in the development of a nationally consistent approach to access and benefit-sharing issues by Commonwealth, State and Territory Governments.

Compatibility with the development of a nationally consistent approach by Commonwealth, State and Territory Governments

1.9 In developing this scheme I have borne in mind the importance of a nationally consistent approach to access to biological resources and the work undertaken towards this goal by the Commonwealth, State and Territory Governments over more than eight years. Accordingly, the scheme is designed to be broadly compatible with existing and possible future State and Territory regimes.

1.10 To this end the Inquiry has considered the differing forms of land tenure in State and Territory jurisdictions. I believe the use of benefit-sharing contracts protects the common-law rights of landholders and ensures the owner of biological resources shares directly in their use. This applies whether the area is in public or private ownership and whether or not ownership of the plants, animals and micro-organisms has been asserted.

The Inquiry's Guiding Principles and Considerations

1.11 In developing the proposed scheme I have been guided by a range of principles and considerations. Foremost among them are the Inquiry's terms of reference and the Commonwealth Government's Biotechnology Strategy. Additional guiding principles and considerations are outlined below and others are detailed in Chapter 3, 'Background to the Inquiry'.

Terms of Reference

1.12 The terms of reference require the Inquiry to advise on a scheme that could be implemented through regulations under s301 of the Environment Protection and Biodiversity Conservation Act 1999 to 'provide for the control of access to biological resources in Commonwealth areas'. The Inquiry's terms of reference are at Appendix 2 and the press release from the Minister for the Environment and Heritage, announcing the Inquiry, is at Appendix 3.

1.13 The terms of reference require the proposed scheme to take into account Australia's obligations under the Convention on Biological Diversity and the objectives of the National Strategy for the Conservation of Australia's Biological Diversity. The terms of reference drew the Inquiry's attention to the provisions in the Convention dealing with equitable sharing of benefits arising from the use of biological resources and from the use of Indigenous knowledge. Attention was also drawn to the objectives of the National Strategy, such as to ensure there are no adverse effects on the viability or conservation status of species or population and that the social and economic benefits from using Australia's biological resources accrue to Australia.

1.14 When considering these points, I have taken the view that there are some commonalities in the ideas of the equitable sharing of benefits and of accruing social and economic benefits to the country. Both involve consideration of

public and private benefits and both require the application of fairness and the concept of ownership to allow distribution to be determined. I have sought to identify each of the factors applying in each case so that when these considerations are compared with the recommended scheme, the scheme can be seen to meet these criteria.

1.15 The arrangements I have recommended are designed to fit in with the EPBC Act's integrated permit system for easier administration and to help ensure environmental protection.

1.16 The terms of reference also require that the scheme meet four other goals. These are that it:

a) promotes certainty for industry and facilitates access to biological resources for environmentally sound uses;

b) promotes a cooperative approach to the protection and management of the environment involving governments, the community, land-holders and Indigenous peoples;

c) recognises the role of Indigenous people in the conservation and ecologically sustainable use of Australia's biodiversity; and

d) promotes the use of Indigenous peoples' knowledge of biodiversity with the involvement of, and in cooperation with, the owners of that knowledge.

1.17 Simple, transparent regulations with low transaction costs make for certainty. The use of a model contract developed and endorsed by industry, government, Indigenous owners and other key stakeholders also adds to the certainty and confidence of all parties and reduces the adverse consequences of any inequality in bargaining power between the proponent and the provider.

The Commonwealth Government's Biotechnology Strategy

1.18 On 3 July 2000 the Minister for Science, Industry and Resources, Senator Nick Minchin, launched the National Strategy for Australian Biotechnology. The Strategy includes, as an objective, 'The development of measures to enhance access to Australian biological resources'.

1.19 Among the strategies to meet that objective is the need to:

a) address issues of access to biological resources within Commonwealth areas including through regulations under the EPBC Act;

b) address matters involving Indigenous people and their ownership of biological resources; and

c) work with the States and Territories to achieve nationally consistent regimes on access.

1.20 I believe the Inquiry has made a significant contribution to meeting these goals.

Guiding Principles

1.21 Reviewing the extensive literature on the subject of access to biological resources has illustrated the complexity of this subject. In our discussions with stakeholders, expressions of good luck were almost invariably offered in recognition of this. To deal with this complexity, I established the following principles to guide the work of the Inquiry:

a) the owner of land or the holder of sovereignty over the seabed is entitled to secure benefits flowing from the use of that land or seabed and the plants, animals and miro-organisms growing or living within it;

b) the state is entitled to regulate activities on land or at sea, in the public interest;

c) to the extent possible, the use of existing laws and administrative structures is preferable to the creation of new ones;

d) any regulations must be consistent with Australia's international obligations and existing Commonwealth law;

e) any scheme must not put at risk Australia's existing ease of importation of genetic resources for food and agriculture;

f) the responsibilities and entitlements of public bodies in Commonwealth areas are qualitatively different to those of people who have leased land to the Commonwealth, particularly in the case of land owned by Indigenous people and leased to the Commonwealth;

g) in the case of land owned by Indigenous people, the prior informed consent of the owners must be demonstrable;

h) appropriate recognition should be given to Indigenous knowledge and, in the absence of statutory instruments for protecting Indigenous knowledge, practical legal solutions must be found;

i) nothing in the access scheme should reduce the existing rights of Indigenous owners in Commonwealth areas;

j) the scheme should contribute to the environment through protection of biodiversity conservation;

k) access to biological resources should be facilitated but not without appropriate consideration of mutually agreed terms, prior informed consent and sharing of benefits; and

l) regulations must take into account the diversity of land tenures and marine controls in Commonwealth areas and be capable of integration into a nationally consistent approach for regulating access to biological resources.

1.22 I also drew on the four 'overarching principles, or desirable features', for development of an access scheme put forward in Environment Australia's submission. These are that the scheme should:

a) provide effective protection of biological diversity and important natural heritage sites;

b) provide incentives for the conservation and sustainable use of biological resources;

c) be equitable and transparent; and

d) be simple and efficient.

Concerns of traditional owners

1.23 I have listened carefully to the concerns of traditional owners in Commonwealth areas, particularly about the misuse of their knowledge of biodiversity. This issue has also been the subject of many submissions and representations. The Inquiry has sought to come to terms with the limitations of the existing legal system in protecting and valuing this knowledge. I believe the best protection presently available for the rights of Indigenous peoples to their biological resources and their intellectual property can be achieved through inclusion of appropriate contractual terms. The solutions the Inquiry recommends are practical and, most importantly I believe, empowering for the Indigenous communities which have leased their land to the Commonwealth.

1.24 In addition, I have recommended further consultations with Indigenous owners to help them understand the issues and to undertake projects which will preserve and protect Indigenous knowledge.

1.25 I have considered the situation where Indigenous knowledge is shared among communities beyond the boundaries of Commonwealth areas and have made recommendations which may help Indigenous communities in Commonwealth areas address this issue.

Practicality

1.26 Many of the elements in the proposed model contract will reflect existing commercial contracts and will therefore be familiar to industry, science and governments and promote certainty – both within Australia and abroad. Australia has the good fortune to have a well developed legal and administrative system that integrates with systems in the rest of the developed world. The approach taken in the course of this Inquiry takes advantage of this integration.

1.27 Australia has a further comparative advantage in that, unlike many biodiversity-rich countries, it is also a developed country and one which is both a user and provider of genetic resources. It is therefore well placed to strike a balance between ensuring that, in exchange for facilitating access to

its biological resources for biodiscovery purposes, there is a reasonable sharing of the benefits produced.

Urgency

1.28 Australia has about 13 per cent of the world's biodiversity. The genetic and bio-chemical make-up of this rich biota is a potential source of new chemical and pharmaceutical products.

1.29 However, Australia has only a limited window of opportunity to take advantage of current interest in its biodiversity and to share in the benefits from its use. From evidence given to the Inquiry and discussions with stakeholders, it is clear that the technology involved in bio-assaying and screening is advancing rapidly. The speed at which plants, animals and micro-organisms are analysed and their potential use assessed has accelerated dramatically over recent years. This fact, coupled with rapid advances in the broader biotechnology industry, means that if Australia is to secure a share in the benefits flowing from this revolution it needs to have its legal and regulatory house in order at both the Commonwealth and State levels.

The Inquiry's Consultation Process

1.30 When the Minister announced the Inquiry, he said it would consider public submissions and conduct hearings around Australia. The Minister appointed an expert reference group to help the Inquiry Chairman: the group comprised Ms Katherine Wells (environment), Professor Ronald J Quinn (industry), Ms Elizabeth Evans-Illidge (science), Ms Henrietta Fourmile (now Marrie) (Indigenous issues) and Mr Sandy Donaldson (intellectual property law).

1.31 Calls for submissions were advertised in the national press and major metropolitan newspapers on 15 January 2000. I sent letters inviting submissions to key organisations and individuals with interests in environment, industry, research and Indigenous issues. The Inquiry Secretariat also sent notices to approximately 600 organisations and individuals. Submissions were due by 3 March 2000 but late submissions were accepted and considered. The Inquiry received 80 submissions. A list of submissions received is at Appendix 4.

1.32 I held meetings with key stakeholders and conducted public hearings in Canberra and Brisbane. This included the presentation of evidence by telephone at the public hearings. A list of my consultations and the people who presented evidence at the hearings is at Appendix 5.

1.33 Chapters 5, 6 and 7 detail how consultations were conducted in relation to environmental, Indigenous, industry and research interests respectively. In each of these chapters I have sought to reflect, in some detail, the issues and concerns relating to the immediate interests of each group. It should be noted, however, that, to some extent, this division is arbitrary as many

submissions (particularly those from key stakeholders) addressed issues not only of concern to their immediate mandate, but also related issues (for example environmental groups discussed Indigenous issues) and aspects of a possible scheme in general. I have sought to reflect this in each chapter.

1.34 The Inquiry made considerable efforts to consult key stakeholders within its terms of reference and timeframe. Nevertheless, my consultations revealed that many stakeholders would benefit from further opportunities to understand the issues and, particularly where they will be directly affected by the scheme, to contribute to its development and implementation. I have made specific recommendations to this end to ensure the concerns of particular groups are met.

1.35 In addition, I believe publication of this report will promote increased understanding of these complex issues in the community and that all stakeholders' interests would be served through opportunities to comment on the draft regulations. I believe this will also encourage stakeholders to commit themselves to working in a constructive and cooperative way towards development of a nationally consistent system.

1.36 Through the course of the Inquiry I engaged in discussions with senior officials from State Governments and encouraged them to make submissions. I sought to hear their views on policy issues and, in particular, to understand what they saw as key elements in an access scheme. I put forward the view that this was an opportunity for the States to have input into developing the Commonwealth's scheme. I made the further point that, by so doing, they could contribute to developing a nationally consistent approach through introduction of a Commonwealth scheme that would be compatible with their approaches.

1.37 I was met with cooperation and frankness and gained valuable insights. Queensland, in particular, expressed a strong interest in participating in working with the Commonwealth towards developing a nationally consistent approach. South Australia, at officials level, has independently come to similar conclusions to that of the Inquiry about the principles and practical approaches underlying any access regime and has developed options for consideration by government and the community.

1.38 The input I received from the States and Territories has informed my thinking and influenced the scheme I am recommending. It has provided additional confidence to my belief that our recommended scheme has the capacity to make a substantial contribution to development of a nationally consistent approach to managing access to Australia's biological resources. Chapter 8 discusses State and

Territory issues in more detail.

1.39 I have made recommendations about consultations with certain stakeholders, particularly traditional owners of national parks and State and Territory governments, in later chapters.

Recommendation

1. That this report be printed and circulated widely to stakeholders and interested parties.

Other issues

What is meant by 'Access to Biological Resources'?

1.40 The Inquiry has observed some confusion about the meaning of the phrase 'access to biological resources', particularly with regard to where to draw the line between bioprospecting (for biodiscovery purposes) and harvesting animals and plants for commercial use. This is partly because of the breadth of the definition of biological resources in s528 of the EPBC Act. The definition states:

> biological resources includes genetic resources, organisms, parts of organisms, populations and any other biotic component of an ecosystem with actual or potential use or value for humanity.

1.41 The term 'biological resources' is often used interchangeably with 'genetic resources'. However, in the EPBC Act (and the Convention on Biological Diversity, on which the Act's definitions are based), they are defined separately. 'Biological resources' includes 'genetic resources', among other things. In some respects, 'genetic resources' is a more helpful term when discussing access because it is the genetic and biochemical make-up of biological resources, not the biological resources as such, in which biodiscovery companies are generally interested.

1.42 The problem also arises from the lack of a definition of 'access' in s528. However, the Explanatory Memorandum provides some guidance:
This clause [s301] provides that the regulations may control access to biological resources (as defined in clause 528) in Commonwealth areas. Examples of access to biological resources are: collecting living material, viewing and sampling stored material, and exporting material for purposes such as taxonomic research, conservation, research, and potential commercial product development.

1.43 In undertaking its task, the Inquiry has taken the view that 'access to biological resources' refers to the process whereby samples from individual organisms are gathered, their genetic and biochemical make-up and other attributes determined, and their potential use assessed.

1.44 The boundary between this process and harvesting for commercial use is reached when the material is required for a different purpose, such as for producing a product or for consumption. Such activities are beyond the scope of the scheme we have developed. They do, however, come within the ambit of other provisions of the EPBC Act relating to environmental impacts or other Commonwealth legislation dealing with the commercial use of living resources more generally, such as the Fisheries Management Act 1991 or the Great Barrier Reef Marine Park Act 1975.

1.45 The Inquiry nevertheless considered the situation where collection of material for commercial use was not otherwise regulated and the use was related to extraction of its biological components. I suggest that in such circumstances this gap would be filled if the regulations under s301 of the EPBC Act applied.

Biological resources proposed to be regulated

1.46 The Inquiry has concluded that the scheme should apply to biological resources native to Australia and not to exotic plants and animals that have come here since European contact. In reaching this conclusion the Inquiry has been guided by Articles 3 and 15 of the Convention on Biological Diversity which recognise the right of sovereign states to exploit their own resources and their responsibility not to damage the environments of other countries or impose restrictions that run counter to the objectives of the Convention.

1.47 The Inquiry has taken the view that if Australia were to seek to gain benefits deriving from using other countries' biodiversity, it would be acting counter to the objectives of the Convention. In such circumstances it would be open to criticism and possible accusations of biopiracy. Similarly, in the Inquiry's view, Australia would not wish other countries holding Australian native biological resources to obtain benefits from using its genetic content. The Inquiry is aware that extensive holdings of Australian biota are in public and private overseas collections from where they are made available to other countries.

Exclusion of biological resources in ex situ collections affected by international agreements

1.48 The Inquiry has considered the degree to which the scheme should cover resources held in Commonwealth ex situ collections. This has been complicated by legal advice to the effect that the power to make regulations about ex situ collections is arguable and that the regulations would need to be examined before a concluded view could be drawn. The difficulty arises because s301 of the EPBC Act appears to deal only with access to in situ biological resources while the Explanatory Memorandum expresses the intention to include ex situ collections. I have taken the view nevertheless that, in principle, ex situ collections should be covered by the scheme. I am supported in this view by legal advice which, while qualified on the point, concludes that the power to do so exists. However, I am persuaded that material which is the subject of existing international agreements, such as the

Food and Agricultural Organisation International Undertaking on Plant Genetic Resources, should be excluded. Collections of non-native species would also be excluded, while some collections may not be relevant, such as collections whose constituting instruments would preclude bioprospecting.

1.49 The submission from the Chair of the Council of Heads of Australian Herbaria points to the development of a nationally consistent approach to access and benefit sharing among their constituent ex situ collections as part of their participation in developing the Common Guidelines for participating Botanic Gardens on access to genetic resources and benefit sharing (Appendix 6). Accordingly, I am of the view that it would be appropriate for the Minister to consider deferring application of the scheme to those Commonwealth organisations involved, pending the outcome of the development of the Common Guidelines if, in his view, deferral would aid progress to a common Australian position.

1.50 This step would also contribute to the momentum towards a nationally consistent approach by the Commonwealth and the States and Territories.

1.51 These matters are discussed in detail at Chapter 8.

Biopiracy

1.52 Submissions and representations to the Inquiry raised the dangers of biopiracy, that is, where biological resources are taken unlawfully (often out of the country). Biopiracy denies the originating community the opportunity to share in benefits which may flow from use of their resources. At first glance the problem seems difficult to address satisfactorily, but the Inquiry has made recommendations which should help. These recommendations are directed at:

a) closing loopholes in the export controls in the Commonwealth's Wildlife Protection (Regulation of Exports and Imports) Act 1982; and

b) setting appropriate (deterrent) penalties for taking resources without a permit.

1.53 They also involve using the model contract across Australian jurisdictions and establishing a nationally consistent approach to managing access to biological resources. This issue is discussed in detail in Chapter 2 'Penalties' and Chapter 8 'Export of biological resources'.

CHAPTER 2: THE PROPOSED SCHEME UNDER S301 OF THE EPBC ACT AND AN OUTLINE OF THE PROPOSED REGULATIONS, ACCESS PERMITS AND BENEFIT-SHARING CONTRACTS

How the proposed scheme would operate

2.1 A major objective of the Inquiry was to develop an administration and decision-making system which is consistent, to the extent possible and appropriate, with other provisions in the EPBC Act, particularly the integrated permits scheme, environmental assessment provisions, and the objects in s3 which relate to Indigenous people. Policy issues relating to the environment, Indigenous people and industry and their implications for aspects of the operation of the scheme, are discussed in more detail in Chapters 5, 6 and 7.

Interaction with related provisions of the EPBC Act: the integrated permit scheme

2.2 The Inquiry has attempted to design a scheme which is consistent with, and can therefore be integrated into, the general permit scheme under the EPBC Act.

2.3 The Act provides for two main types of permits.

a) Permits for activities in Commonwealth areas including reserves, parks, conservation zones and external territories (reserve permits).

b) Permits for the taking, keeping, moving etc of listed threatened, migratory, marine and cetacean species and communities in Commonwealth areas (wildlife permits).

2.4 Proposed amendments to the Act would see the inclusion of the permits currently issued under the Wildlife Protection (Regulation of Exports and Imports) Act 1982.

Administration and decision-making in the proposed scheme

2.5 Many submissions favoured a centralised system of administration and decision-making for the scheme. Since most Commonwealth Government agencies have had limited experience with access and benefit-sharing arrangements, the Inquiry considers there would be value, at least for the foreseeable future, in making one agency (Environment Australia) responsible for administering the scheme. This would also be administratively convenient where more than one agency was involved in access negotiations. It is also consistent with Environment Australia's responsibility for assessing other permits under the EPBC Act.

2.6 In assessing access permit applications, Environment Australia would be required to consult with relevant agencies (including independent sources of advice, where necessary) and then prepare a recommendation to the Minister

for the Environment and Heritage as to whether the permit should be granted or refused. This would include assessing and making a recommendation about the proposed benefit-sharing contract. Environment Australia's role would include being the first point of contact for information about the scheme.

2.7 It may be appropriate for some administrative and decision-making functions to be delegated (with Environment Australia retained as the first point of contact) when agencies have more experience in dealing with the issues.

Recommendations

2. That the Department of the Environment and Heritage be the central administering agency for the access scheme.

3. That the Minister for the Environment and Heritage be given responsibility under the EPBC Act to make decisions whether to grant or refuse applications for access permits.

4. That applications for access permits be handled through the Department of the Environment and Heritage's permits web site which should be linked to the Access to Biological Resources in Commonwealth Areas page on the Department's web site.

2. That the Department of the Environment and Heritage's standard permit application be amended to include the information that applicants must provide when seeking access to biological resources under s301.

Timeframes

2.8 The Inquiry acknowledges that applicants will want permit applications and contract negotiations finalised within reasonable timeframes. It considered, however, that it was not consistent with the principles of prior informed consent and mutually agreed terms to impose time limits on contract negotiations. In any event, commercial contracts are complex and often require considerable negotiation before they are concluded.

2.9 Once the parties have submitted a contract to Environment Australia, however, the Inquiry considered that some limits on the timeframes within which Environment Australia should make its recommendation to the Minister and within which the Minister should make a decision were reasonable and in the interests of both parties. These should be consistent with the timeframes which apply to comparable decisions under the EPBC Act.

Recommendation

6. That the regulations include timeframes (consistent with comparable decisions under the EPBC Act) within which:

2. after receiving the benefit-sharing contract, the Department of the Environment and Heritage is required to make a recommendation to the Minister about the permit, and

3. after receiving the recommendation, the Minister is required to make a decision to grant or refuse the permit.

Register of agreements

2.10 Several submissions recommended that the agency responsible for administering the scheme should maintain a register of agreements under s301 of the EPBC Act.

Recommendation

4. That the Department of the Environment and Heritage maintain a register of contracts under s301 of the EPBC Act and the permits which relate to them. To the extent possible, allowing for reasonable concerns of the parties about confidentiality (for example, for commercial, cultural or other reasons) information about the agreements should be made public.

Detailed description of the access scheme

2.11 The following is a description of how the proposed scheme will work. A flow chart of the scheme appears at Appendix 7.

a. Applicant submits an application to Environment Australia using standard form designed for all permit applications under the EPBC Act, with specific provisions for s301 access requests.

b. Environment Australia assesses the application — addresses threshold questions.

* Is the collecting in a Commonwealth 'area' under s525?

> No — Environment Australia advises applicant where to seek permit, eg State or Territory government agency.
> Yes — Environment Australia continues to assess the application.

* Does it involve a request for wildlife, reserve and/or export permits?

* Does it involve collection of threatened species (s201), migratory species (s216), cetaceans (s238) and/or listed marine species (s258)? (wildlife permits)

  > If yes, is an environmental assessment required? (environmental assessment procedures must be completed before the permit can be granted or refused).

b. Permit for these activities may be granted or refused.

* Does it involve a request to export samples?

  > If yes, procedures must be completed so the applicant is aware of whether they will be able to export samples before proceeding with the application for permit and benefit-sharing agreement.

[**Note:** At this point Environment Australia should ensure that the applicant is aware of the requirement to conclude a contract with the resource provider and, if necessary, advise the applicant of the provider's contact details etc.]

* Once these issues are resolved, Environment Australia assesses application to access resources under s301, seeks advice from relevant area (eg a division of Environment Australia such as Marine and Water Division, Parks Division, or other government agency) and further information from other sources, if required, as to whether the permit should be granted or refused.

[**Note**: In 'areas' not administered by Environment Australia – Environment Australia refers the application to the appropriate agency, eg Department of Defence, CSIRO, GBRMPA, etc.]

* Following submission of the benefit-sharing contract, Environment Australia makes a recommendation to the Minister that the permit be granted or refused, including a recommendation regarding the contract.

* Minister refuses or grants the permit.

* Parties may seek review of the decision.

[**Note:** Applicants may need to seek further permits, eg for recollection. It is suggested, however, that as far as practicable there should be only one contract (when the first permit is sought) and that this contract should anticipate the possibility of further permits. Further permits would be granted on the basis that there is an existing contract which requires no further Ministerial assessment.]

Matters to be covered in s301 Regulations

2.12 The regulations should incorporate the general principles of ensuring that access to biological resources in Commonwealth areas is conducted in accordance with ecologically sustainable development principles, including environmental assessment procedures where applicable, and promotes the conservation of biological diversity and the sustainable use of its components.

2.13 With regard to operational aspects of the scheme, the regulations should:

a) set out a simplified outline of the access scheme;

b) set out the requirements for:

i) lodging voucher specimens in Australian public institutions accredited with the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES);

ii) information about the specimens collected; and

iii) ensuring at least some benefits are used for biodiversity conservation in the area from where the biological resource was obtained (Recommendation 27); and

c) stipulate that bioprospectors should not collect human remains (Recommendation 42);

2.14 With respect to access permits, the regulations should:

a) set out the requirement to obtain a permit to access biological resources in Commonwealth areas;

b) require use of the standard permit application form, while allowing scope to include conditions for particular circumstances;

c) require that the Minister give notice of each permit application to each person and body registered under s266A of the Act, and to invite them to make written submissions about whether a permit should be issued (addressing possible environmental concerns only), and to take these into account in making his decision;

d) set out conditions to be included in the permit, including:

i) the requirement that applicants enter into a benefit-sharing contract with the resource provider;

ii) arrangements and conditions regarding access, eg who, when, where, what (including any follow-up collecting, if applicable);

iii) environmental conditions, including the collecting protocols to be observed; and

iv) the requirement to report to Environment Australia, with a copy to the resource provider;

e) stipulate that the Minister's decision to grant/refuse a permit must take into account that:

i) environmental assessment (if required) was undertaken and the process is completed;

ii) the Minister is satisfied that the collection protocol attached to the permit will provide adequate environmental protection;

iii) the submissions from persons and bodies registered under s266A of the EPBC Act have been taken into account;

iv) the precautionary principle has been applied, where appropriate;

v) any variations to the model contract are acceptable;

vi) there is a benefit-sharing contract between the parties and that it addresses major issues, such as:

* prior informed consent,

* mutually agreed terms,

* adequate benefit sharing arrangements, including protection for and valuing of Indigenous knowledge (where provided by the owner); and

vii) some benefits will be used for biodiversity conservation in the area from which the resource was obtained;

viii) where access is granted, access arrangements meet the requirements of leases, management plans and any other relevant documentation, where applicable;

f) stipulate that it is an offence to access resources without a permit or to breach the conditions of a permit (including a cross reference to civil and criminal penalties in the Act);

g) set a timeframe within which the access permit is valid (a maximum of three years);

h) allow transfer of the access permit only with permission of the Minister;

i) detail the circumstances for revocation or suspension of the access permit by the Minister;

j) detail provisions to request information or set conditions relevant to particular situations, eg Defence, such as:

i) issues of safety, security and operational needs;

ii) requirements in respect of the length of advance notice required for entry; and

iii) the need to consult with a range of management staff where a training area is involved; and

k) set fees (fees should be consistent with other fees charged under the EPBC Act, with provision for differential fees depending on the length and complexity of environmental assessments).

2.15 With regard to the benefit-sharing contract, the regulations should:

a) recognise and encourage use of the model contract (but note that its use is not mandatory);

b) state that the contract must include a provision that it takes effect only if an access permit has been issued;

c) set out indicia which may evidence that there is prior informed consent by the party which is providing access to biological resources:

i) where traditional owners are involved, the regulations should provide for:

* adequate time to consider applications, consult with other parties (eg, owners who live outside the area) and seek advice;

* adequate information from and consultations with the applicant;

* benefit-sharing provisions to cover the costs of consultation;

* minimum requirements for notification and consultation to be met if beneficiaries are wider than traditional owners;

* availability of information and education about access and benefit-sharing issues;

* representation by the relevant land council;

* independent legal advice;

* advice from the Director of National Parks, if requested;

* confirmation from relevant land council that these procedures have been followed; and

* where access is refused, no review and a minimum time before another application can be made;

d) in all other cases, the regulations should deem prior informed consent to exist unless there is evidence to the contrary;

e) ensure adequate benefit sharing, including benefits to Australia through improved knowledge and sharing of information about biodiversity;

f) stipulate that distribution of benefits is for the traditional owners to determine, and

g) include examples of possible monetary and non-monetary benefits.

Examples of monetary benefits include:

* up-front payments;

* milestone payments;

* royalties;

* research funding;

* licence fees; and

* salaries and infrastructure provided to owners of the resource, or landholders, as part of access arrangements;

Examples of non-monetary benefits include:

* participation of Australians in research activities;

* sharing of research results;

* a set of voucher specimens left in Australian CITES-accredited institutions;

* support for research for conservation and sustainable use of biological diversity;

* strengthening the capacities for technology transfer, including biotechnology;

* strengthening the capacities of local and Indigenous groups to conserve and use their genetic resources and, in particular, to negotiate the benefits arising from the use of the intangible associated components of genetic resources and their derivatives;

* assistance for language revival and maintenance programs for traditional owners;

* recovery and recording of the biodiversity knowledge of traditional owners;

* reasonable access by Australians to duplicates or, as appropriate, originals of specimens deposited in international ex situ collections;

* receipt by providers, without payment of a royalty, of all technologies developed from research on endemic species;

* donation to national institutions of equipment used as part of research;

* reasonable access to technology and products resulting from the agreement;

* information exchange;

* protection of local existing applications of intellectual property rights;

* building capacities in controlling aspects of bioprospecting methods, such as collection and preparation of samples, biodiversity monitoring, socio-economic monitoring, and/or nursery and agronomic techniques (increased conservation capacity);

* institutional capacity-building;

* intellectual property rights; and

* participation in commercialisation or product development or manufacture. Some other important non-monetary benefits may include:

* biological inventories and taxonomic studies, integral components of many bioprospecting activities, which can provide important benefits for conservation and sustainable use of biological diversity;

* contributions to the local economy through value-added activities such as the cultivation of a species that is needed in large quantities for natural-products research, development and production as a commercial commodity;

* public-health benefits, for example, in cases where access and benefit-sharing agreements encompass a commitment by a firm seeking genetic resources to invest in or support research on locally important diseases for which there is relatively little private sector investment;

* the institutional and personal relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities under it, such as between a local university and an international research centre, for example, are in themselves an extremely important non-monetary benefit. Often these relationships lead to important follow-on scientific collaboration and increased access to international funding sources; and

* human and material resources to strengthen the capacities of personnel responsible for administering and enforcing access regulations.

Recommendation

8. That the proposed scheme be implemented through regulations under s301 of the EPBC Act.

Matters to be covered in the EPBC Act

Review provisions

2.16 Review provisions should provide:

a) that the decision of the Indigenous owners of biological resources to deny access to their resources (ie not to enter into a contract) is not reviewable (and to prevent undue pressure on them to negotiate, there should also be a time limit before the application may be re-activated);

b) merits review by the parties of the Minister's decision not to grant an access permit; and

c) merits review by third parties of that part of the Minister's decision which relates to the conditions in the access permit itself, but not the conditions in the contract.

Recommendations

9. That the decision of traditional owners of biological resources to deny access to their resources (ie not to enter into a contract) not be reviewable.

10. That the parties to the contract be able to seek merits review of the Minister's decision not to grant an access permit.

3. That third parties only be able to seek merits review of that part of the Minister's decision which relates to the conditions in the access permit itself, but not the conditions in the contract.

Penalties

2.17 The Act should also provide for penalties for bioprospecting without a permit and for breaches of the terms and conditions of a permit which are consistent with other penalties in the EPBC Act for comparable offences. In this regard the level of penalty must be sufficient to deter biopiracy.

2.18 Biopiracy denies the community from which the resource originates the opportunity to share in benefits which may flow from its use. While its incidence is difficult to quantify, enough examples have been cited internationally and drawn to my attention in submissions and discussions for me to conclude that this is a matter which warrants a serious penalty response to create a deterrent.

Level of penalty

2.19 The EPBC Act contains both civil and criminal penalties, with the civil penalties having a lower standard of proof and higher maximum fines than the criminal offences. It also has some strict liability offences (see Division 1 of Part 13).

2.20 The civil penalties relating to listed biodiversity and protected areas range from 500 to 5,000 Penalty Units (PUs), and the criminal penalties range from 500 to 1,000 PUs, and two years' gaol. I suggest the Act include both civil and

e) Duration of the contract.

f) Monitoring and review of the contract.

g) Collector becomes owner of the samples/continuing rights of provider in relation to the samples and biological resources.

h) Exclusivity or otherwise of the Agreement.

i) Benefit sharing arrangements (Schedule), including provision to ensure at least some benefits are used for biodiversity conservation in the area from where the biological resource was obtained.

j) Any other conditions, such as requirements for applicant to provide information about developments to the resource provider.

k) Agreement regarding intellectual property rights.

l) Contract takes effect only if Minister issues an access permit.

m) Provision anticipating the possibility that further permits may be required, and consequences for the contract if refused.

n) Provision regarding effect on the contract if the permit is breached, suspended or revoked etc.

o) Successors are bound by the contract.

p) Arrangements where third parties are involved, eg where there is a series of contracts, to ensure there is no dilution of benefits, eg royalties.

q) Standard clauses, eg variations (including that the contract and any amendments be subject to the Minister's approval), waiver, severability of provisions, governing law, entire agreement, dispute resolution, termination, notices costs, goods and services tax.

r) Permit could be included as a Schedule.

Recommendations

14. That the Department of the Environment and Heritage develop a model contract to guide and assist the parties in their negotiations over possible benefit-sharing arrangements.

15. That the model contract be endorsed by stakeholders including Biotechnology Australia, the Australian Biotechnology Association, the Indigenous Advisory Committee, key land councils and peak environment organisations and subsequently submitted for endorsement by the Minister for the Environment and Heritage.

16. That the regulations and model contract be used in discussions with State and Territory Governments as the basis of a proposed nationally consistent scheme.

CHAPTER 3: BACKGROUND TO THE INQUIRY

Australia's international obligations

3.1 Australia's obligation to facilitate access to, and benefit sharing arising from the use of our biological resources, is based on our responsibilities under the Convention on Biological Diversity which include:

a) Article 1: 'The objectives of this Convention … are … the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into accounts all rights over those resources and to technologies, and by appropriate funding.'

b) Article 15(2): 'Each contracting party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties …'

c) Article 15(4): 'Access, where granted, shall be on mutually agreed terms …' and

d) Article 15(5): 'Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources …'

3.2 There is also developing international recognition of Indigenous rights in biological resources and associated traditional knowledge. Relevant sections of the Convention on Biological Diversity are as follows:

a) preambular paragraph 12: recognition of 'the close and traditional dependence of many Indigenous and local communities embodying traditional lifestyles on biological resources, and the sustainability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components.'

b) Article 8(j): to 'respect, preserve and maintain knowledge, innovations and practices of Indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and acknowledgment of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices', and

c) Article 10(c): 'Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable components.'

3.3 Among other relevant developments are the International Labour Organisation Convention No 169 (ILO 169) and the Draft Declaration on the

criminal penalties for accessing biological resources within Commonwealth areas without a permit.

2.21 To be consistent with the biodiversity provisions of the Act, the criminal penalties should probably be within the ranges indicated above (the criminal penalties mentioned above apply to various activities involving listed biodiversity unless the Minister has granted a permit for the activity).

2.22 However, I would support much higher civil penalties (eg, 50,000 PUs), given the amount of potential profit to be made from bioprospecting, and given the 50,000 PUs penalties set out in the environmental assessment provisions of the Act. This will require an amendment to the Act.

Recommendation

12. That civil and criminal penalties in the EPBC Act for unlawfully accessing biological resources be sufficient to deter such activities, having regard to the potential profits from biopiracy.

The proposed model contract

Comments about particular contractual issues

Exclusivity of agreements

2.23 With respect to the issue of 'exclusivity' of agreements, the Queensland Government commented as follows:

> 'Exclusivity' terms in agreements should be explicit as to the extent and duration of their exclusivity. In negotiating exclusivity, it would be more appropriate to offer biodiscovery agencies the exclusive utilisation of the samples collected for a stipulated period as opposed to providing exclusive access to natural resources, as has sometimes been the case. It should be explicit in any exclusivity agreement that access to particular biological resources is conditional and assigned only to the physical samples and not extending to the species or localities from which they were collected; and assigned for set periods after which time the resources become publicly accessible.

2.24 The Inquiry notes these comments, as well as the concerns of Indigenous communities that by allowing access to biological resources on their lands, they may be prevented from continuing to use the biological resources from which samples are derived. However, the Inquiry also notes that the parties to the contract are free to negotiate 'exclusivity' terms in whatever manner they wish and that a range of terms is possible. The example Queensland proposed is one possibility.

2.25 The Inquiry has decided that it is not necessary to make any recommendations on this matter as the proposed scheme requires the Minister, in deciding whether to grant or refuse a permit, to consider the fairness of 'exclusivity' clauses in the contract, among other issues, against the indicia of prior informed consent, mutually agreed terms and adequate benefit sharing.

2.26 The Inquiry does suggest, however, that terms of a more 'exclusive' nature which benefit the bioprospector should be reflected in the nature and/or amount of benefits payable to the resource provider.

Research or commercial interests

3.5 Many submissions, particularly those from research organisations, commented on the importance of access to biological resources for scientific research and of ensuring that an access system does not inhibit access for such purposes. The Inquiry considered possible implications of these concerns for the proposed system and, in particular, for the model contract. In view of the fact that in many cases research will have unforeseen commercial implications or possibilities at some point, the Inquiry decided that, as far as possible, this should be considered at the outset of contract negotiations and reflected in the contract.

Recommendation

13. That terms in the proposed model contract anticipate that most contracts will be for commercial purposes but that in some cases, terms which reflect non-commercially motivated research purposes may need to be drafted, and benefit sharing negotiated accordingly.

Possible provisions

2.28 This section lists possible provisions for the model contract to aid later discussions with stakeholders.

a) The parties – names and brief descriptions of functions and objectives. [Note: there may be cases where there are more than two parties to the contract, eg Environment Australia in relation to Norfolk Island (see discussion in Chapter 8 'Norfolk Island').]

b) Definitions of, for example:

i) sample,

ii) bioprospecting,

iii) monetary and non-monetary benefits, and

Iv) resource owner.

c) Interpretation.

d) Purpose of the contract.

Rights of Indigenous Peoples. The ILO 169 (not yet ratified by Australia) contains provisions upholding Indigenous rights to lands, environments, and the biological and genetic resources on these (Articles 7, 13(1), 13(2) and 14(3)) and the Draft Declaration includes the following articles:

a) Article 24: 'Indigenous peoples have the right to their traditional medicines and health practices, including the right to the protection of vital medicinal plants, animals and minerals …' and

b) Article 29: 'Indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property … they have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs and visual and performing arts.

3.4 The United Nations Convention on the Law of the Sea includes provisions relating to marine scientific research, including where this may have commercial implications. The relevant articles are:

a) Article 246(3): 'Coastal States shall, in normal circumstances, grant their consent for marine scientific research projects by other States or competent international organizations in their exclusive economic zone or on their continental shelf to be carried out in accordance with this Convention exclusively for peaceful purposes and in order to increase scientific knowledge of the marine environment for the benefit of all mankind. To this end, coastal States shall establish rules and procedures ensuring that such consent will not be delayed or denied unreasonably.' and

b) Article 246(5): 'Coastal States may however in their discretion withhold their consent to the conduct of a marine scientific research project of another State or competent international organization in the exclusive economic zone or on the continental shelf of the coastal State' in several circumstances, including where that project 'is of direct significance for the exploration and exploitation of natural resources, whether living or non-living'.'

Australia's domestic obligations

3.5 Australia's domestic obligations to facilitate access to and benefit sharing arising from use of our biological resources are based on:

a) our commitment to implementing the National Strategy for the Conservation of Australia's Biological Diversity, in particular:

i) Objective 1.8: 'Recognise and ensure the continuity of the contribution of the ethnobiological knowledge of Australia's Indigenous peoples to the conservation of Australia's biological diversity'; and

[1] Reports by ANZECC (March 1994), the office of the Chief of Scientisits, Department of the Prime Minister and Cabinet (March 1994) and the Commonwealth State Working group (October 1996) include detailed lists and some discussion of other relevant international agreements

ii) Objective 2.8: 'Ensure that the social and economic benefits of the use of genetic material and products derived from Australia's biological diversity accrue to Australia';[1]

b) our responsibility for promoting the objectives of the Environment Protection and Biodiversity Conservation Act 1999, in particular:

i) to promote a cooperative approach to the protection and management of the environment involving governments, the community, land-holders and Indigenous peoples (s3(1)(d));

ii) to assist in the cooperative implementation of Australia's international environmental responsibilities (s3(1)(e));

iii) to recognise the role of Indigenous people in the conservation and ecologically sustainable use of Australia's biodiversity (s3(1)(f)); and

iv) to promote the use of Indigenous peoples' knowledge of biodiversity with the involvement of, and in cooperation with, the owners of the knowledge (s3(1)(g));

c) s301 of the Environment Protection and Biodiversity Conservation Act 1999 which provides the mechanism to implement Australia's international and domestic obligations for the control of access to biological resources in Commonwealth areas; and

d) the Coalition's 1998 election commitment in Our Living Heritage to introduce regulations to regulate access to genetic resources in Commonwealth areas.

Policy developments on access and benefit sharing

3.6 Following Australia's signature of the Convention on Biological Diversity in 1992, the Australian and New Zealand Environment and Conservation Council submitted a report to First Ministers in February 1993 on the Implementation of and Implications of Ratification of the Convention on Biological Diversity. In addressing Article 15 of the Convention on Access to Genetic Resources, the report noted that: 'the control of access to genetic resources is an issue of national importance requiring urgent attention … the introduction of procedures governing access … would enable Australia to take full advantage of the opportunities provided by this article and also protect our interests. Currently, under existing legislation and guidelines it is possible to export a large range and volume of genetic resources for use in overseas research and development without appropriate returns to Australia.'

3.7 Since then there have been three national reports on access and benefit-sharing issues.

ANZECC: Access to Australia's Genetic Resource

3.8 In March 1994, ANZECC released an issues paper on Access to Australia's Genetic Resources. The ANZECC report outlined relevant international agreements, described the situation governing access arrangements internationally and domestically, identified various issues relevant to Aboriginal and Torres Strait Islander peoples, and outlined collection, intellectual property and conservation issues.

Office of the Chief Scientist: Access to Australia's Biological Resources

3.9 Also in March 1994 the Office of the Chief Scientist in the Department of the Prime Minister and Cabinet released Access to Australia's Biological Resources – a discussion paper, a paper prepared for the Coordination Committee on Science and Technology. The paper covered similar issues to the ANZECC paper, although in somewhat greater detail, and recommended that the following principles be adopted in further work on the issues:

* That Australia will control access to Indigenous biological resources in accordance with the provisions of the Convention on Biological Diversity, and
* That international access to Australian Indigenous genetic resources may be granted on the basis that the contracting parties recognise Australia's rights:
* of ownership of the genetic material collected;
* to involvement in research on biological material of Australian origin; and
* to fair and equitable returns on, and proportionate ownership, of commercial products developed fromAustralian biological resources; and
* That the Commonwealth and the State Governments reserve the right to set fees/royalties or other charges relating to the granting of access to Australia's genetic resources and to receive all data, materials and reports of research relating to the commercial potential of those resources.

3.10 In support of these principles the paper also recommended four approaches as suggested in the National Strategy for the Conservation of Australia's Biological Diversity. The approaches were:

* Controls and regulation should ensure that Australia participates in research and development, and shares in the benefits from any commercial opportunities, including the development of biotechnologies that are based on genetic resources collected from areas within Australia's jurisdiction.
* Ensure that collection of genetic resources for research and development activities does not adversely affect the conservation status of the species being collected.

* Encourage and support the establishment of screening programs within Australia to identify genetic products of social and economic benefit.

* Establish property rights that relate to the development and sale of genetic products and establish intellectual property rights derived from knowledge of genetic diversity, particularly regarding Aboriginal and Torres Strait Islander peoples.

The Commonwealth State Working Group

3.11 First Ministers established the Commonwealth State Working Group in May 1994 following advice from ANZECC. The Working Group discussion paper, Managing Access to Australia's Biological Resources — Developing a Nationally Consistent Approach, was completed in October 1996. The paper was subsequently released and submissions received in April 1998.

3.12 The principles identified by this discussion paper were that access management regimes should:

* Facilitate access to, and use of Australia's biological resources, in ecologically sustainable ways.
* Foster a balanced approach to access to biological resources which promotes the conservation of biological diversity, and which encourages the development of ecologically sustainable uses of biological resources for the benefit of Australia.
* Ensure that Australia captures appropriate economic and other benefits from access to its biological resources, and ensure the widest possible sharing of those benefits.
* Ensure the administrative and regulatory practices are transparent, consistent and minimise duplication and regulation, building wherever possible on existing regulatory mechanisms.
* Ensure continued access for Australia to biological resources in other countries for research and commercial purposes by developing an approach which Australia would be prepared to comply with if the same approach were used by other countries.
* Be based on consultation with affected communities who should be given sufficient information to make informed decisions.
* Be comprehensive, in terms of the coverage of biological resources on Australian territory and in waters under Australia's sovereignty, the types of collection activity, and whether collections are made by Australian nationals or overseas individuals/organisations.
* Take into account the interests of Aboriginal and Torres Strait Islander peoples, and communities and rural landholders/owners.
* Be consistent with:
  - Australia's responsibilities and interests in international instruments, such as the Convention on Biological Diversity, the United Nations Food and Agriculture Organization International Undertaking on Plant Genetic Resources and the United Nations Convention on the Law of the Sea;
  - The Intergovernmental Agreement on the Environment; and
  - National Competition Policy and the Trade Practices Act
* Provide for sharing of information between the Commonwealth, States and Territories on biological resources and their conservation and management.

* Provide adequate mechanisms for monitoring and enforcing the requirements of contracts and permits.

* Where possible, provide opportunities for active participation by Australians in all stages of the development of biological resources, including collection, screening, research and product development.

3.13 In particular, the Working Group paper expressed the belief that jurisdictions would need to give consideration to:

* examining the relevant legislative instruments under their control, to ensure that those instruments are adequate to manage access to all biological resources within the jurisdiction, and to ensure capture and sharing of benefits from those resources;

* determining the extent to which the multipurpose contract system can (and should) be applied in the jurisdiction; and

* where necessary, clarifying questions of title to, and ownership of, biological resources, particularly the role of the Crown in owning such resources.

3.14 The Working Group's terms of reference also included the obligation to take into account 'the interests of Aboriginal and Torres Strait Islander peoples in the use and ownership of traditional knowledge, innovations and practices and biological resources on Aboriginal lands'. The discussion paper addressed the issue briefly, concluding, however, that it was not within its terms of reference to resolve this complex matter, and suggesting that it was more appropriately dealt with in other fora, because wider policy issues concerning the treatment of Indigenous people were involved.

3.15 A working group, including Environment Australia, the Department of Agriculture, Fisheries, Forestry – Australia and representatives of State Governments, was formed to write a report to First Ministers addressing the above recommendations, based on Commonwealth and State input and the submissions to the October 1996 Commonwealth State Working Group discussion paper. This work was effectively put on hold during the Inquiry.

Commonwealth Interdepartmental Committee on Access to Australia's Biological Resources.

3.16 The working group operates in conjunction with a Commonwealth Interdepartmental Committee on Access to Australia's Biological Resources. Environment Australia and Agriculture, Fisheries, Forestry – Australia jointly chair the Committee which includes representatives from departments and agencies with a varying range of interests in the issues. Two meetings of the Committee were held during the course of the Inquiry (December 1999 and April 2000).

Relationship between the Inquiry and the Access Work Program of Biotechnology Australia

3.17 Biotechnology Australia was established to coordinate and undertake non-regulatory functions to position Australia to benefit from biotechnology. This includes measures to enhance access to genetic and biological resources.

The Inquiry is one of the major activities under Biotechnology Australia's Access Work Program and is funded through this Program.

3.18 Biotechnology Australia was established in the Industry, Science and Resources portfolio but comprises five departments: Industry, Science and Resources, Environment Australia, Agriculture, Fisheries and Forestry – Australia, Health and Aged Care and Education, Training and Youth Affairs. It is overseen by a Ministerial Council, of which the Minister for the Environment and Heritage is a member, and a Committee of departmental Secretaries.

3.19 The first Ministerial Council meeting, on 21 June 1999, endorsed the:

a) development of a National Biotechnology Strategy,

b) development of a strategy for a public awareness program,

c) implementation of a program which seeks to enhance the management of biotechnology intellectual property, and

d) proposed work program to accelerate the development and implementation of a national policy and programs on access to biological resources.

3.20 The second Ministerial Council meeting, on 11 August 1999, approved a Work Program for implementation of the access strategy, including expenditure for 1999–00 and 2000–01.

3.21 Biotechnology Australia released a Discussion Paper, Developing Australia's Biotechnology Future, in September 1999 which, among other things, invited public comment on a wide range of matters relating to development of a biotechnology strategy, including access to biological resources. The Discussion Paper also referred to the Inquiry into Access to Biological Resources.

3.22 In the May 2000 budget, the Commonwealth Government announced the allocation of an additional $30.5 million over four years to Australian biotechnology, for targeted initiatives under the Commonwealth's National Biotechnology Strategy.

3.23 The Minister for Industry, Science and Resources, Senator Nick Minchin, announced the National Biotechnology Strategy on 3 July 2000 at the Australian Biotechnology Association conference in Brisbane.

3.24 The work of the Inquiry is reflected in the Strategy as it includes, as an objective, 'The development of measures to enhance access to Australian biological resources' and includes among the strategies to meet that objective the need to:

a) address issues of access to biological resources within Commonwealth areas including through regulations under the EPBC Act;
b) address matters involving Indigenous people and their ownership of biological resources; and

c) work with the States and Territories to achieve nationally consistent regimes on access.

Relationship of Biotechnology Australia's Access Work Program to the Commonwealth State Working Group

3.25 The major outcome proposed from Biotechnology Australia's Access Work Program is a streamlined path for the biotechnology industry to access Australia's biological resources. Current access mechanisms are slow and cumbersome and hamper industry development. The establishment of a streamlined Commonwealth access regime is anticipated to act as an incentive to State and Territory participation in a nationally consistent approach to access, in accordance with the recommendations of the October 1996 Working Group report.

3.26 I have prepared this report with the Working Group recommendations in mind and made recommendations about developing a nationally consistent system.

ATSIC's Indigenous Cultural and Intellectual Property Taskforce

3.27 The Aboriginal and Torres Strait Islander Commission established this Taskforce to address the protection of Indigenous cultures, in particular through protecting Indigenous intellectual property.

3.28 The focus of the Taskforce was an ATSIC commissioned report called Our Culture, Our Future: Report on Australian Indigenous Cultural and Intellectual Property Rights which was released in September 1999. The report's major concern was Indigenous intellectual property issues relating to arts and cultural expression. However, in relation to the issue of the appropriation of Indigenous biodiversity knowledge, the report stated that:

> A major concern of Indigenous people is that their cultural knowledge of plants, animals and the environment is being used by scientists, medical researchers, nutritionists and pharmaceutical companies without any benefits flowing back to them [2].

3.29 An Interdepartmental Committee convened by the Department of Communications, Information Technology and the Arts has considered these issues further, particularly in relation to copyright, trademarks and designs. The Committee is finalising a Cabinet Submission regarding measures to enhance protection for Indigenous intellectual property relating to arts and cultural expression.

International developments

Convention on Biological Diversity — Access and Benefit Sharing

The Panel of Experts on Access and Benefit Sharing

1. The Fourth Conference of the Parties (COP4) to the Convention on Biological Diversity, held in May 1998 in Bratislava, in the Slovak Republic, addressed 'Access and Benefit sharing'.
2. As part of Decision IV/8, COP4 decided to establish a regionally balanced Panel of Experts on Access and Benefit Sharing. The Panel's mandate was to draw on all relevant sources, including legislative, policy, administrative

2.Terri Janke, 1999: p.24

measures, best practices and case studies on access to genetic and biological resources and benefit sharing arising from the use of those resources (including biotechnology) to develop a common understanding of basic concepts. In addition the Panel was to explore all options for access and benefit sharing on mutually agreed terms, including guiding principles, guidelines and codes of best practice for access and benefit-sharing arrangements.

3.32 The Convention Secretariat selected Ms Elizabeth Evans-Illidge, a research scientist at the Australian Institute of Marine Science, to attend the meeting of the Panel in Costa Rica on 4–8 October 1999. The Panel reported to COP5 in Nairobi, Kenya in May 2000.

3.33 The Costa Rica meeting brought together individuals to represent their own views and experiences rather than any particular sectoral or institutional position. While discussions were at times lively and controversial, all Panel members were committed to finding areas of consensus and common understanding as a point from which to move forward.

3.34 The Panel observed that the issues of access and benefit sharing are controversial. They involve a wide range of sectors including industry, research, Indigenous communities, non government organisations and governments. The key conclusions for COP5 consideration included the Panel's view that individual contracts were currently the main mechanism for achieving access and benefit sharing.

3.35 The Panel went on to say that, while effective legislative, administrative and policy measures set in sound national strategies were the ideal way in which parties to the Convention should implement access and benefit sharing, no country had yet achieved this (although some were in the developmental stages). Accordingly, the Panel saw the need for interim measures. To provide legal certainty and clarity, it suggested measures which included adopting voluntary guidelines and government involvement in, or endorsement of, individual contracts.

3.36 The Panel further suggested that legislation for access and benefit sharing should not be overly prescriptive, and needed to ensure low transaction costs and allow for flexibility in the negotiation of mutually-agreed terms in individual contracts. Intellectual property rights could influence implementation of access and benefit sharing arrangements, and needed to be taken into account. Prior informed consent was a core requirement, which must be based on comprehensive information about all issues, and might be required at a number of levels from governments to communities. Improved capacity is required in many countries in all aspects of access and benefit sharing.

3.37 The Panel saw a national focal point and competent authorities as essential facilitators of access and benefit sharing, and proposed to ask COP5 to encourage parties to establish such mechanisms.

3.38 The Panel saw the Costa Rica meeting as successful in tackling the ambitious mandate set by the COP. It developed a common understanding of basic concepts, begun to explore the many options for access and benefit

sharing on mutually agreed terms, and identified the key areas for further work.

3.39 The value placed on the Panel's work was reflected by the decision of COP5 to reconvene the Panel to continue its work. The Panel will report to an Ad Hoc Open-ended Working Group on Access and Benefit sharing established by the COP.

3.40 The COP5 decided to take the work forward in the following terms:

> 11. Decides to establish an Ad Hoc Open-ended Working Group, composed of representatives, including experts, nominated by Governments and regional economic integration organizations, with the mandate to develop guidelines and other approaches for submission to the Conference of the Parties and to assist Parties and stakeholders in addressing the following elements as relevant to access to genetic resources and benefit sharing, inter alia: terms for prior informed consent and mutually agreed terms; roles, responsibilities and participation of stakeholders; relevant aspects relating to in situ and ex situ conservation and sustainable use; mechanisms for benefit sharing, for example through technology transfer and joint research and development; and means to ensure the respect, preservation and maintenance of knowledge, innovations and practices of Indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity, taking into account, inter alia, work by the World Intellectual Property Organization on intellectual property rights issues.3

3.41 The Inquiry found the work of the Panel of Experts useful in its analysis of issues and identification of the complex factors affecting any access schemes.

The ad hoc Open-ended Inter sessional Working Group on the Implementation of Article 8(j)

3.42 Decision IV/9 of COP4 established the ad hoc Open-ended Intersessional Working Group on the Implementation of Article 8(j) and related provisions.

3.43 This Group's mandate includes providing advice to the COP on applying and developing legal and other appropriate forms of protection for the knowledge, innovations and practices of Indigenous and local communities; identifying objectives and activities falling within the scope of the Convention on Biological Diversity; and recommending priorities and activities on benefit sharing. This Group met in Madrid, Spain in November 1997 and in Seville, Spain, in March 2000 and reported to COP5 with a recommended program of work.

3.44 At the COP5 meeting in Nairobi, the elements of the recommended work program were refined and allocated priorities (see Appendix 8). In addition, the COP emphasised communication and cooperation with the World Trade Organization and the World Intellectual Property Organization and decided, among other things, that it would:

> 9. … extend the mandate of the Ad Hoc Open-ended Inter-Sessional Working Group on Article 8(j) and Related Provisions of the Convention on Biological Diversity to review progress in the implementation of the priority tasks of its

3. Report of the Fifth Meeting of the Conference of the Parties (COP5) to the Convention on Biological Diversity – UNEP/CBD/COP5/23:P.196.

programme of work according to reports provided by the Executive Secretary, and the Parties to the meeting of the Working Group and recommend further action on the basis of this review. The Working Group should further explore ways for increased participation by Indigenous and local communities in the thematic programmes of work of the Convention on Biological Diversity. The Working Group should report to the Conference of the Parties at its sixth meeting; …, and

14. Recognize[d] the potential importance of sui generis and other appropriate systems for the protection of traditional knowledge of Indigenous and local communities and the equitable sharing of benefits arising from its use to meet the provisions of the Convention on Biological Diversity, taking into account the ongoing work on Article 8(j) and related provisions, and transmits its findings to the World Trade Organization and the World Intellectual Property Organization, as suggested in paragraph 6 (b) of recommendation 3 of the Inter-Sessional Meeting on the Operations of the Convention (UNEP/CBD/COP/5/4, annex) …4

Participation of Indigenous people in the work of the Convention on Biological Diversity and other international environmental fora

3.45 The Parties to the Convention consider implementation of Article 8(j) and related provisions of the Convention a cross-cutting issue affecting virtually all sectoral and thematic areas and work programs dealt with under the Convention. These include:

a) forests,

b) agro-biodiversity, inland waters,

c) coastal and marine ecosystems,

d) incentive measures,

e) access and benefit sharing,

f) in situ conservation,

g) public education and awareness, and

h) environmental impact assessment.

3.46 References to Article 8(j), 'traditional knowledge, innovations and practices' and 'involvement of indigenous and local communities' occur, for example, in no less than 11 of the 19 decisions made at COP4.

3.47 In addition to the Ad Hoc Working Group on Article 8(j), the Executive Secretary of the Convention Secretariat has established a liaison group, comprised of representatives of Indigenous and local communities, to act as an informal reference group to provide advice on preparing documents for various meetings. Indigenous peoples in Australia have representation on this liaison group.

3.48 Representatives of Indigenous and local communities have had a very direct input into Convention processes and a direct bearing on the outcomes of all the decisions referred to above. In fact, the COP, in its meetings, has been very concerned to explore ways of increasing the direct and effective participation of Indigenous and local communities in the work of the Convention.

3.49.1 Indigenous peoples from Australia have generally been well-represented at meetings, and because of continuity of attendance, provide considerable leadership at the international level when dealing with issues being addressed by the COP under the Convention on Biological Diversity.

Recommendation

17. That the Department of the Environment and Heritage, as the national focal point for the Convention on Biological Diversity and other international environmental agreements, consider means of promoting the full and effective participation of Indigenous peoples in Australia in such agreements, including by disseminating to Indigenous organisations relevant information from the secretariats of these agreements.

Other international developments

National systems for access and benefit sharing

3.50 A summary of access and benefit-sharing systems in several nations is at Appendix 9. While to date, examples of other national approaches have been limited, delegates to COP5 were advised that over 50 nations are now developing legislation and other legal instruments to establish access schemes.

3.51 The Inquiry has carefully considered other nations' approaches to these issues and the decisions taken at COP5 but, in developing our recommendations, has been mindful of the need for a system which is appropriate to Australia's particular political, legal and institutional structures.

International Undertaking on Plant Genetic Resources

3.52 When the Food and Agriculture Organization Commission on Genetic Resources for Food and Agriculture adopted the International Undertaking on Plant Genetic Resources in 1983, genetic resources were regarded as the common heritage of mankind. The Convention on Biological Diversity, however, recognised national sovereignty over biological resources. Negotiations to revise the Undertaking to bring it into harmony with the Convention have been under way since 1993 in the Commission on Genetic Resources for Food and Agriculture. Australia, as both a supplier and importer of genetic resources, has significant interests in the outcomes of these negotiations. In common with other Parties to the Convention, Australia holds the view that national systems for access to biological resources should not include material covered by the Undertaking. I have taken this into account in the Inquiry and reflected this in my recommendations.

Trade-Related Aspects of Intellectual Property Rights

3.53 The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement requires, as a general rule, that patents be granted in all areas of technology without discrimination (Article 27).

3.54 Article 27.3(b) provides a limited exception to this rule: World Trade Organization (WTO) members do not have to, but may, provide protection for plant and animal inventions and for essentially biological processes for producing plants or animals. Members do have to provide patent protection for micro-organisms, and for non-biological and microbiological processes. They also have to provide some form of protection for new plant varieties — this could be patents, a sui generis system such as plant breeder's rights, or a combination of both.

3.55 The International Union for the Protection of New Varieties of Plants (UPOV) system is accepted to be one such sui generis system. It is, however, criticised in some quarters and cannot be regarded as the single or definitive means of implementing TRIPS obligations for plant variety protection.

3.56 Article 27.3(b) was a negotiating compromise, and essentially imported the text of European law existing at the time of the TRIPS negotiations. Other parties, principally the United States, considered there should be more limited exceptions to the general principal that patent protection be available in all fields of technology. This led to agreement to review the provisions of Article 27.3(b) in 1999, four years after TRIPS came into force.

3.57 That review is still taking place. There are two general approaches to the review:

a) a factual consideration of how individual Members have implemented Article 27.3(b) (a review of implementation at the national level), and

b) demands for the actual treaty text to be amended (a 'review' in the sense of rewriting the text).

3.58 The TRIPS Agreement only came fully into effect for most developing countries in January 2000 — hence the original exchange of factual information in 1999 concentrated on the approaches taken by industrialised countries (a few developing countries made voluntary contributions to the review, but most did not provide information).

3.59 The actual legal scope of Article 27.3(b) is very limited — it is a limited exception to a general rule on the scope of patentable subject matter. The review process has been seen as an opportunity to address a much broader range of concerns, covering:

a) abuse of intellectual property rights;

b) scope of allowable exceptions to intellectual property rights, such as farmers' privilege;

c) creation of a wholly distinct new form of intellectual property rights protection, for traditional knowledge as such; and

d) the role of government in protecting the environment and in controlling and regulating access to and use of biological resources.

3.60 Overlapping with this review process was the WTO Ministerial Conference at Seattle late in 1999. Preparations for Seattle saw the tabling of several substantive proposals for amending the provisions of TRIPS, which were more far-reaching than the original scope of the Article 27.3(b) review. This reflects the interests of some parties in linking biotechnology intellectual property and environmental issues with broader WTO negotiations.

3.61 The factual aspect of the Article 27.3(b) review has resulted in the tabling of information on the approach taken by some 35 WTO Member countries in relation to intellectual property protection for plant and animal inventions.

3.62 Many countries have exceptions to scope of patentability roughly corresponding to the text of Article 27.3(b) (partly because this mirrors existing European Union law), and most have plant variety rights systems corresponding to the UPOV system. Developing country members of the WTO are in the process of notifying their national intellectual property laws and undergoing separate reviews of their national legal systems for TRIPS consistency – while this process is distinct from the Article 27.3(b) review as such, it will nonetheless shed light on the approach they have taken to implementing Article 27.3(b).

3.63 It is increasingly difficult to distinguish between proposals for substantial renegotiation of TRIPS, specifically tabled under the Article 27.3(b review, and general proposals tabled in the context of an overall round of trade negotiations, such as the proposals tabled in the lead-up to the WTO Seattle Ministerial Conference.

3.64 In addition, TRIPS as a whole is due for a general review of implementation commencing in 2000. This review will see concerns raised about the linkage between TRIPS and the Convention on Biological Diversity and related issues, such as protection of traditional knowledge and access to biological resources.

3.65 Substantive proposals fall into three general categories:

a) clarifying the legal effect of the Article, (eg on the basis that a distinction based on ‘micro-organism’ may be difficult to define in national law, there is a proposal that, instead of requiring patenting of micro-organisms, TRIPS should exclude patents for any organisms;

b) defining in detail what an effective plant variety protection system is (including enshrining the ‘farmer’s privilege’ of using farm-saved seed for successive plantings regardless of the existence of plant breeder’s rights, and extending protection to traditional or Indigenous knowledge); and

c) making explicit legal linkages with obligations for protecting biodiversity, including making mandatory the disclosure of the source of genetic materials used in deriving a patented invention. One specific proposal would require acceptance of a patent application conditional on providing confirmation that any biological resources used in the invention had been obtained consistent with the Convention on Biological Diversity principle of prior informed consent,

and full disclosure of the source of any biological resources or related traditional knowledge.

3.66 In the immediate term, debate is likely to continue without a clear conclusion, although the progress towards TRIPS implementation by developing countries should provide a broader factual basis for determining the real scope and impact of the provisions of Article 27.3(b).

Recommendation

18. That the Department of the Environment and Heritage, in cooperation with other relevant Commonwealth agencies, monitor developments in other countries and in international fora to ensure the access scheme established by regulations under s301 of the EPBC Act meets Australia's international obligations.

CHAPTER 4: OWNERSHIP OF BIOLOGICAL RESOURCES IN COMMONWEALTH AREAS

Introduction

4.1 Debate about methods of regulating access to biological resources has been complicated by a lack of understanding about who owns the resources in question. The issues of ownership, sovereignty and control of biological resources were addressed in the Commonwealth State Working Group discussion paper Managing Access to Australia's Biological Resources: Developing a Nationally Consistent Approach. Many submissions to the Inquiry also raised the issue, commenting on the importance of clarifying the ownership of biological resources in Commonwealth areas.

4.2 I believe stakeholders need to understand the law regarding ownership of biological resources and have therefore included in this report excerpts from the legal advice which the Inquiry sought on the issue.5 However, I do not propose to make any recommendations which would affect the existing ownership arrangements.

4.3 The advice explains the legal status of the elements of the terrestrial and marine biota affected by differing forms land tenures and sovereignty in Commonwealth areas. The effect of the advice is that in all Commonwealth areas, it is possible to determine either a legal owner of biological resources or a holder of the sovereign authority to control access and derive benefits from the biological resources.

On the land

Commonwealth-owned land

4.4 The Commonwealth is the owner of biological resources in the land which it owns in accordance with the common law principles discussed below. The Commonwealth has not legislated to vest property in itself in the biological resources in these areas.

Commonwealth-leased land

5.34 Ownership of biological resources in land leased by the Commonwealth will be determined in accordance with the common law principles discussed below and, in relation to leased land in the States and self-governing territories, in accordance with any relevant law of the State or Territory.

5. The advice was provided by Paul Minogue, Counsel Biodiversity Group, Environment Australia in consultation with the Australian Government Solicitor.

Terrestrial plants

4.6 At common law, ownership of land includes all the substrata below the surface. Natural things attached to land (or its substrata) or growing on (or in) it, whether cultivated or not, form part of the land and will be the property of the owner of the land. It would seem to follow that biological resources generally that are attached to or growing on or in land would be regarded as the property of the landowner. The common law rule would be subject to valid legislation or to any agreement (lease, licence, contract) to the contrary into which the landowner had entered.

Terrestrial animals

4.7 The common law recognises two distinct classes of animals: domestic animals and wild animals.

4.8 At common law, there is no absolute property in wild animals while they are alive. A person may gain only a qualified property that is defeasible (ie it may be terminated or annulled). This qualified property may be gained in three circumstances:

a. *Per industriam* -- By lawfully taking, taming or reclaiming wild animals, until they regain their natural liberty and have not the 'mind to return'.

b. *Ratione impotentiae et loci* -- The owner of land has a qualified property in the young of wild animals born on the land until those animals can fly or run away.

c. *Ratione soli and ratione privilegii* -- The owner of land who has retained the exclusive right to hunt, take and kill wild animals on that land has a qualified property in those animals while they remain on that land.

4.9 In these circumstances title is retained only while the animal is in the person's keeping or actual possession. If the animal regains its natural liberty, with no 'mind to return' and not under pursuit, its former owner's property ceases and may be taken by another person.

4.10 The limited property rights in relation to wild animals would be subject to any valid legislation (eg restricting the right to possess wild animals) or any agreement under which a person may have parted with possession.

4.11 At common law, when a wild animal is killed or dies, absolute property vests in the owner or occupier of the land upon which the animal dies, or in the grantee or licensee of the shooting or sporting rights.

4.12 It would seem likely that biological resources generally that are not attached to or do not form part of land would likely be regarded in the same way as wild animals at common law.

In the waterways and the seas

Internal Waters

c. Generally speaking no-one may own (have exclusive proprietary rights in) free swimming fish and other biological resources in the water column of the sea, the foreshore, and tidal, navigable (and possibly all navigable) internal waters. On the other hand, biological resources that are attached to, or that are usually in contact with, the beds and banks of internal waters will be owned by the owner of the beds and banks (generally the Crown).

4.14 The common law has long recognised the existence of public (non-proprietary) rights to fish and navigate which exist independently of and are not subject to the existence of any proprietary rights. It has also long been recognised that these public rights exist in the area of the foreshore (ie between high and low water marks) and in respect of tidal, navigable waters which lie inland, where property has usually been held by the courts to be vested in the Crown.

4.15 The public right to fish applies without doubt to free-swimming fish and, by extension, it would seem to other biological resources in the water column. However, unlike offshore areas (where the Crown did not historically have title to the seabed), the public right to fish in internal waters does not extend to marine wildlife which normally remains in contact with the beds and banks of internal waters.

4.16 Being a public not a proprietary right, the right to fish is freely amenable to abrogation or regulation by a competent legislature.6

The Sea

2. The Commonwealth has constitutional power to enact laws in relation to the coastal sea, continental shelf and Exclusive Economic Zone on the basis of the physically external aspect of the external affairs power (s51(xxix) of the Constitution) and on the basis of other Commonwealth powers such as the fisheries power (s51(x)).7

4.18 The common law has not allowed private rights to interfere with the right of the public to freely navigate the seas below the low-water mark and to exploit its resources. Rather, the common law has consistently given priority to the greater public interest in maintaining the seas as public highways open to all and in the common sharing of its resources as against all private interests and even as against the Crown. In these waters, it has been held that the public share a right in common with the people of all nations to fish and to navigate, subject to the Parliament reserving fisheries in waters adjacent to its coast to its own nationals and otherwise subject to statutory regulation and restriction.

6. Harper v Minister for Sea Fisheries (1989) 168 CLR314 at 330 per Brennan J, with whom Dawson, Toohey an McHugh JJ expressed agreement, while Mason CJ, Deane and Gaudron JJ expressed ‘general agreement’.
7. See Endnote A at the end of this chapter.

3. Application of the public rights to fish and to navigate is not dependent upon the vesting of any proprietary rights in the Crown. They apply irrespective of whether the Crown has a proprietary interest although, where the two coincide, the public rights operate to limit the extent of the Crown's title. Accordingly, these rights have been regarded as applying in the waters below the low-water mark, in the territorial sea and generally in the high seas and irrespective of whether the Crown was regarded as having a title to those areas.

4.20 The public right to fish in the sea without doubt applies to free-swimming fish (with the exception of 'royal fish' which are part of the prerogatives of the Crown). Further, the law in Australia is that the right, at least as it applies to sea areas, includes the right to freely take shell-fish and other marine life attached to the seabed, as well as free-swimming fish.8 As noted in relation to internal waters, the public right to fish in the sea is subject to abrogation or regulation by a competent legislature.

The Coastal and the Territorial Sea

4.21 The Coastal Sea is the inner three nautical mile strip of the Territorial Sea measured from the Territorial Sea baseline. Power to legislate and title to the seabed within this area is vested in the adjacent State or Northern Territory by specific Commonwealth legislation. The Coastal Sea is excluded from the scope of Commonwealth areas for the purposes of s301 of the EPBC Act. See Chapter 8 for a more detailed discussion.

4.22 The Territorial Sea is a 12-nautical-mile-wide strip of sea offshore from the Territorial Sea baseline. Section 6 of the Seas and Submerged Lands Act 1973 ('SSL Act') declares that 'sovereignty' in respect of the Territorial Sea, the airspace over it and its bed and subsoil is vested in and exercisable by the Crown in the right of the Commonwealth. This reflects the position under Article 2 of the United Nations Convention on the Law of the Sea. Sovereignty signifies independence. That is, a right to exercise in that area, to the exclusion of any other State, the functions of a State. However the proclamation of a territorial sea and the acquisition of sovereignty over that zone, did not of itself result in the Commonwealth acquiring proprietary rights. In particular, the Commonwealth did not declare in the 1990 proclamation of the territorial sea, nor has it done so subsequently, that it claimed proprietary rights to the resources located within the waters and seabed of the Territorial Sea. Consequently, the Crown has no proprietary rights over the biological resources of the waters and seabed until, by legislative or executive act, ownership of property is vested in the Crown.

8. Harper v minister for Sea Fisheries, per Brennan J, with whom the remainder of the High Court agreed

4.23 Accordingly (subject to the operation of s246 of the EPBC Act) no-one presently owns the biological resources of the Territorial Sea, and the public right to fish (including the right to take shell-fish and other marine life attached to the seabed) applies, in the Territorial Sea, subject to competent legislation.

Continental shelf

4.24 The United Nations Convention on the Law of the Sea provides that the coastal State exercises, over the continental shelf, sovereign rights for the purpose of exploring it and exploiting its natural resources. It also provides that these rights are exclusive in the sense that, if the coastal State does not explore the continental shelf or exploit its natural resources, no one may undertake these activities without the express consent of the coastal State. The 'natural resources' consist of the mineral and other non-living resources of the seabed and subsoil together with living organisms belonging to sedentary species (ie organisms which, at the harvestable stage, either are immobile on or under the seabed or are unable to move except in constant physical contact with the seabed or the subsoil).

4.25 Under s11 of the SSL Act it is declared 'that the sovereign rights of Australia as a coastal State in respect of the continental shelf of Australia, for the purpose of exploring and exploiting its natural resources, are vested in and exercisable by the Crown in the right of the Commonwealth'. This section does not however purport to vest ownership of the resources in the Commonwealth but it is intended to indicate both to the international community and the Australian States and Territories that the control over exploration and exploitation of the natural resources of the continental shelf lies with the Commonwealth.

Exclusive economic zone

b. The United Nations Convention on the Law of the Sea provides that, in the exclusive economic zone, the coastal State has sovereign rights for exploring and exploiting, conserving and managing the natural resources, whether living or non-living, of the water column, and seabed with regard to other activities for the economic exploitation and exploration of the zone, such as production of energy from the water, currents and winds. Unlike the continental shelf, these rights are not expressed to be 'exclusive', in the sense that they do not arise until a coastal State asserts its rights over the resources. Also unlike the continental shelf, the Convention does not define what the 'natural resources' are for the purposes of the exclusive economic zone. Presumably, however, biological resources, as defined in the EPBC Act, would be natural resources for the purposes of the Convention.

4.27 Australia has asserted its sovereign rights in the exclusive economic zone. Section 10A of the SSL Act declares and enacts that the rights and jurisdiction of Australia in its declared exclusive economic zone are vested in and exercisable by the Crown in right of the Commonwealth. As with the continental shelf, this section does not, however purport to vest ownership of the resources on the seabed or in the water column of the exclusive economic zone in the Commonwealth.

Australia's sovereign rights in the continental shelf and the exclusive economic zone

c. The 'sovereign rights' which Australia has in relation to the continental shelf and the exclusive economic zone are specific rights accorded to the coastal State under international law and are to be distinguished from the more comprehensive rights inherent in the concept of 'sovereignty' discussed above in relation to the territorial sea of Australia. Therefore any legislation, be it State or Commonwealth, which purported to grant title to areas of the sea or of the seabed beyond 12 nautical miles would be inconsistent with international law.

4.29 The nature of Australia's sovereign rights is not entirely clear as a matter of international law. However, the view on which the Commonwealth has acted is that they are not proprietary rights. Therefore, in the absence of legislation, the Commonwealth does not have a proprietary right in the fish and other marine living resources that occupy the exclusive economic zone or the sedentary species that occupy the continental shelf, nor does any other person. The Commonwealth could, through legislation, declare its ownership of those resources but has not done so. In considering any legislation, account would have to be taken of Australia's rights and entitlements under the United Nations Convention on the Law of the Sea, and the rights of other States to have access to certain biological resources. It is considered doubtful whether a claim of ownership would be consistent with the position under the Convention, particularly were a claim to ownership to prejudice the position of other States in relation to exploitation of biological resources. Until the present time, however, the Commonwealth has not found it necessary to claim ownership of biological resources in any of the marine areas under its jurisdiction and control.

Impact on ownership of the EPBC Act or regulations under s301 of the Act

4.30 The ownership of biological resources will not be affected by the EPBC Act (other than by s246 in relation to cetaceans). The exercise of rights by the owner of biological resources may however be subject to particular provisions of the Act. For example, in so far as biological resources are members of a listed species under Part 13 of the Act, the taking etc in a Commonwealth area is subject to Part 13. Listed threatened and migratory species are also matters of national environmental significance, and action that has, will have or is likely to have a significant impact on a matter of national environmental significance are referred to as 'controlled actions' and prohibited, unless certain

conditions relating to approval are met.

4.31 Where biological resources are in a Commonwealth reserve that is not Commonwealth owned land, such as at Uluru-Kata Tjuta and Booderee National Parks and parts of Kakadu National Park, the rights of the land owner as owner of biological resources may be regulated by the EPBC Act or regulations made under the Act in relation to Commonwealth reserves. For example s354(1)(a) of the Act requires that a member of a native species be taken etc in accordance with a management plan for the reserve, although the Act would not affect the exercise of 'traditional' rights to use Aboriginal land in accordance with the Aboriginal Land Rights (Northern Territory) Act 1976 (s71) or native title rights in accordance with the Native Title Act 1993. Subsection 8(2) of the EPBC Act provides that the operation of those Acts is not affected by the EPBC Act.9

Rights to control access to biological resource in Commonwealth areas (other than marine areas)

4.32 People with an interest in land which gave them a right of exclusive possession may exclude other people from that land, and thereby prevent them accessing biological resources on that land. For example, if the Commonwealth has a right of exclusive possession in relation to land (whether because it is the owner of the land, or a lessee) it would have the right, subject to any applicable law abrogating that right, to exclude or control access by others to the land, and thus control access to biological resources on the land.

Commonwealth powers to control access to biological resources in Commonwealth areas other than marine areas

4.33 However, within the limits of their respective constitutional powers, the States and the Commonwealth would have power to enact laws permitting people to enter onto land for the purpose of accessing biological resources on that land.

a. The Commonwealth has exclusive power, under s52(i) of the Constitution, to make laws with respect to places acquired by the Commonwealth for public purposes (ie purposes for which the Commonwealth has power to legislate). This power would permit it to regulate access to biological resources in relation to those 'Commonwealth areas' which are 'Commonwealth places' for the purposes of s52(i).

b. It also has power, under s122 of the Constitution, to make laws for the government of any territory surrendered by any State, or of any territory placed by the Queen under the authority of and accepted by the Commonwealth, or otherwise acquired by the Commonwealth. This power would permit it to make laws regulating access to biological resources in any Territory.

9. If the operation of the EPBC Act or regulations under the Act would result in an acquisition of property from the owner of biological resources, that would otherwise be invalid because of paragraph 51(xxxi) of the Constitution, s519(1) of the Act provides that the Commonwealth must pay the person a reasonable amount of compensation.

4.36 Section 301 itself is a law controlling access to biological resources in 'Commonwealth areas'. The definition of 'Commonwealth areas' appears to be based on the Commonwealth's constitutional powers discussed above, as well as the external affairs power.10

Ownership of ex situ collections

4.37 It is not possible to make any definitive, general statement as to the ownership of all ex situ collections of biological resources. Each collection would have to be considered on its own merits having regard to a range of factors, including the ownership, if any, of the material when it was in situ and the circumstances under which the material passed into the possession of the ex situ holder, including the terms and conditions of any relevant agreement, or any relevant legislation. I have considered this issue and have made recommendations suggesting a way forward at Chapter 8.

Ownership of intellectual property rights

4.38 Prima facie, the intellectual property rights in any processes or products (ie patent rights) derived from or developed from ex situ collections of biological resources held by Commonwealth agencies will belong to the person responsible for developing those processes or products (the inventor).11 This is regardless of the ownership of any resources from which those processes or products are derived, or where those resources may be held.

4.39 However, it would be open to a Commonwealth agency to permit access only on the condition that intellectual property rights in any products derived from these resources are vested in a certain way, eg jointly in the inventor, the Commonwealth and a representative of the traditional owners.

Conclusion

4.40 From the advice above it is clear that where an authority is able to control access to areas containing biological resources and to control activities within those areas, it is able to derive the same benefits and exercise the same control as if it owned the resources in the conventional sense. This clarification has informed the Inquiry's considerations in developing a flexible and practical scheme which contributes to development of a nationally consistent approach.

10 See Endnote B at the end of this Chapter
11 Patents Act 1990 (Cth), s15 (1)(a).

Endnotes

A. The States and the Northern Territory would also have power to enact laws in relation to biological resources in this area:
Paragraph 5(c) of the Coastal Waters (State Powers) Act 1980 and Coastal Waters (Northern Territory Powers) Act 1980 provide that the legislative powers under the constitution of each State and the Northern Territory (Self-Government) Act 1976 extend to the making of laws with respect to fisheries in Australian waters beyond the outer limits of the coastal waters of the States and the Northern Territory. The laws must be laws applying to or in relation to those fisheries only to the extent to which those fisheries are to be managed in accordance with the laws of the relevant State or the Northern Territory, under an arrangement to which the Commonwealth and the State or the Northern Territory are parties.

More generally, each State and the Northern Territory has a general extra-territorial competence to legislate for the peace, order and good government of the State or the Northern Territory provided there is a sufficient connection between the enacting State or the Northern Territory and the extra-territorial persons, things and events on which a law operates. The test of a relevant connection is liberal '... any real connection -- even a remote or general connection -- between the subject matter of the legislation and the State' (Pearce v Florenca (1976) 135 CLR 507 at 518 per Gibbs J). Note that this general legislative competence is not affected by the Coastal Waters (State Powers) Act 1980 and Coastal Waters (Northern Territory Powers) Act 1980. Paragraph 7(b) of each Act provides that nothing in the Act should be taken to exclude any other powers which States or Northern Territory might have apart from the Act to make laws having extra-territorial effect.

Any inconsistency between legislation of the Commonwealth and legislation of a State or the Northern Territory would, as noted earlier, be resolved in favour of the Commonwealth legislation.

B. The States and self-governing Territories are able to enact laws that will apply to Commonwealth land. In the States, if Commonwealth land is not a 'Commonwealth place' for the purposes of s52(i) of the Constitution, a State law will apply of its own accord, subject to inconsistency with a Commonwealth law (in which case, s109 of the Constitution provides that when a State law is inconsistent with a Commonwealth law, the latter prevails, and the former is, to the extent of the inconsistency, invalid, ie inoperative), or if it is prevented from applying by virtue of any implied Commonwealth immunity. If Commonwealth land is a Commonwealth place for the purposes of s52(i) of the Constitution then a State law will apply to the extent permitted by s4 of the Commonwealth Places (Application of Laws) Act 1970. This section operates to apply the provisions of State law as Commonwealth law in and in relation to Commonwealth places, except to the extent that the State law would have been invalid or inoperative for a reason other than s52(i) of

CHAPTER 5: ENVIRONMENT ISSUES AND PERSPECTIVES

Inquiry terms of reference

5.1 The Inquiry's terms of reference require the scheme under s301 of the Environmental Protection and Biodiversity Conservation Act 1999 to take into account:

1. Australia's obligations under the Convention on Biological Diversity, including the obligation to encourage the equitable sharing of the benefits arising from the use of biological resources. The scheme should particularly focus on the equitable sharing of benefits arising from the use of traditional knowledge, innovations and practices (Article 8(j)); and

2. the objectives of the National Strategy for the Conservation of Australia's Biodiversity such as:
   - ensuring that the collection of biological resources for research and development purposes does not adversely affect the viability or conservation status of any species or population; and
   - ensuring that the social and economic benefits of the use of biological resources derived from Australia's biological diversity accrue to Australia.

Consultations with environmental interests

5.2 In considering this aspect of the Inquiry's terms of reference, the Inquiry was assisted by its expert reference group member, Ms Katherine Wells, an environmental lawyer, formerly of the Environment Defenders' Office, Sydney.

5.3 The Inquiry also made particular efforts to ensure environmental organisations had an opportunity to contribute. I wrote to key environmental organisations and the Inquiry Secretariat sent notices to about 50 organisations with responsibility for, or an interest in, environmental issues, drawing on a comprehensive mailing list provided by Environment Australia and from other sources. About 15 submissions focused on environmental issues, although environment issues were raised in most submissions. The Australian Conservation Foundation and the Environmental Defenders Office Network also made oral presentations via telephone hook-up at the Canberra hearing in which they expanded on their submissions.

Issues not covered by the Inquiry

5.4 Several submissions expressed concern about wildlife (particularly kangaroo) harvesting. However, wildlife harvesting is outside the terms of reference of the Inquiry and, accordingly, the Inquiry has not addressed this issue. I would also observe that wildlife harvesting is more appropriately dealt with (and, indeed, has been dealt with) in other forums.

5.5 Another issue raised in several submissions was that Australia's patent laws should not allow patenting of living organisms, whether modified or not. Again, this issue is outside the terms of reference of the Inquiry and, accordingly, the Inquiry has not addressed it.

Environmental issues raised in submissions

5.6 The major issue raised in the submissions which focused on environmental issues was the need for environmental assessment of bioprospecting and when and how this should be carried out.

5.7 However, the Australian Conservation Foundation and the Environmental Defenders Office Network (particularly through their presentations at the hearings) also made valuable contributions to the Inquiry's consideration of a possible scheme for implementation under s301 of the EPBC Act.

5.8 In its submission, the Australian Conservation Foundation suggested the following (not exclusive) principles for a scheme of control of access to biological resources.12 In the Foundation's view, the scheme should:

a. be consistent with the principles of ecologically sustainable development, as defined in the EPBC Act;

b. be consistent with Australia's obligations under relevant international instruments;

c. be consistent with and enhance existing Commonwealth, State and Territory environment protection legislation;

d. ensure that, if access is granted, access is permitted in ways that avoid environmental impacts and promote the conservation of biological diversity;

e. ensure that a thorough assessment of the environmental impacts of access takes place;

The principles have been summarised slightly.[12]

12. The Principles have been summarised slightly

f. ensure that benefits arising from a grant of access flow to the environment and other appropriate Australian recipients from all stages of the development of biological resources, including collection of samples, screening research and product development, even where third parties become involved;

g. provide for sharing of information between the Commonwealth, States and Territories on biological resources and their conservation and management;

h. ensure comprehensive consultation with the resource owner in order to seek the owner's prior informed consent before access is granted;

i. provide for adequate monitoring, evaluating and enforcing compliance with conditions of access and periodic review;

j. establish an independent regulator to administer the scheme

k. precisely define conditions of access; and

l. ensure the rights and interests, knowledge, innovations and practices of Indigenous peoples are adequately protected.

5.9 The Environmental Defenders Office Network submission supported similar principles, particularly concerning the need for environmental assessment. The Inquiry broadly supports these principles. The proposed access scheme is designed to reflect these principles, as well as ensure that the decision-making process is equitable, transparent and accountable.

Environmental impact assessment

5.10 Many submissions commented on the importance of ensuring that bioprospecting is conducted in an environmentally sensitive manner, but the article by Professor David Farrier and Linda Tucker, Centre for Natural Resources Law and Policy, Faculty of Law, Wollongong University was one of few to present evidence about the possible adverse environmental impacts of bioprospecting. Farrier and Tucker observed that:

> While the initial screening of biological material collected by bioprospectors may not involve significant amounts of biological material, larger quantities of samples which show useful biological activity must then be collected for detailed chemical and biological investigation. If large amounts of an organism have to be collected to isolate a particular chemical, or to determine its structure, this may undermine the claim to sustainable use.

5.11 The submission referred to an article by Mary Garson 13 which argues that the Convention on Biological Diversity 'has played a role in encouraging a more environmentally sensitive approach'. According to Garson,

> research groups and non-governmental organisations have now compiled guidelines for collection and these typically include a requirement to collect no more than is strictly necessary. Developments in bioprospecting practices and technology -- particularly increased sensitivity to the bioassays that test for bioactivity of compounds -- have led to continuing reductions in the impact of prospecting and harvesting.

13. Garson M, 1996 and 1997.

5.12 Farrier and Tucker commented, however, that,

> obtaining enough material is only the first stage of the process. Even if the initial prospecting is low impact, the nexus with sustainable use will be broken if subsequent product development demands quantities of material which can only be obtained by mining the resource.

5.13 In this context, they further commented that, 'replication in the laboratory of the biological material required for product development is legitimate, and entirely desirable where the alternative is unsustainable mining of wild strands'. Farrier and Tucker referred to the argument of one author that the focus should be on carrying out syntheses of bioactive chemicals isolated from nature or using them as lead compounds to trigger the design and synthesis of analogues.[14] However, some novel chemicals may be either too structurally complex or too expensive to produce synthetically, and in these circumstances management of wild strands or farming of the resource are the only alternatives.[15]

5.14 At the Canberra hearing, the Australian Conservation Foundation's legal adviser, Michael Kerr, also made useful comments about environmental impact assessment:

> ... it is critical that a thorough assessment of the environmental impacts of the granting of access takes place. Given that it is the intention of the Commonwealth to establish this scheme within the Environment Protection and Biodiversity Conservation Act, which is the Commonwealth's newest and most central piece of environmental protection legislation, it would be ludicrous to argue that environmental assessment is not relevant. In any event, it is my understanding of the Act that environmental impact assessment will be required under the Act's existing trigger mechanisms ... the trigger mechanisms that I am referring to are at s23 and s26 of the EPBC Act ...
> Section 23 requires an environmental assessment of an action in a Commonwealth marine area that has, will have, or is likely to have, a significant impact on the environment. Now, s26 is similar to that trigger mechanism but applies to Commonwealth land, and ... require[s] an environmental assessment.
>
> So, for example, if a proponent or a bioprospector requests access to biological resources in a Commonwealth area and that access will have or is likely to have a significant impact on the environment, an environmental assessment must take place in any event under the existing triggers of the EPBC Act ... the threshold question that then arises is, 'when might access to biological resources be deemed to have a significant impact on the environment?', because that wording, 'significant impact', is a threshold question for all triggers. Now, it is our recommendation to this Inquiry that two things might be done to assist the appropriate authority in the task of determining what might be a significant impact.
>
> Firstly, the regulations enacted under s301 which are the subject of this Inquiry could give guidance as to when access is likely to have a significant

14. Farnsworth, NF 1994
15. King SR and Tempsta MS 1994.

> impact or, secondly, there are some guidelines for determining significance under the Act which are currently being drafted by the Government. And these guidelines could have specific reference to situations when access is likely to have a significant impact. In any event, it is our own view that anything above the initial collection of a biological resource for scientific analysis would have a significant impact on the environment and would require an environmental assessment to take place under the provisions of the EPBC Act.

5.15 Don Anton of the Environmental Defenders Office Network made similar comments at the Canberra hearing:

> There are various gradations of assessment in the EPBC Act, but I would tend to echo what [the Australian Conservation Foundation] indicated, most of these would require an assessment simply so we would know, if nothing else, whether the use, the access to ... particular biological resource, will be environmentally sound.

5.16 The Queensland Government said that most primary biodiscovery collections involve relatively small samples sizes of less than 100 grams per species and, provided the target species are readily available with a sustainable population in the target area, are not considered threatened or endangered, and proper collection methods are used, the environmental impact may be minimal. Secondary collections of a specific species, conducted after a lead has been identified, may first require an environmental impact and species distribution analysis to determine the viability and ecological sustainability of the proposed second or any subsequent collection.

5.17 The Australian Institute of Marine Science suggested that all access must be undertaken on a sustainable basis:

a. for primary collections, it is desirable to set out allowable collection methods and procedures that will ensure minimal environmental impact and avoidance of rare species (the Institute has set out collection protocols for this purpose);

b. for medium-scale secondary collection, the Institute would support the requirement for a separate permit as the re-collection would be targeted on a particular organism, species-specific environmental impact scrutiny becomes an option; and

c. requests for large-scale collections should be subject to full-scale environmental impact assessment and mandatory concurrent investigation of alternatives (eg synthesis, culture) for long-term large-scale supply.

5.18 The Institute added that, 'In order to secure a level of confidence and certainty to attract industrial research support, generic conditions of secondary access should be set out at the time of permission for primary collection'.

5.19 Some submissions referred to the possibility of developing guidelines or collecting protocols for bioprospecting. Professor Helene Marsh, Professor of Environmental Science, James Cook University, and Chair, National Committee for the Environment, drew the Inquiry's attention to the report of a 1998 study by the Australian Science, Technology and Engineering Council entitled Environmental Research Ethics: National Principles and Guidelines for the Ethical Conduct of Research in Protected and Environmentally Sensitive Areas.

5.20 Dr Jane Fromont, Curator of Marine Invertebrates, Department of Aquatic Zoology, Western Australian Museum, referred specifically to the paucity of information on marine invertebrate fauna, especially in the waters off Western Australia, as an argument for the importance of 'any collection for use as a resource [being] undertaken with precautionary concepts as fundamental to the project'.

5.21 Don Anton of the Environmental Defenders Office Network also specifically referred to the precautionary principle:

> ... in deciding whether or not to grant a permit or to enter into a contract, it is important that the precautionary principle which applies under s391 of the EPBC Act in decision-making by the Minister also apply in relation to decision-making with respect to determinations about whether a permit should issue and whether or not a contract should be entered into.

Conclusions

5.22 In general, scientific analysis of an organism's genetic and biochemical make-up requires only a small amount of material, such as bark, flowers, leaves or seed, usually about 100 grams or less. A simple re-collection to confirm earlier findings and the continued availability and identity of the specimen initially collected should require no greater amount than the original collection.

5.23 This may lead policymakers to conclude that there are unlikely to be significant environmental impacts. However, there are three problems to consider,

a. the collection method;

b. the nature of the material to be collected; and

c. the nexus between biodiversity and product development.

5.24 The collection method may have adverse consequences, for example, the use of vehicles, the location of campsites, the number of people, or the nature of disturbance to the location may damage particularly sensitive areas. Lack of knowledge about the ecosystem may result in unintended losses of biodiversity. At the same time, the nature of the species and the ecosystem in which it is to be collected needs to be considered. For example, 100 grams of some species may constitute an unacceptably high and damaging number of individuals, whereas 100 grams of a large common species will be inconsequential. Collection methods may result in the inadvertent collection of rare or endangered species or put them at risk.

5.25 In the light of these considerations, the Inquiry considers that environmental assessment of bioprospecting proposals may be required in some situations.

5.26 Environmental assessment would be done under existing triggers in the Act. These are

a. s12 World Heritage properties,

b. s16 Ramsar Wetlands,

c. s18 Listed threatened species and communities,

d. s20 Listed migratory species,

e. s23 Commonwealth marine areas, and

f. s26 Commonwealth land.

5.27 The Minister has approved 'Administrative guidelines for determining whether an action has, will have, or is likely to have a significant impact on a matter of national environmental significance under the EPBC Act' (ss12, 16, 18, 20 and 23 above).

5.28 The Inquiry considers that these guidelines will need to be amended to indicate that, in some circumstances, bioprospecting may have a significant impact on the environment and would therefore require environmental assessment and approval before an access permit could be approved.

5.29 The revised guidelines should take into account that:

a. bioprospecting collecting in Commonwealth marine and land areas may have significant impact on the environment;

b. in general, the initial collection stage (collection of small quantities of a wide diversity of organisms for primary screening) is not likely to have a significant impact; but

c. subsequent re-collection stages (collection of larger quantities of targeted species) may have a significant impact.

5.30 Bioprospecting collecting, at any stage, is likely to have a significant impact if:

a. the proposed methods of collection are likely to cause a significant impact;

b. features of the proposed collection location make it particularly vulnerable to significant damage;

c. the population size and nature of species to be collected is not likely to sustain the proposed collection quantities (for example, 100 grams of bark from a common and abundant tree may cause incidental damage, whereas the same weight of a small marine worm may cause a long-term local depletion of that species); or

d. it is likely to involve collection of a species or community listed under Chapter 5 of the Act, or likely to adversely impact upon an important or substantial area of habitat of a species or community listed under Chapter 5 of the Act.

5.31 When drafting the revised guidelines, as well as considering the criteria for significance described above, consideration should be given to the work of the Australian Institute of Marine Science and the Great Barrier Reef Marine Park Authority in developing a tiered approach to collecting samples for biodiscovery programs. The Authority's submission to the Inquiry noted:

> The Authority is aware of concerns regarding certainty of access to biological resources within the Marine Park. However, the sustainability of an activity is a fundamental criteria in the assessment of its acceptability. Frequently, there is a very low level of knowledge about the biology and ecology of many of the organisms targeted in collections. This makes it difficult to assess the impacts of a collection regime on the viability or conservation status of many species or populations.
>
> Recognising that the risk of environmental impacts increases with the intensity and scale of collecting, the Authority is currently formulating a tiered approach aimed at facilitating reasonable access to biological material for biodiscovery programs while ensuring that activities do not compromise the sustainability of resources.

5.32 There is some synergy in the tiers proposed by both the Authority and the Institute. In summary, they are:

a. Tier 1: The primary or initial collection, where a minimal quantity is collected of each of a wide range of species. Often, species-specific assessment of the collection proposal is not practicable because the species content of the collection will not be known, and poorly understood locations and taxa may be involved. In such cases, assessment should focus on the allowable collection methods and procedures and guidelines for minimum quantities. The methods and procedures should include steps to avoid collecting species likely to be harmed by the proposed activity (eg numerically rare species).

b. Tier 2: A medium scale secondary re-collection to provide enough material to progress a lead (eg to determine chemical structure). Because the re-collection is targeted at particular species, species-specific environmental assessment of the proposal is an option. If existing knowledge is adequate, the re-collection may be satisfactorily assessed through compilation of known data on abundance, resilience and population dynamics of the target organisms.

c. Tier 3: Large scale re-collection to provide material for pre-production assessment of a lead. This should require full environmental assessment to ensure sustainability of the resource.

5.33 The Inquiry considered that this tiered approach provides useful insights into the levels of environmental assessment appropriate at different stages of the bioprospecting collection process. It also considered that to eliminate

undesirable delays in the research and development process, it may be possible, in some circumstances, to avoid a permit assessment process before activating a tier 2 collection.

5.34 To achieve this, the Inquiry considered that it may be possible to include both tier 1 and tier 2 activities within the initial bioprospecting collecting permit, provided the tier 2 collection is restricted to an additional quantity of the same as that allowed in tier 1, and strict permit conditions are imposed under which the applicant may proceed with the tier 2 re-collection.

5.35 The success of such an approach would rely, amongst other things, on the adequacy of information provided in the permit application.

5.36 Revising the guidelines will close a significant gap as far as the environmental regulation of access to biological resources is concerned. Subsequent publication of the revised guidelines will also provide certainty for the owners of biological resources and for industry.

5.37 The Inquiry considers that the States should take into account the criteria for significance and the tiered approach outlined above when developing their positions on this topic. This would help develop a more consistent national approach, as recommended by many submissions.

5.38 Decisions about whether environmental assessment is needed and, if so, what level of assessment (s87 of the Act), will need to be made on a case-by-case basis, with the bioprospecting proposal being assessed against the revised guidelines.

5.39 It should be noted that a lengthy environmental assessment process would not necessarily be required even if the Minister considered a proposal to have a significant environmental impact. Once an action is referred to the Minister under the Act, the Minister has the following environmental assessment choices:

a. an assessment on preliminary documentation;

b. a public environmental report;

c. an environmental impact assessment; or

d. a public inquiry.

5.40 The Inquiry anticipates that assessment on preliminary documentation may often provide a satisfactory means of assessing the environmental significance of the proposed bioprospecting.16

5.41 The Inquiry also notes the proposal in the Australian Institute of Marine Science submission, that collecting activities in tiers 1 and 2, in the model outlined above, be accompanied by the cost-effective collection of appropriate distribution and abundance data to anticipate and support informed assessment of proposals of tier 2 and 3 activities respectively.

16. The Minister can also choose to make a ministrial declaration allowing another Commonwealth body (such as a government department or statutory authority) to carry out the environmental assessment if satisfied about the process to be followed by that body.

5.42 In addition to the environmental assessment requirements discussed above, the access permit system will provide an important source of environmental control, in particular through application of environmental permit conditions. To this end, the regulations will require certain environmental permit conditions to be mandatory, including conditions that the bioprospector comply with collection protocols attached to the permit.

5.43 The access permit system will also include the following safeguards. When considering whether or not to issue a permit, the Minister will be required to consider the precautionary principle. He or she will also be required to be satisfied that the collection protocols attached to the permit provide adequate levels of environmental protection. In addition, it will be an offence, with significant penalties, to fail to obtain a permit when one is necessary, or to contravene permit conditions.

c. The permit system is discussed in more detail in Chapter 2.

Recommendation

19. That the possibility that bioprospecting may be a matter of significance under s23 and s26 of the EPBC Act be considered in assessing permit applications for access to biodiversity on Commonwealth land or in Commonwealth marine areas.

20. That the Administrative guidelines for determining whether an action has, will have, or is likely to have a significant impact on a matter of national environmental significance under the Environment Protection and Biodiversity Conservation Act 1999 (the Administrative Guidelines) be amended to include guidelines to determine whether an action has, or will have a significant environmental impact, on Commonwealth lands.

21. That the Administrative Guidelines be amended to indicate that bioprospecting may be a matter of significance under the Act and to indicate when this is likely to be the case in relation to collection and re-collection.

22. That, in drafting these criteria, the Department of the Environment and Heritage take into account the criteria for significance and the tiered approach described.

23. That State governments take the criteria for significance and the tiered approach into account as part of developing a nationally consistent approach across all jurisdictions.

24. That in deciding whether or not to issue an access permit, the Minister for the Environment and Heritage consider the precautionary principle (this will require an amendment to s391 of the EPBC Act).

25. That, as far as possible, protocols for collecting biological resources be developed and published and that, in developing protocols, guidance be

sought from protocols used by, for example, the Australian Institute of Marine Science, the Great Barrier Reef Marine Park Authority and other relevant institutions.

26. That the adoption of the appropriate collection protocols be a mandatory condition for each permit, whether or not environmental assessment has been required.

Other issues raised in environment submissions

Benefits to the environment

5.45 Some submissions commented on the need for further taxonomic work in Australia. For example, the Tasmanian Conservation Trust recommended that inventory and taxonomic work be given a high priority while the Australian Research Council commented on the need for an increased rate of species identification and description, a need that could be met by increased funding to agencies engaged in taxonomic work.

5.46 The Queensland Government said that bioprospecting has significantly enhanced the discovery and documentation of Australia's biodiversity -- for some phyla most of our knowledge has been gained from biodiscovery -- yet this outcome has not always been a mandatory permitting requirement.

5.47 To maximise potential scientific outcomes, Queensland recommended there be a strict requirement that representative samples of all taxa obtained from biodiscovery are lodged with an appropriate State or Commonwealth CITES-accredited museum, together with appropriate collection data and any other information that may contribute to furthering the scientific knowledge of Australian biodiversity. Lodged specimens must be of sufficient quality for this purpose. A good quality example of a specimen is one that includes taxonomically representative issues that have been fixed and preserved or otherwise treated by a method appropriate to the taxonomic grouping.

5.48 Ideally, there should also be further 'encouragement' for bioindustries to perform some level of taxonomic sorting of these collections, to make them more relevant and accessible to the scientific community.

5.49 The Australian Conservation Foundation also addressed ways in which benefits to the environment could flow from an access regime under s301 of the EPBC Act:

> ... any access scheme should ensure that the benefits arising from a grant of access flow to the environment ... this could be achieved by making it a condition of access that, for instance, an identified level of information about the process of modifying or using the resource is provided to the authorising body for use in a public database.

5.50 Some submissions raised the possibility of establishing national approaches to biodiversity conservation arising from access and benefit-sharing agreements.

For example, the Australian Conservation Foundation suggested at the hearings that 'perhaps an identified percentage of the monetary benefits gained from the access [could be] placed into an environmental fund, managed by independent trustees, for conservation purposes'.

5.51 The Inquiry discussed this idea at some length but considered that, at this point,

a. given the difficulty of predicting the nature and quantum of benefits under future access and benefit-sharing contracts, and

b. that potential providers of biological resources had not been consulted on such a proposal (which could affect their benefits),

5.52 a preferable approach was to attempt to ensure that at least some benefits under the contract were used to promote biodiversity in the area covered by the contract.

5.53 The Inquiry considered that potential providers of biological resources would be more sympathetic to such an approach because it would ensure that all benefits under the contract would flow to them, even if indirectly in some cases. Accordingly, I have simply recommended that the Minister consider the proposal to establish a national environment fund.

Recommendation

27. That regulations under s301 and the model contract include a requirement that at least some benefits (whether of a non-monetary or monetary nature) under the contract should promote biodiversity conservation in the area covered by the contract.

28. That the Minister for the Environment and Heritage consider whether the regulations should require that a percentage of any monetary benefits (such as royalties) under the contract be allocated to a fund for environmental purposes (for example, to fund conservation projects around Australia).

29. That regulations under s301 require the parties to the contract (in practice, this would usually be the collecting body) to lodge voucher specimens and information about the collection with a CITES-approved authority in Australia which has facilities for preservation (and further dissemination, when appropriate) of this material.

Proposed scheme

c. The Australian Conservation Foundation and the Australian Institute of Marine Science [17] were among the few organisations which specifically

17. The Australian Institute of Marine Science's proposal is outlined in Chapter 6.

considered how a scheme under s301 of the EPBC Act could operate. In particular, the Australian Conservation Foundation explained, at the hearing, how it saw the requirement for environmental assessment relating to the subsequent benefit-sharing contract between the parties:

> ... we do see a benefit in maintaining some aspects of a contractual approach ... we advocate ... a dual approach combining both ... a permit system and the contractual system. For instance, we recommend that a permit ... should be required at the initial access stage ... a bioprospector must obtain an access permit from the appropriate authority before access is permitted in the first instance.
>
> ... the permit for access would only be granted after an appropriate level of environmental assessment takes place under the provisions of the EPBC Act, for example, and also would specifically identify, I would imagine, the biological resource that might be accessed to ensure that no endangered species are collected, for example. They are two specifications that might be listed in the permit.
>
> But the permit could then specify -- and this is where the dual approach comes in, that a benefit-sharing contract must then be entered into between the bioprospector, the Government and other specified parties ...
>
> But we recommend perhaps that the regulations enacted under s301 of the EPBC Act could then provide from there regulatory guidance as to what the content of the benefit-sharing contract might be and such specifications might be that there be a creation of a public register to detail information concerning the biological resource.

5.55 In response to this proposal I commented that it closely paralleled the Inquiry's thinking to date on how a scheme under s301 could operate.

Administration

5.56 The Environment Institute of Australia supports the view that Environment Australia, in administering the EPBC Act, needs to establish an inter-agency section which can undertake liaison and monitoring and enforce compliance by all federal government agencies, corporations and business enterprises with the access regulations.

5.57 The Tasmanian Conservation Trust said that it would like to see a Biodiversity Screening Centre established as a major institution in recognition of:

> the profound and far-reaching changes which the biotechnology 'revolution' will engender in Australian commercial, social, cultural and environmental life.

5.58 Such a Centre would establish and manage the institutional arrangements necessary to secure and ensure the equitable sharing of the rental value of sustainable development and use of Australia's biological resources.

A national approach and a nationally consistent system

5.59 The Australian Conservation Foundation supported the need for a national approach and a national system.

5.60 The Tasmanian Conservation Trust, on behalf of the World Wide Fund For Nature (Australia), the Humane Society International (Australia) and the Tasmanian Conservation Trust, stated that Commonwealth legislation will only go part of the way to meeting the Commonwealth's outstanding obligation in ratifying the Convention on Biological Diversity. The Commonwealth has a responsibility, in international law, to ensure a regime is established to allow control of biological resources throughout all areas subject to the jurisdiction of Australian governments. It was suggested, therefore that the Commonwealth's legislation be developed:

a. as model legislation which sets minimum standards for such legislation throughout Australia with respect to access issues, and also resource and information management issues; and

b. as the legislation which establishes the actual regime for trade and benefit-sharing issues.

Legislation

5.61 The Australian Conservation Foundation queried the appropriateness of implementing such a scheme through regulations as they are more easily amended and subject to lower levels of parliamentary scrutiny. It preferred amendments to the EPBC Act.

Economic and social benefits

5.62 The Tasmanian Conservation Trust said that Australia stands to benefit most by ensuring an equitable flow of benefits to both users and owners of biological resources.

5.63 The Trust also put the view that policies, laws and institutions should 'enhance the capacity of the Commonwealth to ensure that the full rental value of the use of Australian biological resources, including genetic resources, is captured by Australian governments, landholders, companies and most importantly Indigenous communities'. The biotechnology industry must 'pay the rent' for access and use of resources.

Indigenous issues

5.64 The Tasmanian Conservation Trust said that an equitable regime has the potential to make a substantial contribution to the process of reconciliation.

5.65 The Australian Conservation Foundation put the view that recognition of Indigenous rights in international legal instruments and crucial issues for implementing Article 8(j) for Indigenous people involves recognition of:

a. the power disparity between traditional knowledge holders and commercial entities, when negotiating access to biological resources;

b. the present inability of Australia's intellectual property regime to protect traditional biodiversity knowledge;

c. participation by Indigenous people in decision-making;

d. Indigenous access to information;

e. loss of critical traditional knowledge;

f. reduced inter-generational transfer of knowledge; and

g. links between the precautionary principle and traditional knowledge as it relates to biodiversity conservation.

5.66 According to the Tasmanian Conservation Trust, registers of custodians of biological resources and associated knowledge are needed to ensure, where possible, eligible beneficiaries of benefit sharing arrangements can be identified and legal sanctions applied to anyone trying to use these resources without sharing the benefits.

Conclusions

5.67 In developing the proposed scheme in Chapter 2, I have given careful consideration to the issues discussed in this chapter.

5.68 The proposed scheme takes into account the major concerns and suggestions in the submissions from environmental interests, in particular:

a. the need for collections of biological resources to be undertaken in accordance with the principles of ecologically sustainable development, including the precautionary principle, and, in certain situations, the need for environmental assessment;

b. the importance of ensuring environmental, social and economic benefits from the contract, and that such benefits accrue, as appropriate, to the areas from which the biological resources are accessed, the Indigenous owners of the areas in question, and Australia;

c. the need for a single point of administration and decision-making in the scheme; and

d. the need to develop a national approach to the issues and a nationally consistent system.

the Constitution, eg inconsistency with a Commonwealth law, or if it is prevented from applying by virtue of any implied Commonwealth immunity.

The Commonwealth Parliament has legislated under s122 of the Constitution to empower the Northern Territory and Australian Capital Territory legislatures to make laws for the peace, order and good government of their Territories. The Commonwealth places power in paragraph 52(i) does not prevent the legislative powers conferred by the Northern Territory (Self-Government) Act 1978 and the Australian Capital Territory (Self-Government) Act 1988 from operating in respect of Commonwealth places in those Territories. The application of Territory laws is however subject to the exceptions referred to earlier in relation to State laws ie inconsistency with a Commonwealth law (not because of s109 of the Constitution, which applies to State laws, but because of the general principle that Territory laws cannot be repugnant to Commonwealth laws) or if their application is prevented by virtue of any implied Commonwealth immunity.

Inconsistency between a law of the Commonwealth and the law of a State or Territory may arise when the State or Territory law would directly qualify or impair the operation of the Commonwealth law. It may also arise when although there is no 'direct inconsistency' the Commonwealth Parliament has indicated that it intends its law to 'cover the field' with respect to the relevant subject matter to the exclusion of any State or Territory law dealing with the same subject. I note in this regard that the EPBC Act is, prima facie, not intended to cover the field. Section 10 provides that the Act is not intended to exclude or limit the concurrent operation of any law of a State or Territory, except so far as the contrary intention appears.

In relation to Commonwealth land in Norfolk Island the position will be the same as in relation to the Northern Territory and Australian Capital Territory. The legislative power conferred on the Norfolk Island Legislative Assembly by the Norfolk Island Act 1979 to make laws for the peace, order and good government of the territory enable it to make laws that will apply to Commonwealth land, subject to any inconsistency with a Commonwealth law or any implied Commonwealth immunity.

I observe that in the territories of Christmas Island and Cocos (Keeling) Islands the laws of the State of Western Australia are in force generally in each territory under the Christmas Island Act 1958 and the Cocos (Keeling Islands) Act 1955 respectively. Those Acts also provide that a State law that is in force in the territory has no effect so far as it is inconsistent (not capable of operating concurrently) with a Commonwealth Act.

CHAPTER 6: INDIGENOUS ISSUES AND PERSPECTIVES

Inquiry terms of reference

6.1 The terms of reference directed the Inquiry to address Indigenous issues in the following terms:

> The scheme should particularly focus on the equitable sharing of benefits arising from the utilisation of traditional knowledge, innovations and practices (Article 8(j) of the Convention on Biological Diversity)
>
> and further that:
>
> Consistent with the objects of the EPBC Act, the scheme should:
> - promote a cooperative approach to the protection and management of the environment involving governments, the community, land holders and Indigenous peoples;
> - recognise the role of Indigenous people in the conservation and ecologically sustainable use of Australia's biodiversity; and
> - promote the use of Indigenous peoples' knowledge of biodiversity with the involvement of, and in cooperation with, the owners of that knowledge.

Consultations

Consultations with Indigenous interests

6.2 The Inquiry's expert reference group included an expert on Indigenous knowledge issues, Ms Henrietta Fourmile (now Marrie), Associate Professor at the Centre for Indigenous History and the Arts, University of Western Australia. In March 2000, Ms Marrie returned to work with the Convention on Biological Diversity secretariat in Montreal but she remained a member of the Reference Group.

6.3 Ms Fourmile (now Marrie) provided the Inquiry with a copy of her Master of Laws thesis, an unpublished paper on Indigenous knowledge and a detailed and wide-ranging analysis and review of the Indigenous issues dealt with by the Inquiry. This has been of great value to the Inquiry and, with her permission, I have included it as Appendix 10 of this report.

6.4 I sent letters inviting submissions, and the Inquiry Secretariat sent notices, to approximately 40 organisations and individuals with a specific interest in Indigenous issues. On behalf of the Inquiry, Ms Fourmile (now Marrie) also sent letters to several organisations and individuals.

6.5 The Inquiry received 15 submissions from organisations and individuals with a particular interest in Indigenous issues. The following people made additional presentations at hearings:

Mr Michael Davis, Canberra.
Ms Eleanor Gilbert on behalf of Mr Anderson of the Euahlayi: Nyoongar Ghurradjong Murri Clan Group and Sovereign Union, NSW.
Mr Peter McMahon, Mr Bob Phelps, Australian GeneEthics Network, Melbourne, in association with the Gunggalidda Association, and Ms Wadjularbinna, the Doomadgee Aboriginal Association, Queensland (by telephone).
Ms Christine Morris, Australian Key Centre for Cultural and Media Policy, Griffith University, Brisbane.

6.6 In view of the particular importance of Kakadu, Uluru-Kata Tjuta and Booderee National Parks as Commonwealth 'areas' under s525 of the EPBC Act, owned by Indigenous people and administered by Environment Australia under leasing arrangements, I met with traditional owners of the Parks and their representatives. (These meetings are listed at Appendix 5 and discussed in relation to each Park below.)

Comments about the consultation process

6.7 A few submissions expressed concerns about the Inquiry's consultation processes.

6.8 The Northern, Central and Kimberley Land Councils (supported by the Kimberley Aboriginal Law and Culture Centre) recommended a research and consultation process to develop mechanisms for access and benefit sharing which would be carried out by Land Councils and controlled by Indigenous people, and which would include consideration of a wide range of models and options (including from overseas) for protecting Indigenous rights.

6.9 Mr Michael Anderson, for and on behalf of the Euahlayi: Nyoongar Ghurradjong Murri Clan Group and Sovereign Union, commented that the process assumed that Aboriginal peoples are informed on the issues and matters covered by the Convention on Biological Diversity. The Kimberley Aboriginal Law and Cultural Centre said that it lacked the resources to make complex submissions.

6.10 There was also some concern about the limited coverage of the Inquiry. Mr Anderson, for example, submitted that the Commonwealth Government should show leadership and respect for Aboriginal peoples by seeking to coordinate national negotiations between State and Territory Governments. He observed that a failure to do so would confirm that the Commonwealth is falsely representing, to the international arena, an Act to satisfy possible international scrutiny.

6.11 Similar comments were made in the hearings. Mr Bob Phelps of the GeneEthics Network said,

> ... we are very unhappy if the Commonwealth is not going to exercise its rights and responsibilities to deal with this issue on a national uniform basis and to recommend to the nation as a whole certain actions in relation to the biota of Australia.

6.12 The Inquiry has noted these concerns, but in view of the limitation of its terms of reference to Commonwealth areas, our primary concern was necessarily the interests of the traditional owners of Kakadu, Uluru-Kata Tjuta and Booderee. However, because of the complexity of the issues and the limited opportunities which the Parks' traditional owners have had to consider them, I have made recommendations for further consultations on the development and implementation of the regulations.

Consultations with the traditional owners of Uluru

6.13 On 22 March 2000, accompanied by the Inquiry Secretariat, I met the following people at Uluru: Mr Fraser Vickery, Manager Uluru-Kata Tjuta National Park, Mr Paul Josif and Ms Kathy Bannister, Office of Joint Management; Mr Graham Lightbody and Mr Tony Keys, Central Land Council, Alice Springs; and Mr Tony Tjamiwa and Mr Ginger Wikilyiri (traditional owners of Uluru).

b. The main issue the traditional owners raised was concern that they do not receive adequate benefits and recognition from current users of the Park (for example, from tourism and scientific research) and that this would need to be addressed in any future bioprospecting agreements. Although other owners were not available for discussions, the Inquiry was advised that my visit was appreciated. I accepted an invitation to attend the next Board of Management meeting for further discussions with traditional owners. This meeting occurred on 19 May 2000.

6.15 Following this meeting, I wrote to Mrs Joanne Wilmot, Chair of the Board, confirming, as I had said in the discussion with the Board, that there would be an integral recommendation in my report that there be further consultation with traditional owners on the development of the regulations. I would also recommend that funds be made available to hold workshops for traditional owners in all Commonwealth areas to implement the regulations.

Consultations with the traditional owners of Kakadu

6.16 Accompanied by the Inquiry Secretariat, I met with the Northern Lands Council, Darwin, on 20 March 2000 (Mr Leon Morris and Mr Peter Cooke) and park management (including Indigenous staff), Kakadu, on 21 March 2000.

6.17 Unfortunately it was not possible during this visit to meet any of the traditional owners of Kakadu because of the recent death of a member of the Board of Management. In conformity with cultural practice, the owners felt obliged not to undertake any formal business until the appropriate grieving process was concluded.

6.18 However, I returned to Kakadu for a further meeting with the newly appointed Board of Management and the Northern Lands Council on 22 May 2000. At

this meeting the Board requested an opportunity to respond to the Inquiry's proposals for regulations and a workshop or conference in Darwin to enable traditional owners from northern Australia to meet and discuss the issues.

6.19 Following this meeting, I wrote to the Chair of the Board in terms similar to those in my letter to the Chair of the Uluru Board, above. In response to the Board's request for further information about the issues, the Inquiry Secretariat prepared a detailed fact sheet in 'question and answer' format which the Board of Management discussed on 15 June 2000 (see Appendix 11). The Board then made a valuable submission to the Inquiry, the key points of which are summarised at paragraphs 6.45 and 6.46 below.

Consultations at Booderee

6.20 On 5 April 2000, accompanied by the Inquiry Secretariat, I met Ms Dawn Waddy, Chair, Board of Management, and Mr Scott Suridge, Manager, Booderee National Park, Jervis Bay Territory together with Indigenous and other Park personnel. On 6 April 2000 we met Mr Reuben Ardler, Community Liaison Officer, Wreck Bay Aboriginal Community Council, Wreck Bay, Jervis Bay Territory.

6.21 During the course of lengthy discussions, Mr Ardler explained that the anticipated meeting with the Council could not occur at that time owing to unresolved matters concerning the role of the Council in relation to the Park Board of Management. Mr Ardler, however, extended an invitation on behalf of the Council for the Inquiry to return when these matters were resolved and suggested that, in the meantime, the Inquiry prepare some written material about the Inquiry and the issues it was considering. This suggestion was taken up and the materials sent (see Appendix 11).

6.22 Unfortunately the difficulty Mr Ardler referred to was not resolved within the timeframe of the Inquiry. I am concerned that the community continue to be consulted and have recommended that further consultations occur.

Recommendation

30. That the Department of the Environment and Heritage ensure that traditional owners and their representatives are further consulted on, and given adequate opportunities to contribute to, development of the regulations under s301 of the EPBC Act.

31. That funds from the Department of the Environment and Heritage's Access Work Program be provided to hold educative workshops or other activities with traditional owners and their representatives in all Commonwealth areas to implement the regulations.

32. That the Indigenous Advisory Committee (formed under s505A of the EPBC Act) be consulted on development of the regulations

33. That the Indigenous Advisory Committee continue to play an advisory role in relation to operation of the regulations, in accordance with its function under s505B(1) of the Act, ie 'to advise the Minister on the operation of the Act, taking into account the significance of Indigenous peoples' knowledge of the management of land and the conservation and sustainable use of biodiversity'.

34. That, in making appointments to the Indigenous Advisory Committee, the Minister for the Environment and Heritage include a member with expertise in access and benefit-sharing issues.

Legal and management regimes in Indigenous owned Commonwealth areas administered by Environment Australia

Rights in the land and ownership of biological resources

6.23 All of the land in Uluru-Kata Tjuta National Park and approximately half of the land in Kakadu National Park is vested in an Aboriginal Land Trust by grants made under the Aboriginal Land Rights (Northern Territory) Act 1976 (Land Rights Act). The Aboriginal land in Kakadu is vested in three separate Land Trusts. Almost all of the remaining land in Kakadu is subject to claim for a grant under the Land Rights Act.

6.24 Under the Land Rights Act, an Aboriginal Land Trust holds title to land, and is the owner of the land, for the benefit of Aboriginals, entitled by Aboriginal tradition,[18] to the use or occupation of the land concerned, whether or not the traditional entitlement is qualified as to place, time, circumstance, purpose or permission (see ss4(1) and 5(1)).

6.25 The land in Booderee National Park, and the land known as the Booderee Botanic Garden, and the Wreck Bay Aboriginal Community land, is vested in the Wreck Bay Aboriginal Community Council by grants made under the Aboriginal Land Grant (Jervis Bay Territory) Act 1986 (Land Grant Act). The Council holds title to land, and exercises its powers as the owner of the land for the benefit of the members of the Wreck Bay Aboriginal Community (s6).

6.26 The Uluru-Kata Tjuta Land Trust and the Kakadu Land Trusts and the Wreck Bay Aboriginal Community Council accordingly hold and exercise all rights as the owner of their respective land, including the rights described earlier in relation to biological resources for the benefit of the Aboriginal people specified in the Land Rights Act and the Land Grant Act. In addition, in relation to Aboriginal land in Kakadu and Uluru-Kata Tjuta National Parks, the Land Rights Act preserves traditional rights in relation to the land.[19]

18. 'Aboriginal tradition' is defined in s3(1) of the Land rights Act to mean the body of traditions, observances, customs and beliefs of Aboriginals or of a communtiy or group of Aboriginals, and include those traditions, observances, customs and beliefs as applied in relation to particular persons, sites, areas of land, things or relationships.

19. Section 71 of the ACT provides – (1) Subject to this section, an Aboriginal or a group of Aboriginals is entitled to enter upon Aboriginal Land and use or occupy that land to an extent that that entry, occupation or use is in accordance with Aboriginal tradition governing the rights of that Aboriginal or group of Aboriginals with respect to that land, whether or not those rights are qualified as to place, time, circumstances, purpose, permission or any other factor. (2) Subsection (1) does not authorise an entry, use or occupation that would interfere with the use or enjoyment of an estate or interest in the land held by a person not being a Land Trust or an Aboriginal Council or other incorporated association of Aboriginals.

6.27 The Inquiry also sought legal advice in relation to Commonwealth areas which may be subject to native title.

6.28 The advice considered the issue, including relevant court decisions, and concluded that native title rights can include the right to access and use biological resources, and to control the right of others to access and use biological resources in relation to particular land. It went on to point out that, on current authority, native title would not encompass a right to control all uses of a resource wherever it was located.

6.29 It nevertheless identified s301 of the EPBC Act, providing for regulations to be made regulating access to biological resources in Commonwealth areas, as an Act which could affect native title. The advice also pointed out that s8 of the EPBC Act provides that the Act does not affect the operation of the Native Title Act 1993 or the Aboriginal Land Rights (Northern Territory) Act 1976.

Legal mechanisms controlling access to biological resources and Indigenous people's role in controlling access

6.30 Aboriginal land in the three National Parks is leased to the Director of National Parks in accordance with the Land Rights Act and the Land Grant Act. The leases contain reservations in favour of Indigenous people to enter, use and occupy the Park in accordance with Aboriginal tradition and to continue to use the Park for hunting and food gathering. Under the leases the Director has covenanted to encourage maintenance of the Aboriginal tradition of relevant Aboriginals and to promote and protect the interests of relevant Aboriginals. The leases also require the Director to manage the Park in accordance with the EPBC Act and the regulations and management plans made under the Act.

6.31 The EPBC Act provides for joint management, by the Director and a Board of Management, of Commonwealth reserves that consist of or include Indigenous people's land (as defined in s363 (3)). A majority of the Board must be Indigenous people nominated by the traditional Aboriginal owners of the Indigenous people's land in the Park (s377(4)). The functions of a Board of Management are (s376(1)): to make decisions relating to the management of the reserve that are consistent with the management plan in operation for the reserve; and, in conjunction with the Director, to prepare management plans, monitor the management of the reserve and advise the Minister on all aspects of the future development of the reserve.

6.32 The Boards, in conjunction with the Director, are required by s366(3) of the EPBC Act to prepare management plans for each of the three Parks. In preparing a management plan the Director and the Board must take account of, among other things, the interests of the traditional owners of any Indigenous people's land in the reserve and any other Indigenous persons interested in the reserve.

6.33 There is a management plan in operation for Kakadu National Park. A plan for Uluru-Kata Tjuta National Park will come into operation shortly (unless

disallowed by either House of Parliament). A plan for Booderee National Park is being prepared.

6.34 The Director is required to perform the functions and exercise the powers of the Director under the EPBC Act to give effect to a management plan that is in operation for a Commonwealth reserve (s362(1). Also, the Commonwealth and Commonwealth agencies must not perform functions or exercise powers inconsistently with the management plan for a reserve (s362 (2)).

6.35 Regulations about activities in Commonwealth reserves are being prepared under s356 of the EPBC Act and will prohibit, among other things: activities affecting organisms that are members of a native species; and, the carrying out of scientific research unless, among other things, authorised by a permit issued by the Director.[20] In addition, activities in relation to species and communities listed under Part 13 will require permits issued by the Minister.

6.36 The management plans for Kakadu and Uluru-Kata Tjuta National Parks include prescriptions relevant to the rights and role of the traditional owners of Aboriginal land in relation to managing biological resources. The relevant sections are reproduced below:

Kakadu National Park Management Plan

Section 14 -- Native Plants

In line with the lease agreements and the Act, Bininj/Mungguy will continue to be able to exercise their traditional rights to gather plants and plant material for food and making cultural artefacts. The impacts of Aboriginal use of resources will be monitored and where necessary may be regulated through consulting with Bininj/Mungguy.

Traditional owners will be involved in management programs for native plants. Bininj/Mungguy will be encouraged and supported to use traditional knowledge and skills in managing plants and habitats. With permission, such traditional knowledge and skills will be recorded and used in managing the park.

Section 16 -- Native Animals

In line with the lease agreements and the Act, Bininj/Mungguy will continue to be able to exercise their traditional rights to fish and hunt wildlife within the park. If there is concern about the impact of Bininj/Mungguy use of particular species, Parks Australia will consult with traditional owners and scientists and seek to monitor the levels and impacts of use. If monitoring suggests that adverse impacts on populations are occurring, Parks Australia will consult with traditional owners to develop cooperative approaches to managing and conserving these species.

20. The terms ‘organism’ and ‘native species’ are defined in s528 of the EPBC Act.

Traditional owners will be involved in management programs for native animals. Bininj/Mungguy will be encouraged and supported to use traditional knowledge and skills relating to managing animals and their habitats. With permission, such traditional knowledge and skills will be recorded and used for park management purposes.

Section 46 -- Other Commercial Activities

Applications for commercial activities in this category will have to be approved by the Board. If a proposal is to be considered it will need to detail: how the proposed activity will benefit the park and the local community of Bininj/Mungguy; how it will promote the value of the park while making sure the park is not unduly compromised; and how the proposal will assist visitors to appreciate the park. Approved activities will be controlled by permits similar to those used for commercial tour operations. Permit conditions will be developed on an individual basis.

Section 50 -- Research, Surveys and Monitoring

The Board will direct what research is most important in the park and will be briefed regularly on options, methods and effects of research.
A detailed long-term strategy for research and monitoring will be developed for the park within two years of this Plan coming into effect. The strategy will be developed through consulting with Bininj/Mungguy, park staff, the Kakadu Research Advisory Committee and the Bining Heritage Management Committee. The strategy will be submitted to the Board for approval and will be reviewed every two years, assisted by the Kakadu Research Advisory Committee. The strategy will outline the goals for research in the park, the priorities, and ways of measuring how effective the research is.

Parks Australia will negotiate with traditional owners a Memorandum of Understanding (MoU) to oversee the development of research directions and the planning and implementation of all research in the park.

Parks Australia will do everything it can to make sure that Bininj/Mungguy and district staff have the opportunity to be included in all stages of developing and implementing research projects. Wherever practicable, Bininj/Mungguy and park staff will be involved in monitoring programs.

Project staff will guide consultant researchers to enable them to involve Bininj/Mungguy and district staff in their projects. Research projects may be supervised by a team of people including project staff, district staff and Bininj/Mungguy.

Collecting specimens: Collecting specimens in the park will only be permitted if the work:

- will not threaten the conservation status of a species;
- will not affect significant sites or traditional owners in a negative way;

- is for scientific and not for commercial purposes, except where commercial use is specifically allowed by the Board;
- is done by a researcher who can demonstrate good research credentials to the satisfaction of traditional owners and Parks Australia; cannot reasonably be done outside the park; and
- is conducted in line with all conditions of the relevant scientific permit.

Uluru-Kata Tjuta National Park Management Plan

Section 4.13 -- Bioprospecting

Bioprospecting, or biodiversity prospecting, can be defined as a combination of the processes of exploration, extraction and screening of biological diversity and the use of Indigenous people's knowledge to obtain genetic or biochemical resources that have potential commercial value.

Issues

- Bioprospecting is a rapidly developing industry with potential for significant commercial rewards.

- Anangu have important cultural and intellectual property rights that must be respected.

Aims

- to protect the traditional, and possibly commercial, interests of Nguraritja
- to protect the biodiversity of the Park

Actions

Review. The Director of National Parks and Wildlife, the Office for Joint Management and the Central Land Council will conduct an urgent review of the implications of bioprospecting for Nguraritja and the Park. The review will develop, as a priority, advice on the handling of proposals relating to bioprospecting and intellectual property for the Board of Management.

Requests for research or collecting permits of a bioprospecting nature will be referred directly to the Central Land Council acting on behalf of traditional owners, in keeping with the terms of the Park Lease.

Section -- 4.15 Research and monitoring

Strategy. A research and monitoring strategy will be developed for the Park early during the currency of this Plan. The research and monitoring strategy will be developed in consultation with Nguraritja, the Board of Management, Environment Australia's Australian and World Heritage Group, and the Scientific Consultative Committee.

Guidelines. Parks Australia will prepare for the approval of the Board of Management, research guidelines for distribution to staff, consultants or permit holders doing research work in the Park. The guidelines will include a requirement that all proposals and outcomes be fully cross-culturally presented and understood and may include specific requirements for specimen collection.

Proposal submission. Before research is done in the Park by external researchers a proposal stating all project details including aims, the proposed extent of Anangu and staff participation, and financial and other resource costs will be submitted to the Park Manager.

Anangu briefings. Parks Australia and the Office for Joint Management will ensure that Anangu are fully briefed about, understand the implications of, and are empowered to direct and take part, in research projects.

Proposals for a possible scheme under s301 of the EPBC Act

149.39 Several submissions put forward proposals for a scheme under s301.

6.39 ATSIC proposed the following elements of a scheme:

a. effective measures to build capacity for Indigenous management and control in biological resources and traditional knowledge; and

b. an Indigenous biodiversity trust regionally based to control and manage access and use of resources and associated traditional knowledge.

6.39 The key elements of ATSIC's proposed model for regulations under s301 are:

a. adequate definitions of 'traditional knowledge, innovations and practices' and 'Indigenous rights';

b. establishment of partnership arrangements with Indigenous peoples, to advise and recommend on the introduction of capacity-building structures, such as Indigenous regional trusts;

c. establishment of a process, in agreement with the relevant trust, for formulating benefit-sharing arrangements and agreements for access;

i. royalties must be adequate and reflect realistic market prices;

e. benefits may include various combinations of financial payments such as up-front payments, research and development payments, 'milestone' payments, capacity building, infrastructure and community support payments;

iii. benefits should include non-financial payments such as capacity building, community infrastructure and support such as training and education, community participation, language, cultural, heritage and ethnobotanical programs and projects;

d. processes for seeking access must be conducted only after having identified and sought the consent of the Indigenous owners, holders and custodians;

e. prior informed consent of the Indigenous owners, custodians and managers must be the basis for any agreements regarding access to and use of biological resources and traditional knowledge;

f. agreements should contain the following information:

i. details of the community/locality/source/region of origin of the resources sought;

ii. details of any actual or potential traditional knowledge associated with the resources sought;

iii. details of actual or potential uses of the resources sought;

iv. details of the purposes for which the resources are sought;

v. details of the parties seeking access;

vi. details, if known, of the commercial and market potential of the resources sought, including any potential intellectual property aspects, such as proposals for patenting;

g. contracts must be based on mutually-agreed terms between the parties;

h. agreements must contain provisions;

i. aimed at preserving customary and traditional uses;

ii. ensuring protection of Indigenous rights and interests in resources, traditional knowledge, including protection of secrecy, confidentiality and Indigenous intellectual property rights;

iii. ensuring that such agreements do not limit or impose constraints on or restrict customary uses of such resources and knowledge;

i. provisions may be made for supporting the development of community (or national) registers or inventories of resources and knowledge -- to be owned, controlled and managed by local and/or regional Indigenous community organisations; and

j. adequate penalties and sanctions for breaches of Indigenous rights in resources and knowledge.

6.40 Professor Stephan Schnierer submitted that the regulations should acknowledge the traditional ownership of biodiversity and related knowledge by Aboriginal people; ensure their continued access for spiritual and practical uses and protect their intellectual property rights. In addition, the following conditions (not necessarily comprehensive) should be placed on collectors:

a. identify the species of interest, the exact location and the traditional owners of the environment in which the species are found;

b inform the traditional owners of their interest and the basis of that interest;

c, seek prior informed consent for access and use;

d. enter into contracts with traditional owners based on mutually-agreed terms;

e. obtain permission from traditional owners before biodiversity c an be accessed and collected;

f. conform to ethical codes of practice in the collection of biodiversity; and

g. ensure that benefits derived from access be shared equitably with the traditional owners of biodiversity.

6.41 The GeneEthics Network, in association with the Gunggalidda Association, Doomadgee Aboriginal Community, Queensland, also made recommendations regarding the processes associated with and content of access and benefit-sharing agreements. Among them were that:

a. The cultural value of Australian biota to Indigenous peoples must be recognised, with extensive consultation provided to Indigenous communities, especially community elders, on access to native biota.

b. A bioprospecting contract for research could be based on a research agreement between a bioprospecting company, Indigenous owners and a public research institution.

c. Prior informed consent would be required via Environment Australia

d. Bioprospecting would be monitored by a Federal regulator who would incorporate a wide range of community views.

b. Some benefits (whether royalties or not) from products that are developed from Australian biota should be put directly into a conservation fund and a general Indigenous fund that could be accessed for supporting Indigenous concerns.

6.42 Traditional owners and/or land councils also submitted detailed proposals for the operation of schemes in relation to Uluru and Kakadu.

Central Land Council proposal

6.43 The Central Land Council addressed issues that relate specifically to Uluru-Kata Tjuta National Park, which is the most significant Commonwealth area in the Council's region. The Council noted that while some recommendations may have some relevance to other jointly-managed Commonwealth reserves and to other Commonwealth areas, it did not wish to speak for other stakeholders in Aboriginal-owned Commonwealth areas. The Council also commented that it may be most appropriate for some of the s301 regulations to be confined to Uluru-Kata Tjuta National Park.

6.44 The key elements of the Central Land Council's proposed model are:

a. The regulatory system should differentiate between Aboriginal-owned, jointly managed Commonwealth reserves and other Commonwealth areas.

b. The regulatory system should be based on the principle of informed group consent (see s19(5) of the Land Rights Act).21

c. in the Lease between the Uluru-Kata Tjuta Aboriginal Land Trust and the Director of National Parks and Wildlife and the Plan of Management.

d. The mechanisms for consultation with traditional Aboriginal owners in s19 of the Land Rights Act should be used in dealing with requests for access to biological resources in jointly-managed Commonwealth reserves. The regulations should provide that a Memorandum of Understanding between the traditional Aboriginal owners and another person, with respect to accessing biological samples, may apply instead of the regulations.

e. The regulations should include the traditional owners' right to grant or deny access to the resources on their land.

f. The regulations should provide a mechanism for the Land Council to negotiate, on behalf of owners, agreements between the owners and industry regarding access which will provide social and economic benefits to affected communities, including employment and training opportunities, and financial returns. (The provisions in Part IV of the Land Rights Act regarding access to mineral resources should be used as a prototype.)

21. s19(5) A Land Council shall not give a direction under this section for the grant, transfer or surrender of an estate or interest in land unless the land council is satisfied that:

a) the tradional Aboriginal owners (if any) of that land understand the nature and purpose of the proposed grant, transfer or surrender and, as a group, consent to it:

c) any Aboriginal community or group that may be affected by the proposed grant, transfer or surrender has been consulted and has bad adequate opportunity to express its view to the Land Council: and

c) in the case of a grant of an estate or interest – the terms and conditions on which the grant is to be made are reasonable.

g. The regulations should distinguish between commercial and non-commercial uses of biological resources.

h. There should be no commercial use or transfer of ownership without informed consent of the traditional owners. Any transaction entered into in contravention of this regulation should be void. The regulations should also permit the traditional owners to attach terms and conditions to their prior informed consent.

i. The regulations to be drafted pursuant to s356 and s301 of the EPBC ct should be drafted in a complementary manner to provide a one-stop regulator for all requests to access for all purposes.

j. The application fees determined under the regulations should be sufficient to cover all processing costs, which may include the costs of consultations with the traditional owners.

k. Offences against the regulations should be incorporated in amendments to the EPBC Act, rather than within the regulations, to ensure that appropriately substantial penalties for infringements of Indigenous intellectual and cultural property rights are provided.

The proposal of the traditional owners of Kakadu, in conjunction with the Northern Land Council

6.45 This submission expressed two preliminary concerns. They were that:

a. expectations might be raised which might not be realised for years, if at all; and

b. agreements might be worthless and unenforceable.

6.46 The key elements of the proposal are:

a. No distinction to be made between knowledge which can be shown to be derived from traditional Aboriginal usage, and knowledge which is derived from scientific research on plants and animals owned by Aboriginal people.

b. Any company wishing to carry out research or bioprospecting must provide full information specifying comprehensive details of the proposal, including:

i. the precise nature of the resources to be sampled;

ii. the use to which they are to be put;

iii. the locations from which samples will be taken;

iv. whether the research has commercial aspects; and

v. the person or body funding the research or bioprospecting.

c. Aboriginal people be given the opportunity of employment in the project and joint ownership of the intellectual property associated with the material collected.

d. The proposal must be sent to the Kakadu Board of Management and the Northern Land Council. The Land Council will then identify the clan groups who are the owners of the land on which the material is to be collected.

e. Where the Board is of the opinion that there is a possible commercial application for research, a more detailed agreement should be negotiated through the Land Council.

f. The process will only be effective if the proponent company is required to pay the costs of the consultation process on a 'user pays' basis.

g. If negotiations are to proceed, the Land Council should ensure full and comprehensive consultations take place and agreement is reached.

h. Benefits would be the subject of negotiation on a case-by-case basis (these could range from up-front access fees, employment of traditional owners in bioprospecting, funding a representative of owners to verify field sampling and a full range of monetary and non-monetary benefits including royalties and/or licence fees on the final product).

i. A range of conditions and terms would need to be included in any agreement and would require further research and consultation, for example:

i. Copyright or ownership of material collected should, as a minimum, be jointly owned by an appropriate body representing traditional owners.

ii. Protection of naming rights and controls over sampling and harvesting of flora and fauna are important pre-conditions to any agreement.

iii. A way must be found for traditional owners to track the development of commercial products from sampling data, particularly in an industry where development times are long and links between biological resources and commercial products may be difficult to prove.

j. A crucial role for government will be to take measures to ensure that exploitation of biological resource is carefully monitored, accurately recorded and linked to the specific source location and hence the traditional owners. Legislative intervention will be required to ensure that the enforcement of contractual agreements can be guaranteed for all time.

Proposals for Indigenous trusts and community registers

6.47 Several submissions proposed Indigenous trusts as a means of administering and sharing the benefits arising from agreements. Some submissions also proposed establishing community registers of Indigenous knowledge which could be used to provide information to enable organisations or individuals wishing to use Indigenous knowledge to contact the relevant community to obtain their prior informed consent.

6.48 ATSIC proposed a trust which could, for example, be based on a region, such as a bioregion, to be agreed and defined by Indigenous peoples, or on building capacity among a grouping of Indigenous organisations such as land councils and other bodies within a region. The trust would have the functions of:

a. asserting and holding Indigenous collective rights in biological diversity and traditional knowledge for and on behalf of native title holders;

b. making decisions about the control and management, and advocating legal and other forms of protection and recognition of those rights;

c. determining the rightful owners, custodians and managers of Indigenous biodiversity related knowledge and intellectual property;

d. distributing benefits accrued from the wider uses of biodiversity related knowledge, innovations and practices, in accordance with agreed customary rules and procedures; and

e. conducting research, information, education and awareness activities.

6.49 The Northern, Central and Kimberley Land Councils also proposed consideration of a trust model, possibly based on a bioregion.22

6.50 The Kakadu Board of Management suggested that a Trust could hold and distribute moneys, and represent, advocate and litigate on behalf of traditional owners. The first step would be a trust representing the land trusts areas in Kakadu; there may be a role for the trust to represent wider areas but further research and consultation is necessary before extending the trust proposal. Until establishment of such a Trust, the Northern Land Council is the

appropriate body to hold moneys and intellectual property rights in trust and otherwise represent owners' interests.

6.51 The Inquiry observes that the trust and community register proposals are complex and require further consideration. However, it believes that, the scheme should reflect the principle that the disposition of benefits payable to the owners of land must be a matter for those owners to determine. Anything less than this would be a diminution of their rights.

Recommendation

35. That the trust and community register proposals, including (but not limited to) issues such as possible bioregional coverage and beneficiaries of any agreements under s301 of the EPBC Act, be discussed further in consultations on the development of the regulations and in the workshops proposed in Recommendations 30 and 31 above.

36. That the regulations ensure the distribution of benefits derived from a benefit-sharing contract is for traditional owners to determine.

Capacity building -- legal and technical support for Indigenous communities

6.52 Some submissions commented on the need to provide Indigenous communities with legal and technical support. Environment Australia commented that:

> Any access scheme should give appropriate recognition of Indigenous intellectual property rights. Knowledge, innovation and practices should be recognised and benefits based on these should flow back to the relevant traditional owners. The traditional owners of Indigenous people's land (as defined in the Aboriginal Land Rights Act 1976 and the EPBC Act 1999) should have the right to determine who, when and where researchers can access biological resources on Indigenous people's land and a say in the ongoing security arrangements for the data or biological resources collected.
>
> The definition and defence of intellectual property rights may be complex and expensive, however. Design of the access scheme should thus consider providing an appropriate level of independent legal and technical support, and recovers the full cost of negotiation of appropriate commercial arrangements by traditional owners. Any scheme should seek to minimise such costs by recognising and incorporating existing sources of legal advice for traditional owners, and facilitate the sharing of such advice.

22 The Model referred to id based on recommendations by Langton, Epworth and Sinnamon, 1999.

6.53 ATSIC recommended that:

> Consideration [be] given to implementing, through the Regulations, appropriate forms of capacity building or Indigenous institutional support. The Indigenous Biodiversity Trust model ... provides an example.

Recommendation

37. That the Director of National Parks, as part of the responsibility for administering Commonwealth reserves and conservation zones under s514B(1)(a) of the EPBC Act, provide traditional owners with resources to enable them, if they choose, to seek independent legal or other advice in negotiations over possible access and benefit-sharing agreements.

The right of Indigenous people to protect their knowledge, innovations and practices

6.54 Submissions to the Inquiry acknowledged the need to respect the particular relationship between Indigenous people, their ancestral territories and the species in those territories, as well as the need to respect traditional knowledge associated with their territories and species.

6.55 Many submissions (and not only those which specifically focused on Indigenous issues) expressed concern about the use of Indigenous knowledge without consultation, prior informed consent or benefits.[23] For many Indigenous people, the Smokebush incident in particular confirmed their worst fears about the continuing misappropriation of their biodiversity and associated knowledge. According to Our Culture, Our Future:

> The Smokebush [Conospermum] grows in the coastal areas between Geraldton and Esperance in Western Australia. Indigenous people from this region have traditionally used Smokebush for healing. Fourmile (now Marrie) reports that in the 1960s, the Western Australian Government granted the US National Cancer Institute a licence to collect plants for screening purposes. In 1981, specimens of the Smokebush plant were sent to the National Cancer Institute to test for the presence of cancer-fighting properties.
>
> The specimens were found to be ineffective, but were held in storage until the late 1980s when they were tested again in the quest to find a cure for AIDS. Out of 7 000 plants screened from around the world, the Smokebush was one of only four plants found to contain the active property Conocurovone, which laboratory tests showed could destroy the HIV virus in low concentrations.

23. Various terms are used in the literature, for example: traditional knowledge, traditional ecological knowledge, Indigenous knowledge, and traditional biodiversity-related knowledge. For the purposes of consistency, the Inquiry refers, in this report, to 'Indigenous knowledge' on the basis of Article 8(j) of the Convention on Biological Diversity which refers to 'knowledge, innovations and practices' of Indigenous and local communities.

> This 'discovery' was subsequently patented. The US National Cancer Institute has since awarded Amrad, a Victorian pharmaceutical company, an exclusive world wide licence to develop the patent.
>
> Under amendments to the Conservation and Land Management Act 1984 (WA) in 1985 and the National Parks and Wildlife Act (WA), the Western Australian Minister of the Environment has the power to grant exclusive rights to Western Australian flora and forest species for research purposes. In the early 1990s, the Western Australian Government also awarded Amrad the rights to the Smokebush species, to develop an anti-AIDS drug ... Amrad paid $1.5 million to the WA government to secure access to Smokebush and related species ... if Conocurovone is successfully commercialised, the WA government will recoup royalties of $100 million per year by 2002.
>
> Indigenous people are concerned that they have not received any acknowledgment, financial or otherwise, for their role in having first discovered the healing properties of Smokebush. According to the Centre for Indigenous History and the Arts (WA):
>
> The current legislation disregards the potential intellectual property rights that Indigenous peoples in WA have in flora on their lands. Furthermore, multinational drug companies could be sold exclusive rights to entire species of flora, preventing anyone from using these species for any other purpose without the consent of the companies.
>
> Indigenous peoples in WA face the possibility of being prevented from using any of the flora which is the subject of an exclusive agreement.
>
> It is therefore vital that any reform of the intellectual and cultural property laws include provisions for the recognition of Indigenous peoples as the native title owners of all the biological resources of the flora and fauna that are on their lands.24

6.56 There is considerable commercial interest in Indigenous knowledge of plant and animal species for food, medicine and other purposes. Much of this knowledge has already been published and is readily available to the public. This knowledge helps to locate species that could be used, for example, by:

a. the pharmaceuticals industry for developing new drugs;

b. herbalists and the medical profession in developing natural therapies and neutriceuticals;

c. the bush food industry, for new herbs, spices, flavours and food staples;

d. agricultural, aquaculture and floriculture industries;

e. industries based on developing personal care products, ie cosmetics, soaps, shampoos, fragrances, sun-screens, aromatic oils, etc.; and

24. See *Our Culture, Our Future*, 1998: p.24-25

f. biotechnology industries, in which biotechnology can be used to develop products associated with any of the above industries, as well as in the development of industrial products and processes.

6.57 A few examples from the submissions illustrate the extent and depth of concerns about the unauthorised use of Indigenous knowledge.

6.58 Mr DD Brown expressed concern that industry has patented knowledge, innovations and practices which are not theirs and submitted that Indigenous communities should only share their knowledge if they choose to do so, and on their terms and conditions, without coercion.

6.59 Mr Michael Anderson expressed concerns about the continuing expropriation of traditional knowledge and culture and said that it was imperative that the intellectual property rights of the owners of knowledge be provided protection and owners not be forced to share the benefits gained from this knowledge.

6.60 Euroka Gilbert and Kathryn Looke also expressed concerns about the exploitation of Aboriginal people's intellectual property, exemplified by the Smokebush incident, and said that industry, governments and multinational corporations should not be able to use Aboriginal peoples and their traditional knowledge for their own gains without fair forms of reparation for injustices.

6.61 The Kimberley Aboriginal Law and Culture Centre, representing traditional Aboriginal cultural leaders across the Kimberley, expressed their rights to be acknowledged and respected, to benefit from the development of their intellectual property and to be included in the process and decision making.

6.62 The Queensland Government noted that 'issues of intellectual property may arise with respect to Indigenous communities, where traditional knowledge may lead to a significant discovery by bioprospectors'. In such cases, it supports the intellectual property rights of Indigenous people.

6.63 Some attempts have been made to address these issues overseas. For example, ATSIC briefly outlined various approaches, which include 'traditional resource rights', the 'community intellectual rights' scheme developed by the Malaysian-based Third World Network, and the model advocated by the Canadian-based advocacy organisation Rural Advancement Foundation International.

6.64 I am sensitive to the views expressed in submissions, as well as discussions and hearings, that Indigenous people's knowledge, and therefore their culture and spirit, has been taken from them. The Inquiry acknowledges the right of Indigenous people to their knowledge and has recommended creation of practical means to protect it under the proposed access system without the further delays which would arise from development of legislation. I do, however, support the work being undertaken to protect Indigenous knowledge.

Protection of rights to biological resources through contractual terms

6.65 Submissions to the Inquiry (and other literature on the issue) tend to discuss the issue in general terms, that is, as it might be addressed on a national basis, rather than in relation to the Indigenous-owned lands which are Commonwealth areas under the EPBC Act to which the Inquiry's terms of reference are limited.

6.66 Having examined this matter carefully, the Inquiry believes that protection for Indigenous-owned biological resources and associated knowledge in Commonwealth areas can be achieved either through the right of Indigenous owners not to allow access to their resources (with no right to review this decision), or, where they do enter into such contracts, by including in the contract terms which protect their rights. Such terms could, for example stipulate that:

a. agreements are not exclusive;

b. Indigenous owners may continue to use their biological resources and associated knowledge as they wish;

c. Indigenous owners are not required to divulge any information or knowledge against their wishes; and

d. access and benefit sharing may be determined in accordance with Indigenous owners' traditional laws and customs, if applicable.

6.67 Terms such as those suggested above are consistent with the Patents Act 1990. According to legal advice provided to the Inquiry, nothing in the grant of a patent gives the patentee any right to any source biological or genetic resources, that is, the specimens. Nor does the grant of a patent extinguish the right to use any traditional knowledge from which the patented subject matter was developed, provided the use does not amount to a use of the patent. The patent will also not extinguish any right to assert confidentiality in that information in general (although an exception would be if there has been a disclosure of that information either in the patent application or other published material relating to the derived invention).

6.68 Similarly, the rights of a registered owner under the Plant Breeders Rights Act 1994 are restricted to the actual registered plant variety and not to any source material from which that variety may have been derived. Plant breeders' rights will also not affect the rights of owners of traditional knowledge except where it is used to produce a plant variety of the same type as that which has been registered, or to exercise one of the other rights of the registered owner.

6.69 It is possible for patents to be owned jointly. However, for a joint application to be made, each individual must have made a contribution to the patentable invention. Mere knowledge in relation to the biological or genetic resources on which the patentable process or product is based does not, in itself, confer joint ownership of patent rights.

6.70 The inventor may, however, agree to another party being registered as a joint applicant, even where they have not made a contribution from which it has been derived. The effect of a joint application being granted is that each applicant may exercise the rights conferred by the grant of the patent individually without having to compensate the other owner/s. They cannot, however, grant a licence or assign an interest in the patent without the agreement of all owners.

Protection of rights where there is no contract or where there is a breach of contract

6.71 Where there is no contract, for example, where biological resources and/or Indigenous knowledge have been obtained from Commonwealth areas, either through activities such as illegal bioprospecting or from previous research and/or publications about the area in question, or where there is a contract, but resources and/or knowledge have nevertheless been obtained in breach of its terms, other forms of redress/penalties may need to be considered.

6.72 These could include preventing the export of the resources in question or refusing the grant of patents without proof of their source, that is, a contract evidencing prior informed consent. The latter appears to be the most common of proposals to protect traditional knowledge without actually creating intellectual property in such knowledge. However, IP Australia's submission, as well as legal advice to the Inquiry, indicates that this is not a current requirement of Australia's patent system.

6.73 As I have said above, the issue of protecting Indigenous knowledge outside Commonwealth areas (and therefore the jurisdiction of the EPBC Act) is beyond the Inquiry's terms of reference. This has not prevented the Inquiry from giving some consideration to the issues. However, the Inquiry notes that among the issues which would need to be addressed are whether the Commonwealth has constitutional power to protect Indigenous knowledge and, if so, what would be the best means of providing this protection.

6.74 In view of the complexity of these issues, their extension beyond Commonwealth 'areas' under the EPBC Act, and the fact that discussion about them is relatively recent in the Australian context, the Inquiry believes further research, consultations with stakeholders and community education are desirable.

Recommendation

38. That the Department of the Environment and Heritage monitor international research and debate by the World Intellectual Property Organization and the World Trade Organization (and other fora) on protection of Indigenous knowledge as well as debate and research on the issue in Australia.

39. That, in the event that stronger measures to protect such knowledge are introduced internationally or in Australia, the Department of the Environment and Heritage consider the adequacy of the regulations in protecting Indigenous intellectual property rights.

40. That the issue of protecting Indigenous knowledge be considered further in (but not necessarily limited to) discussions towards developing a nationally consistent system.

41. That IP Australia consider amending patent law to require proof of source and, where appropriate, prior informed consent, as a prerequisite for granting a patent.

Other issues

Relationship between Indigenous knowledge and biodiversity conservation

6.75 The basic framework for defining and recognising Indigenous rights to lands, species and knowledge has been evolving for more than a decade in various international fora. A number of submissions drew attention to this, for example, the Australian Research Council pointed out that:

> An essential framework for the recognition of the rights of Indigenous peoples to their traditional knowledge and to the natural resources upon which they have relied for their subsistence has emerged over the last decade. These rights include the right to manage such natural resources, and to be involved in any decisions regarding those resources.
>
> Article 8(J) of the Convention on Biological Diversity requires the Parties to the Convention to 'respect, preserve and maintain knowledge, innovations and practices of Indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity ...'

6.76 With only a few exceptions, however, the relationship between Indigenous knowledge and biodiversity conservation did not receive much attention in submissions to the Inquiry.

6.77 Dr David H Bennett, Executive Director, The Australian Academy of the Humanities referred to 'the special relationship between Aboriginal and Torres Strait Islander People and Australia's biodiversity and government polices and programs that deal ... with Indigenous access to Commonwealth areas'. Dr Bennett noted in particular Objective 1.8 of the National Strategy for the Conservation of Australia's Biological Diversity:

> Traditional Aboriginal and Torres Strait management practices have proved important for the maintenance of biological diversity and their integration into current management programs should be pursued where appropriate.

6.78 ATSIC commented as follows on this issue:

> There is a close interdependence between biological resources and the Indigenous peoples who are its managers, custodians and owners. Given this interdependence, respect for, and preservation of biological diversity is best achieved by upholding respect for, and preservation of cultural diversity. In other words, support for the diverse, local Indigenous cultures which have managed biological diversity for millennia, is a necessary element of the maintenance of biodiversity.

Reconciliation

6.79 The Council for Aboriginal Reconciliation and the Tasmanian Conservation Trust suggested that addressing Indigenous knowledge issues could contribute towards reconciliation.

6.80 I understand that Environment Australia's Reconciliation Action Plan includes, among the strategies to protect and use traditional ecological knowledge in addressing contemporary environmental issues, the requirement to ensure that Indigenous people have the opportunity to provide input to this Inquiry.

6.81 The Inquiry has attempted to ensure that this has been the case, but I reiterate the importance of ensuring the continuing participation of the traditional owners of Kakadu, Uluru and Booderee, and their representatives, in developing and implementing the regulations, as recognised in Recommendations 30 and 31 above.

Protecting Aboriginal genetic material

6.82 Ms Christine Morris, Research Fellow, Australian Key Centre for Cultural and Media Policy, Griffith University, Nathan Queensland, submitted that the remains of Indigenous people and others found in the soil should be left untouched by bioprospectors. Euroka Gilbert and Kathryn Looke also expressed concern about the lack of protection over Aboriginal human genetic material.

Recommendation

42. That the regulations and the model contract stipulate that bioprospectors not collect human remains.

Codes of practice/ethics

6.83 Several submissions suggested the use of codes of ethics/practice for conducting bioprospecting. ATSIC provided extracts relating to Indigenous people from a 1998 report by the Australian Science, Technology and Engineering Council entitled Environmental Research Ethics: National Principles and Guidelines for the Ethical Conduct of Research in Protected and Environmentally Sensitive Areas.

6.84 Having examined this document, the Inquiry believes that, rather than create an additional document and enforcement mechanisms and sanctions additional to those proposed for inclusion in the EPBC Act, the contract should include terms which would amount to a code of practice/ethics -- these terms would also be enforceable as part of the contract.

Indigenous people's development of their biological resources and associated knowledge

6.85 Professor Noel Dunn, Director, Cooperative Research Centre for Food Industry Innovation outlined a project in which the Centre has been working with an Aboriginal community to set up a mechanism whereby food ingredients can be sourced from Indigenous plants. A proposal has been prepared and ATSIC has given in principle support. The Aboriginal community is establishing a company with board management. Royalties/licences will be shared equally between the Aboriginal company and the Cooperative Research Centre.

Recommendation

43. That participants in the workshops proposed in Recommendation 31 explore the possibility of innovative opportunities for Indigenous people to promote and benefit from their knowledge of biodiversity.

Conclusions

6.86 In developing the scheme proposed in Chapter 2, I have sought to reflect the above issues either in the scheme or in my recommendations regarding the need for further consultations with Indigenous owners and monitoring of international developments in protection of Indigenous knowledge.

6.87 The proposed scheme takes into account the concerns of, and suggestions in, the submissions from Indigenous interests by including in the regulations (among other things):

a. the requirement that the Minister take the following factors into account when deciding whether to grant or refuse an access permit:

i. environmental assessment (if required) was undertaken and the process is completed;

ii. submissions from persons and bodies registered under s266A of the EPBC Act have been taken into account;

iii. the precautionary principle has been applied, where appropriate;

iv. any variations to the model contract are acceptable;

v. there is a contract between the parties which addresses the following major issues:
- prior informed consent (the regulations also include indicia of evidence of prior informed consent);
- mutually-agreed terms; and
- adequate benefit-sharing arrangements, including protection for and valuing of Indigenous knowledge (where used); and

vi. the access arrangements meet the requirements of leases, management plans and any other relevant agreements, where applicable; and

b. the provision that the decision of the owners of biological resources to deny access to their resources is not reviewable.

6.88 In addition, I believe that my recommendation that a model contract be drafted will benefit Indigenous owners by:

a. helping parties understand the issues;

b. facilitating negotiations between them; and

c. including model terms which will enable traditional owners to protect their interests, for example, with respect to prior informed consent, mutually-agreed terms and adequate benefit-sharing arrangements.

CHAPTER 7: INDUSTRY AND RESEARCH ISSUES AND PERSPECTIVES

Inquiry terms of reference

7.1 The Inquiry's terms of reference require the access scheme to operate 'in a manner that promotes certainty for industry and facilitates access to biological resources for environmentally sound uses'.

7.2 In the press release announcing the Inquiry (see Appendix 3), Senator Hill said,

> Access to biological and genetic resources for environmentally sound uses is of strategic importance to Australia's capacity to develop a biotechnology industry. The inquiry will therefore look at options for implementing a streamlined access regime that, consistent with the principles of ecologically sustainable development, delivers certainty for industry.

Consultations

7.3 The Inquiry's expert reference group included an industry expert, Professor Ronald J Quinn, Director, AstraZeneca R&D Griffith University and an expert from the science community, Ms Elizabeth Evans-Illidge, a Research Scientist at the Australian Institute of Marine Science, Townsville.

7.4 I sent letters inviting submissions and the Inquiry Secretariat sent notices to a large number of organisations involved in the biotechnology industry, based on a comprehensive mailing list provided by the Department of Industry, Science and Resources. The Secretariat also sent notices to overseas companies with an interest in bioprospecting (from a list provided by Ms Evans-Illidge) and to vice-chancellors of all Australian universities (from a list provided by the Department of Education, Training and Youth Affairs, a member of Biotechnology Australia). Approximately 25 submissions were received from industry and research interests.

7.5 I also met representatives of the Australian Biotechnology Association and key industries.

Bioprospecting and biodiscovery in Australia

7.6 At present, several major companies and organisations are involved in bioprospecting and/or biodiscovery in Australia. These include AstraZeneca, ExGenix (formerly AMRAD), the Australian Institute of Marine Science, CSIRO and BioProspect Limited. The Inquiry received submissions from all of these organisations.

ExGenix (formerly AMRAD)

7.7 AMRAD Discovery Technologies 25 was established in 1993 to secure access to Australia's diverse and extensive biota and to explore its potential for the discovery of novel pharmaceutically active compounds.

7.8 AMRAD's collection agreements provide long-term and exclusive access to a significant proportion the genetic resources of Australia and other countries.

7.9 Agreements relating to plant species were made with:

a. **Victoria**: the Royal Botanic Gardens and Department of Conservation and Natural Resources (the Agreement with the Botanic Gardens provides access to approximately 11,000 species of exotic, non-Australian plants propagated in the Gardens in addition to the 4000--5000 native plant species which grow wild in Victoria).

b. **Northern Territory**: the Northern Territory of Australia and the Parks and Wildlife Commission of the Northern Territory, the Arnhem Land Aboriginal Land Trust and the Northern Land Council; and the Tiwi Aboriginal Land Trust.

c. **Tasmania**: the Tasmanian Herbarium through the Trustees of the Tasmanian Museum.

d. **Malaysia**: the Government of the State of Sarawak.

e. **Papua New Guinea**: the Kalam People of the Kaironk Valley, through the Australian National University.

7.10 Agreements relating to micro-organisms were made with:

a. Antarctic Cooperative Research Centre.

b. Australian Institute of Marine Science (agreement now concluded).

c. University of Hong Kong, Department of Ecology and Biodiversity.

d. Smaller scale and/or one-off arrangements with various microbiology centres around Australia.

7.11 Agreements relating to marine macro-organisms were made with:

a. Australian Institute of Marine Science (agreement now concluded).

25. In December 1999, AMRAD and the Rothschild Bioscience Unit (on behalf of a group of Australian-based investors) announced an agreement whereby AMRAD's interest in AMRAD Discovery Technologies Pty Ltd was sold and a new Australian Biotech company – ExGenix Ltd – was established. Under the terms of the agreement, ExGenix obtains all intellectual property, assets and related liabilities of AMRAD Discovery Technologies Pty Ltd and AMRAD retains a 24 percent interest in ExGenix that will provide AMRAD with high returns throughout screening services to aid AMRAD's own drug discovery programs.

7.12 ExGenix provided the Inquiry with the following 'principles of plant collecting arrangements':

a. enacted with relevant State Government and Indigenous authorities;

b. samples collected by local botanical authorities;

c. voucher specimens maintained by local herbaria;

d. long-term and exclusive to ExGenix;

e. provide for sample/species recollection;

f. provide for maintenance of a register of 'retained' species after initial collection period;

g. intellectual property rights owned by or assigned to ExGenix;

h. benefits to custodians;

i. commercial -- immediate (payment for samples) and long-term (royalties); and

j. non-commercial (flexible) -- training, other benefits.

BioProspect Limited (formerly Bio-Gene Prospecting Limited)

7.13 BioProspect is a non-listed public company, owned almost exclusively by Australians. BioProspect believes that its independence is significant to its success,

> ... in that [it is] not owned or controlled by any pharmaceutical company or any other organisation with a vested interest, either in Australia or internationally and that this independence allows [it] to operate ... as a fair and honest broker of the biological resources to which [it has] access rights.

7.14 BioProspect identified the following as key elements of its contracts:

a. access on the basis of sustainable access;

b. primary ownership of all intellectual property derived from a biological resource remains in the hands of the State or its derivation;

c. the State receives royalties from any commercial activity resulting or derived from that natural resource; and

d. wherever possible the infrastructure and human resources of the State are used to collect, process and value add to the primary biological resource.

Australian Institute of Marine Science

7.15 The Commonwealth Government established the Australian Institute of Marine Science in 1972 to generate the knowledge needed for the sustainable use and protection of the marine environment through innovative, world-class scientific and technological research.

7.16 For over a decade, the Australian Institute of Marine Science research activities have included biodiscovery or bioprospecting research. The goals of this research are:

a. to discover biologically active molecules that can be developed as drugs, industrial herbicides or other products by an industrial partner;

b. to understand the ecological roles that biologically active molecules play in their source organisms; and

c. to support sustainable development of new product leads.

7.17 This research involves the systematic search, through biodiversity present in nature, for novel molecules (chemical entities) that cause a desired action in a molecular process associated with some commercial product, ie are biologically active in ways which might have commercial value. In order to gain access to appropriate world-class expertise and facilities to achieve these goals, the Australian Institute of Marine Science needs to access facilities, funding, logistical support and expertise beyond that available in-house at the Institute. This is achieved through strategic links to various collaborators, particularly within industry.

7.18 The centrepiece of this research is the marine biodiversity collection. The collection includes material from more than 10 000 marine macro-organisms and 7 500 marine micro-organisms, collected and isolated from over 1 500 sites around Australia. The collection was designed for natural products research, but also includes material and data for ongoing expert systematic and taxonomic study of the samples.

7.19 Key points from the Institute's proposal for a model for access and benefit-sharing regulations are as follows:

a. **Sustainable access** -- all access must be undertaken on a sustainable basis.

b. **Ability to transfer samples to third parties** --to provide certainty to investors in biodiscovery research, it is essential that the terms and conditions of third-party transfers are set at the time of permission for primary access to resources.

c. **Benefit sharing** -- a framework for sharing benefits should be established at the outset. This framework should cover issues such as legal certainty over the use of samples; opportunities for Australian capacity building and Australian development of intellectual property in discoveries and their commercialisation; other benefits, eg documentation of biodiversity to support its effective management and conservation; and a generic definition of monetary benefits, eg as a percentage of defined income.

7.20 The Institute's submission recommends that benefit-sharing negotiations be conducted separately from access negotiations, as each requires different kinds of expertise. The Inquiry understands that this would allow a benefit-sharing agreement to be struck with, say, a State government, while details concerning access could be dealt with separately with the various State-based agencies which control access to different parts of the State's biota.

AstraZeneca R&D, Griffith University

7.21 On 11 June 1993, a joint venture agreement was signed between Griffith University, Brisbane and Astra Pharmaceuticals Pty Ltd, Sydney, a subsidiary of AstraAB, a Swedish pharmaceutical company (since April 1999, AstraZeneca). The joint venture project undertakes screening of extracts of plants and marine organisms collected from Australia's rainforests and the Great Barrier Reef. Extracts displaying activity in the screens are examined using bioassay-guided fractionation to identify the structure of the active components. This work is undertaken at facilities located at Griffith University.

7.22 Professor Quinn's[26] submission identified the following benefits to Australia from this arrangement:

a. Natural product screening was established in 1993 with 17 staff which has grown to 43 staff in 2000. Over this time, AstraZeneca has injected A$27 million into research at Griffith University.

b. In 1998, AstraAB extended its contract with Griffith University to 2003, resulting in proposed further investment of A$31 million in research and a further five highly skilled jobs during the period to 2000.

c. Griffith University will receive royalty payments (a percentage of sales) on any product developed.

d. The agreement provides significant employment and training in the pharmaceutical industry.

26. Director, AstraZeneca R&D Griffith University and member of the expert reference group.

7.23 The Queensland Herbarium collects plants and the Queensland Museum collects marine species for the project. Benefits of collaboration with the Herbarium to date are:

a. discovery of 37 new plant species;

b. new populations of threatened species in remote areas, providing the genetic material which can be used to propagate the species;

c. records of weed encroachment in native forests -- these records are useful for forest management; and

d. creation of new distribution records in the Queensland Herbarium.

7.24 Benefits of the collaboration with the Queensland Museum to date are:

a. discovery of approximately 1500 new species; and

b. provision of infrastructure to accurately define distribution of marine sponges in Queensland and adjacent waters -- this provides invaluable data which will eventually produce productive taxonomic expertise in these areas and is of great value to further understanding of marine biota.

7.25 Griffith University has contracts with the Queensland Museum and the Queensland Herbarium under which it pays them a specified rate for samples. Further key terms of these contracts include:

a. agreement, by the collectors, to keep confidential certain matters relating to samples and supply while ensuring that essential taxonomic information is placed in a public collection;

b. the University's exclusive right to the services of the collectors; and

c. payment, by the University, of a percentage of all proceeds which it receives from any commercial exploitation of compounds obtained from samples supplied by the collectors (whether during or after termination of the agreement).

Key issues/perspectives raised by industry and research organisations

Process and costs of drug discovery and development

7.26 Submissions to the Inquiry presented considerable evidence of both actual and potential benefits to the parties involved in bioprospecting agreements, but also of the costs, long lead times and uncertain results of drug discovery and development work. While wanting to ensure that benefit sharing agreements are fair to all parties, the Inquiry is also concerned to ensure that potential

providers of biological resources do not have unrealistic expectations of the monetary or non-monetary returns which future benefit-sharing agreements might offer.

7.27 The submission from the United States National Cancer Institute emphasised the obstacles to drug discovery and development. Based on a four-step process, the Institute identified the chances of a compound tested in the discovery (first step) phase entering the pre-clinical phase (steps two and three), to becoming a drug on pharmacy shelves as one in 10,000. It was calculated that it requires the expenditure of over US$400 million from the discovery phase to clinical trials to commercial success.

7.28 Dr Trowell, from the CSIRO confirmed this experience, describing the likelihood of discovering a useful lead as being like a lottery:

> ... your chances of winning are extremely low and yet, if you do win, the rewards are potentially very high. We are talking of royalties for a successful drug that might run to 10 million -- between $10 million to $50 million per annum. The chances, I think, of doing that are significantly lower than the lottery.27

7.29 The National Cancer Institute also commented on the 'value' of samples (in the absence of any biological assay data) as being probably in the range of US$1.00 to US$5.00, irrespective of the cost of collection. The cost to the Institute of a collection of one kilogram of marine invertebrates is in the order of US$750. The sample then has to be processed, identified and stored before it can be tested. The complete assay that the Institute uses for anti-tumour activity costs around US$250 per sample. The Institute adds that this is only the start of the process. CSIRO also commented that the intrinsic value of biological resources and associated (traditional) knowledge can be quite limited.

7.30 The Queensland Government commented that successful lead compounds require an approximate investment of $700 million and eight to 15 years research and development to realise commercial success. The success versus 'hit' ratio is very disproportionate. Considering the level of research and development investment required, and on the basis of industry estimates that indicate the chance of discovering a new pharmaceutical may be in excess of one in 1 000 000 samples screened, biodiscovery can be considered a 'lottery'. CSIRO made similar comments, first that commercial returns from bioprospecting may be quite limited and, second, that possible monetary benefits from agreements are often overestimated (see also 6.28 above).

7.31 The high costs, long lead times and uncertain outcomes of research and development led the Queensland Government to conclude that onerous benefit-sharing provisions may hinder industry development, impact negatively on the development of positive international research alliances and on trade in biological and genetic resources, and lead to covert and unregulated biodiscovery activities.

27. CSIRO presentation at Canberra hearing, 30 May 2000

Benefits to Australia

7.32 Research institutions and industry were agreed on the importance of ensuring continued access to biological resources for research and commercial purposes (although an industry submission sounded the warning that biological resources are often available from alternative sources). Several submissions commented on the economic, social and environmental benefits to Australia of agreements involving collection and screening of plants and micro-organisms.

7.33 There was support for regulating bioprospecting to ensure that samples and extracts remain in Australia and, also, as far as possible, that the subsequent discovery and development work is done in Australia. In contrast, however, the point was made that, unless the scientific infrastructure exists in the source country to do the discovery work, restrictions on overseas collaboration, by not permitting export of samples, will prevent discoveries.

Impediments to Access -- jurisdictional and administrative

7.34 The Australian Institute of Marine Science commented that,

> Access to Australian biological resources in marine areas, including Commonwealth waters, is controlled by a maze of legislation, principally designed for either fisheries management or conservation. A single activity in one location frequently requires permits from multiple agencies representing more than one tier of government and administering a wide range of access legislation. (This issue is discussed further in Chapter 8.)

7.35 Many submissions expressed concerns about the number and complexity of permits required at Commonwealth and State level to access resources (in both land and marine areas) for research and commercial purposes.

7.36 Various suggestions for reform were made. These included:

a. support Commonwealth leadership and a higher degree of uniformity between jurisdictions in Australia (CSIRO);

b. endorse the policy principles in the 1996 Commonwealth State Working Group discussion paper (CSIRO);

c. support a central focal point and competent national authority approach, including an expert committee (Australian Research Council);

d. streamline the process for seeking access, preferably electronic and handled by a single agency (University of Queensland);

e. establish a database of researchers with active scientific programs linked to biological resources in Commonwealth areas ; and

f. encourage access to biological resources and discourage exclusive agreements with any single multinational or national organisations (other than an independent national organisations responsible for supervising use).

Impediments to access -- concerns about benefit sharing

7.37 In addition to this jurisdictional complexity, the Australian Institute of Marine Science commented that it could:

> document an increased reluctance on the part of some marine access controlling agencies within Australia (including the Commonwealth) to grant permits for biodiscovery research at the Institute. This reluctance has not been due to any environmental grounds, but has rather been over concerns that adequate benefit sharing will not take place, should commercialisation of a discovery occur ... some agencies have attempted to ... require some downstream benefit negotiations in the event of a commercial discovery. In other cases, access has been delayed, restricted or denied.28

7.38 According to the Institute, this has resulted in lost opportunities through stalled projects, sometimes after leads have been identified. In discussions with the Institute, industry indicated a strong preference for negotiating benefit-sharing terms at the outset of a process, rather than having to re-negotiate over such terms later in the process. To address this issue, the Institute recommended that benefit sharing be negotiated at the outset of a project, rather than after a lead has been identified. The Inquiry strongly supports this proposal.

Environmental issues

7.39 Most submissions did not make detailed comments about environmental issues but support for conservation and sustainable use was implicit in many comments regarding the need for continuing access to biological resources. The Australian Institute of Marine Science, for example, described a bioprospecting project involving a species which is extremely rare in nature, resulting in the fishing community placing a voluntary trawling ban on the species' home range, pending formal marine reserve status. Some submissions also commented on the small samples required to enable screening to be carried out.

7.40 CSIRO expressed strong support for the Convention on Biological Diversity and suggested that:

> in dealing with access to biological resources the primary policy principle should be based upon managing the custodianship of biological resources that preserves biological diversity while enhancing the capacity to deliver benefits to all Australians.

28. Sub.50.

7.41 BioProspect stated that its corporate mission statement is based on the Convention on Biological Diversity. Key elements which the company insists be included in any contract are as follows:

a. access to biological resources is strictly on the basis of sustainable access and contingent on agreement to collect only the minimal quantity required to satisfy screening for biological activity;

b. all collections are 'vouchered' and identified by qualified taxonomists -- voucher specimen libraries are maintained by the sovereign State (eg herbaria, museums);

c. no extract collections of endangered or protected species are ever collected from the wild -- collections of protected species only occur if material is sustainably available from cultivated or farmed collections; and

d. any requirement for further quantity of biological material to continue research is from cultivation or farming or, in rare circumstances, from proven sustainable collections from natural sources.

7.42 BioProspect also supported a possible model whereby royalty income derived from bioprospecting would reside in a managed fund or pool and be distributed to protect biodiversity and reward the use of Indigenous knowledge in the sustainable development of that biota.

7.43 Professor L R Webb, Vice-Chancellor, Griffith University suggested that collecting activities should be restricted to professional agencies (such as herbaria and museums) which can house the specimens and undertake taxonomy.

Indigenous knowledge issues

7.44 As in the case of environmental issues, submissions did not address Indigenous/traditional knowledge issues in detail. The Inquiry's informal discussions with industry suggest that Indigenous knowledge is not widely used as a source of information about the potential uses of plants. One explanation offered for this was that, in the absence of clear and fair rules, companies were generally reluctant to pursue the application of Indigenous knowledge to biodiscovery. Companies were concerned that irrespective of the good faith agreements they might make with Indigenous groups, they might be vulnerable to criticism about the adequacy of the agreement unless there were independent standards against which they could be judged. The Inquiry also heard comments that, increasingly, the focus of biodiscovery is on micro-organisms which industry believes did not play a role in Indigenous culture.

7.45 However, the Australian Biotechnology Association stated that Indigenous people's intellectual property rights must be recognised.

7.46 CSIRO suggested two options to recognise the value of Indigenous knowledge about biological resources. One is to create a new property right for all Indigenous knowledge attached to biological resources and negotiate a formula to facilitate benefit sharing. Alternatively, Indigenous knowledge could be declared and validated in a similar way to the declaration of background intellectual property when commercial technology relationships are created. Under this model a more specific benefit-sharing arrangement could be negotiated on a case-by-case basis.

7.47 Professor Barry Conyngham, Vice-Chancellor, Southern Cross University, said that,

> Knowledge held by Indigenous people, if in the public domain, should be open to exploration using the biological resources of Commonwealth areas, ... with the ... proviso that a proportion of any profit arising be attributable to a general fund for the development of all Indigenous people of Australia. Where Indigenous knowledge is not in the public domain [but there is a desire to develop it], this needs to be done through a formal set of protocols.

Ownership and intellectual property

7.48 Several submissions commented on the need to resolve questions of the ownership of biological resources, to ensure industry is able to secure and protect the intellectual property and financial outlay invested in the discovery and development of their inventions. The Inquiry was also advised that industry was unlikely to be willing to enter into joint patenting agreements.

Conclusions

7.49 In developing the proposed scheme in Chapter 2, I have given careful consideration to the issues discussed above.

7.50 The proposed scheme takes into account the major concerns and suggestions in the submissions from industry and research interests, and the terms of reference: to implement a streamlined access regime which, consistent with the principles of ecologically sustainable development, delivers certainty for industry. Accordingly, the proposed scheme includes:

a. proposals for benefit sharing which allow the parties to negotiate a wide range of benefits, while recognising, in view of the uncertain outcomes of biodiscovery work, that monetary benefits, such as royalties, may not be realised;

b. provisions which ensure industry's interest in environmentally sensitive access to biological resources, for initial and subsequent collections;

c. freedom for the parties to negotiate contracts which meet their own interests, while recognising that industry has particular concerns about

issues such as 'exclusivity', up-front negotiations over benefit sharing, and ownership of biological resources, including that providers have clear title to such resources, and that appropriate intellectual property terms can be negotiated;

d. the recommendation that a model contract be drafted to:

   i. promote parties' understanding of the issues,

   ii. facilitate negotiations and agreement between them, and

   iii. promote certainty for industry by ensuring that agreements are based on prior informed consent, mutually agreed terms and adequate benefit-sharing arrangements, which will in turn provide an agreed set of standards against which industry's performance can be judged;

e. recognition of the need for a single point of information about, and administration and decision-making in, the scheme; and

f. recognition of the need to develop a national approach to the issues and a nationally consistent system.

CHAPTER 8: TOWARDS A NATIONALLY CONSISTENT APPROACH TO ACCESS TO BIOLOGICAL RESOURCES

Commonwealth areas not administered by Environment Australia

8.1 The Inquiry identified defence lands and airports as significant 'areas' under the EPBC Act which are not administered by Environment Australia.

Defence lands

8.2 The Department of Defence stated in relation to its holdings that:

> It is Defence's philosophy to facilitate access to the Defence estates, where this does not conflict with the achievement of defence objectives, to any bona fide individual or group wishing to conduct research or having any other genuine scientific interest in the environmental attributes of the area concerned. The mutual benefit from information exchange resulting from Defence's environmental management regimes and studies conducted by other entities assists in the continual review and improvement of Defence's environmental standards.

8.3 Defence stated that it would be prepared to enter into agreements with potential prospector organisations or individuals. Should cases arise where more than one agency or organisation is involved, Defence would agree to Environment Australia coordinating such agreements, provided Defence was consulted throughout the drafting process to ensure agreements with third parties covered:

a. acknowledgement of Defence's prime objectives in terms of the defence of Australia;

b. issues of safety, security and operational needs;

c. requirement in respect of the length of advance notice required for entry to Defence properties;

d. the need to consult with range management staff where a training area is involved; and

e. the rights of Defence to deny access.

Leased Federal Airports

8.4 The Department of Transport and Regional Services supported the development of a regime for regulating bioprospecting on Commonwealth land and leased Federal airports in particular. The Department informed the Inquiry that there is uncertainty over the ownership of biological resources on leased federal airports as the lease between the Commonwealth and the airport lessee company is silent on biological resources. The airport lessee company would also need to be consulted about gaining access to airport areas.

8.5 Legal advice to the Inquiry makes it clear that the Commonwealth owns the biological resources on Commonwealth-owned land in accordance with the principles of common law. As the lease is silent on biological resources it appears that ownership remains with the Commonwealth. The Inquiry is unaware of the terms of the lease, but believes it would be useful for the lease to be read as a whole to see if there are any provisions which might otherwise constrain the Commonwealth from dealing with these resources.

8.6 The views of both agencies support the Inquiry's conclusion that benefit-sharing arrangements are best negotiated by the agency concerned to ensure issues of security, safety and environmental management, together with any conflict with other activities, are dealt with by those who have responsibility for them.

Great Barrier Reef Marine Park

8.7 The Great Barrier Reef Marine Park lies within the Great Barrier Reef World Heritage Area. It was established in 1975 by the Commonwealth Government with the passage of the Great Barrier Reef Marine Park Act 1975. The Park is administered by the Great Barrier Reef Marine Park Authority. Administration involves the cooperation and interaction of various Commonwealth and State authorities under Commonwealth and State legislative and administrative arrangements.

8.8 In relation to the proposed scheme under s301 and its current system for handling access requests, the Great Barrier Reef Marine Park Authority recommended that:

a. the Commonwealth Government and the Authority collaborate in developing guidelines and reporting requirements for projects that require access to resources for commercial purposes;

b. the Authority be included in all negotiations relating to access; and

c. any proposal to regulate access complement, rather than duplicate, the existing permit system within the Authority.

4.33.1 The Inquiry met with Colin Trinder, Director, Ministerial and Parliamentary Liaison, Canberra and Evelyn Scott, Chair of the Commission for Aboriginal Reconciliation and member of the Great Barrier Reef Park Management Authority, but lack of time and logistic problems meant that further meetings

with key personnel to explore all issues in adequate detail could not be arranged in the Inquiry's timeframe. Nevertheless, I agree with the Great Barrier Reef Marine Park Authority's comments, particularly the need for a complementary system. Accordingly, the Inquiry makes the following recommendation.

Recommendation

44. That there be further discussions between the Inquiry Secretariat (the Access Taskforce) and the Great Barrier Reef Marine Park Authority regarding development of streamlined procedures under the s301 regulations to ensure access arrangements for the Great Barrier Reef Marine Park and the Commonwealth are harmonised to the greatest extent possible.

Antarctic Division (Environment Australia)

8.10 Similar issues arise with regard to the Antarctic. In material provided to the Inquiry, Environment Australia's Australian Antarctic Division commented that it 'supports the development of a scheme to control access to these resources and derive a benefit to the Commonwealth'.

8.11 Issues which would need to be taken into account include Australia's obligations under the Antarctic Treaty and the need for the proposed scheme to 'acknowledge the current legislation applying to the Antarctic which require permits and environmental impact assessments. This will also ensure that, in cases where international obligations arise, they will be met'.

8.12 Before considering this recommendation, the Inquiry considered the special status and legislative framework applying to Australia's areas of the Antarctic and Sub-Antarctic.

8.13 This area consists of the Australian Antarctic Territory, the Territory of Heard Island and McDonald Islands, the scientific station on Macquarie Island (administered by Tasmania) and various maritime zones in the Southern Ocean. The Australian Antarctic Division administers all these areas (except Macquarie Island) and it also has a number of ex situ collections of biological specimens, largely taken from these areas.

Legal status

Australian Antarctic Territory

8.14 The legal regime for the Australian Antarctic Territory is provided for under the Australian Antarctic Territory Act 1995. This Act provides for the following laws to apply:

a. Commonwealth laws expressed to extend to the Territory;

b. Ordinances made for the Territory under the Australian Antarctic Territory Act;

c. the laws, other than the criminal laws, in force from time to time in the Australian Capital Territory, so far as they are applicable and not inconsistent with an Ordinance in force in the Territory; and

d. the criminal laws in force from time to time in the Jervis Bay Territory and not inconsistent with an Ordinance in force in the Territory.

Territory of Heard and McDonald Islands

8.15 The regime for the Territory of Heard Island and McDonald Islands is provided for under the Heard Island and McDonald Islands Act 1953 and is the same as outlined above.

Macquarie Island

8.16 Macquarie Island is part of the State of Tasmania. However, the Commonwealth operates a scientific research station on the island.

International obligations

8.17 The area south of 602S is subject to the Antarctic Treaty and the Australian Antarctic Territory is in this area. The Convention on the Conservation of Antarctic Marine Living Resources applies to the area south of the Convergence which, in places, extends north of 602S and includes the Territory of Heard Island and McDonald Islands. Both the Territory of Heard Island and McDonald Islands and Macquarie Island are world heritage properties.

8.18 Commonwealth laws made expressly for the Australian Antarctic Territory and the Territory of Heard Island and McDonald Islands focus largely on protecting the environment and, in the case of the Australian Antarctic Territory, many flow from international obligations arising from Australia's participation in the Antarctic Treaty system. Consequently, Commonwealth laws enacted specifically for the Australian Antarctic Territory are generally to enable Australia to ratify international agreements.

Legislation

8.19 The two most relevant pieces of legislation, from the perspective of accessing biological resources in the Antarctic Treaty area, are the Antarctic Treaty (Environment Protection) Act 1980 and the Antarctic Marine Living Resources Conservation Act 1981. Both Acts, and regulations made under them, implement international obligations.

8.20 Common to both Acts is a requirement to have a permit to undertake various scientific activities, including collecting flora and fauna. Commercial harvesting, such as fishing, requires a permit under the Antarctic Marine Living Resources Conservation Act 1981.

8.21 In addition, most activities also require an environmental impact assessment to be undertaken.

8.22 In the case of the Territory of Heard Island and McDonald Islands, the Environment Protection and Management Ordinance 1987 regulates the territory, which includes the territorial sea. A permit is required for most activities, including collecting fauna and flora.

8.23 Mining and commercial fishing are prohibited within the Territory.

Australian Science Advisory Committee Grants Scheme

8.24 In 1986 the Government established the Australian Science Advisory Committee Grants Scheme to encourage scientists, not employed by government organisations and/or funded primarily by research institutions, to undertake Antarctic research. The Australian Antarctic Division provides secretariat support for the Committee and administers the grants scheme on behalf of the government.

8.25 The primary means of access to the Australian Antarctic Territory and the Territory of Heard Island and McDonald Islands for collecting biological samples is through the Grants Scheme. Where permits are granted for collecting biological resource samples, those samples are to be used for research purposes only. Ownership of biological resource samples collected through this Scheme is retained by the Commonwealth, although custody of some collections is with non-Commonwealth institutions.

8.26 The Inquiry understands that the Committee's form for the next round of applications will include specific reference to commercialisation resulting from collection of biological resource samples for scientific purposes. The Inquiry has been advised, however, that there is no provision, through the Grants Scheme, for bioprospecting.

8.27 The Australian Antarctic Data Centre maintains a database on biological resource samples and where they reside.

8.28 The Inquiry has been advised there are a number of projects currently being undertaken in the Antarctic which involve collection, development and commercialisation of biological resources.

8.29 The Australian Antarctic Division obtained legal advice in 1994 to ensure such activities do not involve any conflict with Australia's international obligations. The Inquiry has been provided with this advice.

8.30 The advice addresses the Antarctic Treaty obligation requiring scientific information to be freely exchanged (Article 3) and how this interacts with commercial obligations, such as commercial-in-confidence requirements in developing products from biological resources and the delayed release of scientific information.

8.31 The advice is, however, particularly important in so far as it makes it clear that commercial activities can be undertaken. This includes the commercialisation of scientific research undertaken on biological resources from within the Commonwealth areas subject to the Antarctic Treaty and the Convention on the Conservation of Antarctic Marine Living Resources.

8.32 The Inquiry has found the advice the Australian Antarctic Division provided a useful adjunct to the broader legal advice specifically obtained to help the Inquiry.

8.33 The Australian Antarctic Division made suggestions to the Inquiry which I have summarised as follows:

a. that any scheme to regulate access to biological resources in the Antarctic needs to take into account Australia's treaty obligations;

b. that any scheme should acknowledge the current legislation applying in the Antarctic which requires permits and environmental impact assessments and ensure that, in cases where international obligations arise, they will be met;

c. that as the Commonwealth currently owns all samples collected In the Australian Antarctic Territory and in the Territory of the Heard Island and McDonald Islands, provision may need to be made to allow ownership and/or rights to be assigned, in whole or in part to the body involved if the samples are to be used to generate commercial rights; and

d. prospecting for biological resources in areas administered by the Australian Antarctic Division should continue to be subject to scientific assessment through the Australian Science Advisory Committee process.

8.34 I have considered these points and the overall special status of Commonwealth Antarctic areas together with the legal advice provided to me and I agree with each suggestion.

8.35 In considering Australia's legislative and administrative arrangements for managing Commonwealth Antarctic areas I have also borne in mind the relationship of regulations to be made under s301 of the EPBC Act and existing Commonwealth law and the Inquiry's terms of reference to, in part, recommend a scheme which is streamlined and provides certainty to Industry.

8.36 From this it is clear that for there to be consistency, certainty and ease of administration, there must be harmonisation between the provisions of the scheme and the Antarctic legislation currently administered by the Australian Antarctic Division.

Recommendations

45. That, subject to any international obligations, the access scheme, as recommended by the Inquiry, apply to Australian Antarctic or SubAntarctic areas as far as practicable.

46. That the Minister for the Environment and Heritage undertake necessary legislative amendment to the Antarctic Treaty (Environment Protection) Act 1980, the Antarctic Marine Living Resources Conservation Act 1981 and such subordinate legislation as is necessary to achieve this and ensure harmonisation with the scheme established under s301 of the EPBC Act.

47. That, in applying the elements of the recommended access scheme, the Australian Science Advisory Committee continue to have a role in assessing applications for access to biological resources.

48. That, where applications are made for bioprospecting in Australian Antarctic or SubAntarctic Commonwealth areas, the Australian Antarctic Division negotiate benefit-sharing contracts.

49. That staff involved in such negotiations be independent of staff involved in considering the grant of an access permit.

50. That the principle of an integrated permits system, as introduced in the administration of the EPBC Act, apply to administrative arrangements for applications for access to biological resources in Antarctic or SubAntarctic Commonwealth areas.

Norfolk Island

8.37 The status of Norfolk Island is unique among Australia's Territories: it is self-governing with a mixture of responsibilities which include local, state and some Commonwealth government matters, with the Commonwealth retaining rights in relation to certain matters.

8.38 It is small (3529 hectares), distant (1700 kilometres northeast from Sydney) and has 1350 permanent residents.

8.39 Biologically the island has more in common with New Caledonia and New Zealand than with mainland Australia. A significant degree of endemism exists in the waters around the island. For the purposes of the EPBC Act some 51.8 per cent of the island is a Commonwealth area. These lands include roads, verges, public reserves, national parks and leased land. In such a small area, with Crown lands (Commonwealth areas) scattered throughout it, action taken in regard to Commonwealth areas is likely to impact on the remainder of the island.

8.40 The Norfolk Island Government has stated it is concerned that:

> ... any regime to control access to biological resources in and around Norfolk Island ensures:
>
> - biodiversity conservation;
> - maximum benefits for the people of Norfolk Island; and
>
> genuine involvement of the government and the people of Norfolk Island in determining access to and exploitation of biological resources on and around Norfolk Island.

8.41 The Government has argued that any potentially valuable biological resource found in a Commonwealth area is just as likely to be present in an adjacent non-Commonwealth area or in a leased area. Accordingly, in its view it would be inequitable and inappropriate for access to that resource and the distribution of benefits from it to be solely or largely a matter for the Commonwealth. This is particularly so as, in its view, Commonwealth agencies as land owners are custodians of that land in the interests of the island and its people.

8.42 I find some force to these arguments and see some limited parallels with the joint management and land ownership arrangements at Kakadu. The Norfolk Island Government also points out that:

- few, if any, terrestrial biological resources are likely to be restricted to a 'Commonwealth area';
- many Crown lands on Norfolk which are presently 'Commonwealth areas' will not be Commonwealth Crown lands in the near future;[29]
- the management of all Crown lands, irrespective of whether they are Commonwealth or territory lands, is primarily for the benefit of the environment (including heritage) and people of Norfolk Island; and
- (control of access should be) consistent with the proposed fishery management regime.

8.43 In these circumstances it suggests that control of access to biological resources on and around the island should be primarily the responsibility of the Government of Norfolk Island in consultation with the Commonwealth. It is also acknowledged that the island has limited technical and legal resources.

8.44 In my view, a fair and equitable approach would be for any application for access to the terrestrial non-exotic biological resources of the island to be on the basis of a jointly negotiated benefit-sharing agreement covering the land on the island over which the Commonwealth and Norfolk Island Governments exercise ownership or similar control.

29. The joint communique, Commonwealth/Norfolk Island Inter Governmental Meeting, 9 June 2000. Senator MacDonald advised that, in principle, he supports the withdrawal of the Commonwealth from the ownership of certain Crown land, subject to a number of planning and other matters being finalised. Senator MacDonald advised that a number of matters needed to be resolved with various Commonwealth portfolios, including environment and heritage agencies, before any transfers could take place.

8.45 Signatories to this agreement would be both governments and the proponent, with any monetary benefits payable to the resource owners divided equally. Non-monetary benefits would be as negotiated. In the case of the Commonwealth, the contract should specify that any amount not payable to the Norfolk Island Government should be paid into the Trust Fund of the Director of National Parks for the conservation and protection of biodiversity on the island. As with other applications for access to Commonwealth areas, an access permit would be required.

8.46 To facilitate a joint management approach, regulations established under s301 would need to be drafted to allow the Minister to approve the grant of a permit in these circumstances.

8.47 As the Department of the Environment and Heritage is responsible for the management of the Norfolk Island National Park and Botanic Gardens, it would be appropriate for it to lead the negotiations on behalf of the Commonwealth and the Department of Transport and Regional Services and to represent the interests of any other Commonwealth agencies with interests in land on the island.

8.48 In relation to the island's marine environment the Norfolk Island Government has drawn my attention to the fact that all the sea around the island to low water, is under Commonwealth jurisdiction and will be a Commonwealth 'marine area' under the EPBC Act.

8.49 It has further advised that the Commonwealth (through the Australian Fisheries Management Authority) and the Norfolk Island Government are moving towards transferring management responsibility for the Norfolk Island Fishery to Norfolk Island. The Norfolk Island community has exclusive rights to this fishery, which is defined by a box around the island providing an area of approximately 67 x 40 nautical miles.[30]

8.50 In light of this, the Norfolk Island Government has recommended to the Inquiry that it would be consistent for Norfolk Island to be responsible for controlling access to marine biological resources within that same geographical area and for the island to be the recipient of any benefits.

8.51 The Department of Transport and Regional Services has also advised the Inquiry about these proposed arrangements and provided additional detail. It confirmed the transfer would give Norfolk Island as much autonomy as possible in managing the fishery. It would also enable management of a 'recreational fishery' in which some sale of fish takes place. This autonomy would not, however, extend to control over foreign fishing vessels or certain tuna or tuna like species.

8.55 Having considered these arguments, I have concluded that, in principle, the benefits flowing from access to the marine biological resources around the island ought to flow to the island and that it would be sensible for the area

30. The Norfolk Island Fishery is bounded by: 28º38’S, 167º40’E; 28º38’S,168º20’E; 29º45’S, 167º40’E; 29º45’S, 168º20’E.

concerned to be consistent with the area defined as the existing Norfolk Island Fishery. In my view the Government of Norfolk Island should therefore be entitled to enter into a benefit-sharing agreement in respect of access to that resource.

8.53 Again, the regulations may need to be drafted to enable such an agreement to be made. The safeguards inherent in the subsequent consideration by the Minister of an access permit would also apply and would include the Minister's satisfaction that prior informed consent had been obtained from the Norfolk Island Government.

Recommendation

51. That benefit-sharing agreements with proponents wishing to access the biological resources on lands owned, leased or otherwise controlled by both Governments on Norfolk Island be negotiated jointly.

52. That the Minister for the Environment and Heritage agree to the principle that benefits under any such agreement be for the benefit of the people of Norfolk Island and its environment.

53. That access to the marine biological resources found in the area known as the Norfolk Island Fishery be reserved for the benefit of the people of the Island with benefit agreements to be negotiated by the Norfolk Island Government.

54. That, in consequence, the regulations under s301 of the EPBC Act be framed to allow for the special circumstances of the island and that the Department of the Environment and Heritage consult with the Department of Transport and Regional Services and the Norfolk Island Government over the administrative arrangements for implementing the regulations.

8.54 The Inquiry Secretariat has discussed the substance of these recommendations in broad terms with officials of the Norfolk Island Government and believes they would be supported.

The views of the States about access issues and a nationally consistent approach

8.55 During the Inquiry I sought to ensure that State and Territory governments had the opportunity to contribute to developing a nationally consistent approach to access to biological resources. I was particularly concerned to understand their views and, as far as possible, to take them into account when drawing up my recommendations. An important goal was to design an access scheme for

Commonwealth areas which would be, as far as possible, compatible with the existing and future State and Territory access schemes.

8.56 I discovered that not all States were engaged with the issue. The Northern Territory advised that the issue was not a priority and that it would not make a submission.[31] New South Wales advised that it had not developed a policy position and accordingly that it would be premature to make a submission. Nevertheless, Queensland, South Australia, Victoria, the ACT, Western Australia, Tasmania and Norfolk Island made submissions and/or participated in discussions. These were of great value and I thank those involved for their thoughtful and frank contributions.

8.57 The views of the States, on the value of a nationally consistent a pproach and the work of the Inquiry, are briefly as follows.

Queensland

8.58 Queensland has advised that it proposes to develop a State-based bioaccess policy over the next 12 months. State officials emphasised the importance of a consistent policy at State and Commonwealth levels and the value to Australia of a consistent policy across all jurisdictions. Queensland emphasised its willingness to achieve such a goal and echoed sentiments made to the Inquiry by a number of States that, to date, progress under existing mechanisms has been frustratingly slow.

8.59 This frustration was made all the more evident given the Queensland Government's success in creating the conditions under which the biotechnology industry in that State is growing. Queensland also drew to my attention the fact that over recent years considerable biodiscovery work has been undertaken through an effective partnership between the Queensland Herbarium and Museum, AstraZeneca and Griffith University and that a benefit-sharing arrangement between the Queensland Government and the Australian Institute of Marine Science is being finalised.

8.60 Queensland's concern about the slowness in developing a nationally consistent policy is in line with sentiments various representatives of industry, science and governments expressed to me.

South Australia

3. South Australia has been giving considerable thought to the issue and has prepared a comprehensive Discussion Paper on the issue of access to its biological resources. The paper, prepared by a working group drawn from a number of government agencies, sets out the issues and identifies options. The paper is currently with the South Australian Minister for Environment and Heritage for consideration.

31. The submission received was from the Fisheries Division, Northern Territory Government

8.62 The Inquiry met with members of this group and has considered an informal version of the discussion paper. From this it is apparent that South Australia's direction of thought closely parallels that of the Inquiry. There is a common understanding of the basic issues and principles relating to benefit sharing, the Convention on Biological Diversity, the treatment of public and private lands, pressures on ex situ collections, the value of a single point of contact, approaches to benefit sharing in relation to Indigenous-owned lands and use of Indigenous knowledge. From this understanding, the South Australian working group has developed a range of possible options -- some of which share key elements with the access regime recommended by this Inquiry.

Victoria

8.63 In Victoria's view, 'any national approach to access to biological resources should be developed in partnership with States and Territories and should include appropriate direct consultation between the Commonwealth, States and Territories rather than relying on submissions to a Commonwealth Inquiry'.

8.64 Victoria's submission went on to say that, 'At this stage, Victorian agencies have not developed or put any proposals to government regarding the conferring of ownership of biological resources, including those on private land. As such, Victorian agencies are cautious about supporting any uniform national approach without considerable further consultation with the Commonwealth, States and Territories governments.'

8.65 Since receiving Victoria's submission, I have received a copy of the Victorian Parliament's Environment and Natural Resources Committee Report of its Inquiry into Utilisation of Victorian Native Flora and Fauna. The report was tabled on 2 June 2000 and seeks to inform thinking on a variety of issues, including that of access to genetic resources in Victoria. It recommends:

> 11.1 That national strategies be developed to ensure a consistent approach to the granting of access rights to the genetic material of Australian native species, and to this end, the Victorian Government actively pursue a common approach through the Australian New Zealand Conservation Council and other appropriate joint ministerial councils.
>
> 11.2 That the Victorian Government develop bilateral/multilateral agreements relating to the use of the States' natural flora and fauna resources, in accordance with national strategies.
>
> 11.3 That the Victorian Government support and pursue consistency of codes of practice and regulations in the relevant national forums and explore mutual accreditation of regulatory controls of other states.

8.66 The report, at page 386, argues the need for a national approach but one which takes into account the benefits of Australia's relatively cost-free access to exotic species and the controlled sharing in the benefits of the genetic resources of the country which could be gained by use of plant breeders' rights, royalty payments and contractual arrangements.

8.67 The Victorian Minister for Environment and Conservation has six months to respond to the Committee's recommendations.

Western Australia

8.68 The Western Australian Government sees the Inquiry as having potentially significant implications for that State.

8.69 In its view, access arrangements for Commonwealth lands in Western Australia and waters under Commonwealth jurisdiction beyond State waters should be compatible with the Western Australian regime. Any Commonwealth protocol for bioprospecting accordingly needs to be developed in close consultation with the States and Territories.

8.70 Western Australia has bioprospecting guidelines for vascular plants and is developing guidelines for agencies to deal with requests for Western Australian biota.

8.71 In Western Australia's view, bioprospecting for material in Commonwealth areas needs to be developed in close consultation with relevant State organisations. State institutions need to be involved in any exploitation of biota and have access to basic information, particularly in museums, herbaria, and conservation and fisheries agencies.

8.72 Western Australia suggested the Commonwealth State Working Group as an appropriate avenue for further consultations and expressed some concern about the lack of a State representative on the Inquiry Reference Group.

Tasmania

8.73 The Tasmanian Government advised that while it does not have a specific policy on access to biological resources, it recognises the issue as one of increasing interest and importance to the State and made a number of important points. In summary these were that:

a. it is critical that policies on access to biological resources are consistent across all levels of government;

b. it is preferable that any future State policy be consistent with Commonwealth policy;

c. a key outcome of the Inquiry should be development of a coordinated and nationally consistent approach facilitating access;

d. policies should provide equity of access for all Australian organisations with State-based organisations not discriminated against in favour of Commonwealth organisations;

e. a balance needs to be struck between protecting Australia's biodiversity, ecologically sustainable use, community benefit, facilitated access and promotion of bioindustry development; and

f. Tasmania supports the principles established by the Commonwealth State Working Group.

8.74 The Tasmanian Government concluded its submission by urging the formalising of nationally agreed principles for managing access to and use of Australia's biological and genetic resources for biodiscovery purposes and suggested this could be done through an intergovernmental agreement

Australian Capital Territory

8.75 The ACT suggested that the Commonwealth State Working Group principles provide a basis for developing related Commonwealth policy.

Norfolk Island

8.76 Norfolk Island provided a detailed submission which reflects its unique relationship with the Commonwealth (see discussion at paragraphs 8.37 to 8.54 above). The Government of Norfolk Island agrees with the principle of a nationally consistent approach in which broad principles for managing access are developed, but which recognises that individual jurisdictions will determine their own access management regimes, as advocated by the Commonwealth State Working Group on access to biological resources.[32]

Conclusion

8.77 It is clear, therefore, that most States and Territories support a nationally consistent approach. Some support has been expressed for the Commonwealth State Working Group, although this is tempered by concern about a continuing lack of progress.

Recommendations

55. That the Minister for the Environment and Heritage endorse the Commonwealth State Working Group principles.

56. That further consultations be held with State and Territory governments to address the broader issue of a nationally consistent approach cross jurisdictions.

57. That the Minister for the Environment and Heritage review the function of the Commonwealth State Working Group and consider steps necessary to increase the involvement of key stakeholders and ensure any future work done by that body is undertaken with defined outcomes and within agreed timeframes.

32. Commonwealth State Working Group on *Managing Access to Australia's Biological Resources: Developing a Nationally Consistent approach*, a discussion paper, October 1996.

Applying the access scheme in the marine environment

8.78 Australia's marine environment, in which the Commonwealth exercises power, consists of four zones. These are the:

a. Territorial Sea, a 12 nautical mile wide strip seaward of the Territorial Sea baseline (the low water line with linear provisions for indentations and rivers, bays etc);

b. Contiguous Zone, which is adjacent to the Territorial Sea and extends to 24 nautical miles from the Territorial Sea baseline;

c. Exclusive Economic Zone, an area extending out to 200 nautical miles from the Territorial Sea baseline; and

d. Continental Shelf, which is the seabed out to 200 nautical miles or to the outer edge of the continental margin as internationally defined (see diagram in Appendix 12).

8.79 Within the Territorial Sea the strip out to three nautical miles is referred to as the Coastal Sea. Title to the seabed and power to legislate within the Coastal Sea was vested in the adjacent State or Northern Territory by the Coastal Waters (State Powers) Act, Coastal Waters (Northern Territory Powers) Act, Coastal Waters (State Title) Act, and the Coastal Waters (Northern Territory Title) Act. This means each State owns the seabed and is able to exercise authority over the Coastal Sea.

8.80 The Australian Fishing Zone covers, with some exceptions, the waters from three nautical miles out to the outer limits of the exclusive economic zone.

8.81 Section 525(1) of the EPBC Act includes, in the definition of 'Commonwealth areas', the:

a. coastal sea of Australia or an external Territory;

b. continental shelf and waters and airspace above it;

c. land, sea or seabed in a Commonwealth reserve; and

d. waters of the exclusive economic zone including the seabed beneath it and the airspace above it.

8.82 Section 525(3) of the EPBC Act, however, has the effect of excluding from the definition of 'Commonwealth areas' waters within the Territorial Sea to a distance of three nautical miles outwards from the Territorial Sea Baseline and

the waters on the landward side of that Territorial Sea, that is, the coastal sea of the States and Territories.

8.83 So far as marine areas are concerned, therefore, regulations under s301 of the EPBC Act deal with access to biological resources in the area between three nautical miles from the Territorial Sea Baseline to the outer limits of Australia's exclusive economic zone or its continental shelf (whichever is further).

Constraints on uniform application of a Commonwealth access regime in Commonwealth offshore waters

8.84 The Inquiry has identified factors affecting application of any Commonwealth access scheme to these Commonwealth waters. The factor with the greatest potential impact is the bilateral arrangements negotiated from time to time between the Commonwealth and individual States and Territories for managing fisheries under the Fisheries Management Act 1991. Under some of these arrangements the Commonwealth has passed control of large parts of the marine biota in Commonwealth areas to the States and Territories. While the purpose of the legislative arrangements is management of fisheries, the definitions used are sufficiently extensive as to apply to the marine biota generally.

8.85 This potentially affects the ability of an access scheme established under s301 of the EPBC Act to apply uniformly across Commonwealth waters. It raises the likelihood that any bioprospector seeking access to Commonwealth waters would have to negotiate access and benefit-sharing agreements with a variety of Commonwealth and State bodies, depending on where access is sought, the nature of the marine biota to be sampled and the methods to be employed.

8.86 In the absence of a nationally consistent approach across jurisdictions, such arrangements would introduce high levels of complexity and associated transaction costs to industry.

8.87 In addition, such complexity has the potential to adversely affect the ability of Commonwealth statutory bodies, such as the CSIRO and the Australian Institute of Marine Science, to conduct activities in Commonwealth waters. I have discussed these problems below and made recommendations to resolve or reduce the problems.

8.88 Without such action, the unintended consequence of earlier Commonwealth legislation would be to impede establishment and operation of a streamlined access scheme under the EPBC Act.

8.89 Only four submissions adverted to the situation. The Director of Fisheries of the Northern Territory wrote that:

> In 1995 the Commonwealth and Northern Territory entered into an arrangement under the Offshore Constitutional Settlement provisions of the respective fisheries legislation. The effect of this agreement is that the fishing

> for all bony and cartilaginous fish, all aquatic invertebrates, all marine algae, and all seagrasses, with exception of some tuna species and prawns, out to the Australian Fishing Zone boundary are now under Northern Territory jurisdiction. Fishing includes the taking of aquatic life for sale, research and related purposes.

8.90 Agriculture Fisheries and Forestry -- Australia stated that:

> Commonwealth legislation in these matters varies in its impact on control over and ownership of biological resources. For example: ...
>
> - some Commonwealth legislation for resource management and conservation activities in certain circumstances extends beyond Commonwealth lands and waters, and involves matters falling within areas of State jurisdiction, eg fisheries management of tuna species. In such cases, separate agreements exist between the Commonwealth, States and Territories as to how they interact in such matters, eg Offshore Constitutional Settlement.
>
> - Commonwealth legislation may establish or reassign access rights to biological resources, eg in the case of fisheries legislation access rights to some public resources are granted.

8.91 The Australian Institute of Marine Science submission outlined the nature of the Offshore Constitutional Settlement, the Fisheries Management Act, and arrangements under that Act and went on to say:

> If the current general arrangements persist, there is complete overlap and potential conflict with any regulations over Commonwealth marine areas that may be attempted under the EPBC Act.

8.92 Attachment 2 to the Institute's submission was the text of a fisheries arrangement between Western Australia and the Commonwealth, conferring fisheries management rights on Western Australia of a similarly general nature to those referred to in the Northern Territory.

8.93 In light of this, the Inquiry sought legal advice. I received this advice in the second week of June 2000. This was after the conclusion of the Inquiry's public hearings and consultations and it has not been possible therefore to discuss the issues with relevant parties.

8.94 The advice confirms that the situation outlined by the Northern Territory is correct and also provides guidance on the relationship between the EPBC Act and the Fisheries Management Act 1991.

8.95 The Inquiry has established that, to varying extents, similar arrangements exist with other States, in particular Victoria, Tasmania, Queensland, South Australia and Western Australia.

8.96 The Inquiry considered the potential implications of this position for the operation of a Commonwealth scheme to regulate access to biological resources in the waters of Commonwealth areas as defined in the EPBC Act. Before discussing those implications, however, it is necessary to consider the relationship between the two Acts.

EPBC Act and the Fisheries Management Act 1991

8.97 The Fisheries Management Act is part of legislation which implements the 1979 Offshore Constitutional Settlement. This Settlement is an inter-governmental agreement concluded at the Premiers' Conference in 1979 dealing with a range of offshore issues. The relevant offshore issue here is the management of fisheries. The description of the agreed arrangements between the Commonwealth and the States includes the following:

> The legislation [to be passed by the Commonwealth Parliament, based on referred powers under section 51(38) of the Constitution] will also give each State powers outside the territorial sea in respect of port-type facilities, underground mining extending from land within a State, and fisheries. The power with respect to fisheries will apply to fisheries that, under an arrangement to which the Commonwealth is a party, are to be managed in accordance with the laws of the State concerned, under the offshore fisheries scheme described below.33

8.98 The section of the arrangements headed 'Offshore fisheries' includes the following:

> The new arrangements will enable a single fishery to be regulated by the one set of laws, Commonwealth or State, as agreed between the Commonwealth and the State or States concerned, and they will provide for the establishment of Fisheries Joint Authorities.
>
> By agreement of the Governments concerned, a particular fishery may be assigned to the management of one of these Joint Authorities. Alternatively, it may be assigned to the administration of the Commonwealth alone or a State alone, if that is agreed.

8.99 One of the Commonwealth Acts giving effect to the Offshore Constitutional Settlement, the Coastal Waters (State Powers) Act 1980, empowers States to make laws applying to fisheries in Commonwealth waters in certain circumstances. Section 5 provides:

> The legislative powers exercisable from time to time under the Constitution of each State extend to the making of:
> (c) laws of the State with respect to fisheries in Australian waters beyond the outer limits of the [three nautical mile] coastal waters of the State, being laws applying to or in relation to those fisheries only to the extent to which those fisheries are, under an arrangement to which the Commonwealth and the State are parties, to be managed in accordance with the laws of the State.34

33. Under these arrangements the Northern Territory is treated as a State for the purposes of the Offshore Constitutional Settlement

34. The Commonwealth made similar provision in relation to the legislativc powers of the Northern Territory Legislative Assembley by paragraph 5(c) of the *Coastal Waters (Northern Territory Powers) Act 1980*.

8.100 The Fisheries Management Act [35] allows the Commonwealth to make an arrangement with a State (or the Northern Territory) that a fishery is to be managed in accordance with the law of the Commonwealth or in accordance with the law of a State. An arrangement under either of these provisions is made by instrument approved by the Governor-General and the Governor of the State concerned, and published in the Gazette.[36] A similar procedure is followed to terminate such an arrangement.[37]

8.101 Under the Fisheries Management Act arrangements do not set out the regulatory requirements applying to fishing in a particular fishery. Rather, the arrangement defines the fishery concerned, and the State or Commonwealth legislation that applies to that fishery which determines what may or may not be done in connection with that fishery.

8.102 Arrangements under Part 5 of the Fisheries Management Act have been entered into with all the States and the Northern Territory. Some are specific to a single type of fish or to groups of fish. Arrangements include situations where Commonwealth law applies, State law applies or management is by Joint Management Authority. Some arrangements are more general in their application.

8.103 The Fisheries Management Act prohibits the taking of fish otherwise than in accordance with a statutory fishing right, licence or permit granted under the Act. Its definitions of fish, fishery and fishing is so wide as to encompass almost all marine biota with some exceptions, including marine reptiles and mammals.

8.104 Of the five 1995 arrangements between the Commonwealth and the Northern Territory, one is general in character. This is the Arrangement between the Commonwealth and Northern Territory in relation to the Fishery for Fish and other Aquatic Life Resources in Waters Relevant to the Northern Territory. This arrangement applies to the Northern Territory coastal waters and the relevant waters of the Australian Fishing Zone. It provides:

> The Commonwealth and Territory hereby arrange that the fishery to which this Arrangement applies is to be managed in accordance with the law of the Territory being the fishery, for any purpose other than recreation, in waters relevant to the Northern Territory ... for all species of fish and aquatic life of the Class Osteichthyes (bony fish) and Class Chondrichthyes (cartilaginous fish), all species of aquatic invertebrates, all marine algae of the Divisions Clorophyta (green algae), Rodophyta (red algae) and Phaeophyta (brown algae) and all seagrasses of the Families Hydrocharitaceae, Posidoniaceae, Zosteraceae and Cymodoceaceae except for [listed classes of fish, including a number of species of tuna and tuna-like fish, billfish, fish taken as bait by a person for his or her own use in accordance with a fishing concession from the Australian Fisheries Management Authority, decapod crustacea of certain families except in certain circumstances, fish of the Class Osteichthyes and the Class Chondrichthyes taken in the area of the fishery in accordance with a licence from the Northern Territory Fisheries Joint Authority].

35. Sections 71 and 72.
36. Section 74.
37. Section 75

8.105 These arrangements do not vest in the Northern Territory Government title to the water column or the seabed, or to any associated resources, but have the effect that fisheries named are to be managed in accordance with the law of the Northern Territory. Furthermore such law is given effect by Commonwealth law.

8.106 This briefly explains how the Northern Territory is able to apply its fisheries law to Commonwealth marine areas adjacent to it and how similar broad arrangements among the Commonwealth and States can produce the same result.

8.107 The effect of these arrangements appears to be that any scheme of regulations under s301 of the EPBC Act runs the risk of conflicting with the application of State or Territory law in areas where they exist.

Primacy

8.108 Legal advice states that, in the event of any inconsistency with either the provisions of State or Territory Law or of the Fisheries Management Act, regulations made under s301 of the EPBC Act cannot prevail. This is because regulations under s301 are Commonwealth delegated legislation and therefore cannot impliedly repeal an earlier Commonwealth Act where there is no specific provision in an Act to this effect and where State or Territory law has effect by virtue of a Commonwealth Act. The advice indicates there is no such provision in any Act, including the EPBC Act, authorising regulations under s301 of the EPBC Act to repeal the Fisheries Management Act or to repeal the Coastal Waters (State Powers) Act or the Coastal Waters (Northern Territory Powers) Act (the authority for the extension of State powers to Commonwealth waters).

Commonwealth marine protected areas

8.109 There is an exception to the general position I have just set out which relates to Commonwealth Marine Protected Areas. Legal advice is that the accepted position in government has been that the National Parks and Wildlife Conservation Act and the Fisheries Management Act operate concurrently in these areas but, to the extent of any inconsistency, the National Parks and Wildlife Conservation Act prevails. This is expected to continue under the EPBC Act but further legal advice will be obtained to confirm this.

8.110 The primacy of Commonwealth reserve legislation/regulations stems \
from the fact that they contain provisions which amend other Commonwealth legislation. In the EPBC Act this intention is illustrated at s354, s356, s357 and s362. Thus it would be reasonable to conclude that no Fisheries Management Act arrangement could extend to any Commonwealth reserve where it would conflict with the provisions of the EPBC Act and related regulations.

Inconsistency between the Fisheries Management Act and regulations under s301 of the EPBC Act

8.111 In light of this, the Inquiry considered the extent to which there might be inconsistency between the EPBC Act and the Fisheries Management Act and State law. The legal advice in relation to this point focused first on operations under the direct application of the Fisheries Management Act and then on operations conducted under State law by way of an arrangement entered into under the Fisheries Management Act.

8.112 Advice suggested that there was no necessary inconsistency but a regulation under s301 was likely be inconsistent with the Fisheries Management Act if it limited the right to fish in accordance with an authority granted under that Act. In addition, it suggested that it might be arguable that the Fisheries Management Act is intended to provide a comprehensive scheme for regulating fishing in fisheries to which the Act applies, and that it therefore 'covers the field'. It also suggests that it could be argued, from s33 and paragraph 17(6)(i) of the Fisheries Management Act, that the Act is intended to cover the field with regard to fishing for scientific research.

8.113 The advice went on to suggest that, on the other hand, regulations under s301 of the EPBC Act that relate to matters outside the scope of the Fisheries Management Act would not be inconsistent with that Act. It took the view that, in general terms, the Fisheries Management Act is concerned with fishing, that is, searching for and taking fish, and engaging in activities with a view to finding and taking fish, as well as processing, carrying and trans-shipping fish.

8.114 Thus the Fisheries Management Act is not concerned with the end-use of 'fish' that have been taken, nor the accrual of benefits as a result of that use. This stands in contrast to any regulations under s301 of the EPBC Act which would be concerned with end use, as they would relate to:

a. the process whereby samples from individual organisms are gathered from Commonwealth areas;

b. determination of their genetic and biochemical make-up;

c. assessment of their potential use; and

d. determination of benefits that may arise.

8.115 This last difference, that is the deriving of benefits and the sharing of those benefits, is particularly significant as it represents one half of the recommended regulatory scheme.

8.116 In considering the issue of potential overlap between the Fisheries Management Act and the operation of any scheme introduced under s301 of

the EPBC Act, the Inquiry's view is that the two pieces of legislation are intended to fulfil separate purposes: one exists to regulate the sustainable management of Australia fisheries; while the other is aimed at enabling bioprospecting and sharing the resulting benefits. I do not see any inherent conflict between these purposes. In coming to this view I have noted the objectives of the Fisheries Management Act at s3 which states:

> 1. The following objectives must be pursued by the Minister in the administration of this Act and by the Australian Fisheries Management Authority in the performance of its functions:
>
> a. implementing efficient and cost-effective fisheries management on behalf of the Commonwealth; and
>
> b. ensuring that the exploitation of fisheries resources and the carrying on of any related activities are conducted in a manner consistent with the principles of ecologically sustainable development and the exercise of the precautionary principle, in particular the need to have regard to the impact of fishing activities on non-target species and the long-term sustainability of the marine environment; and
>
> c. maximising economic efficiency in the exploitation of fisheries resources; and
>
> d. ensuring accountability to the fishing industry and to the Australian community in Australian Fisheries Management Authority's management of fisheries resources; and
>
> e. achieving government targets in relation to the recovery of the costs of the Australian Fisheries Management Authority.
>
> 2. In addition to the objectives mentioned in subsection (1), or in section 78 of this Act, the Minister, the Australian Fisheries Management Authority and Joint Authorities are to have regard to the objectives of:
>
> a. ensuring, through proper conservation and management measures, that the living resources of the Australian Fishing Zone are not endangered by over-exploitation; and
>
> b. achieving the optimum utilisation of the living resources of the Australian Fishing Zone;
>
> but must ensure, as far as practicable, that measures adopted in pursuit of those objectives must not be inconsistent with the preservation, conservation and protection of all species of whales.

8.117 With this in mind, it is essential that the administration of the two Acts be harmonised to ensure each can be administered concurrently with the other. This is reflected in my recommendation.

Recommendation

58. That the Department of Environment and Heritage, as administering agency for the EPBC Act; and Agriculture, Fisheries and Forests -- Australia, as the agency with responsibility for the Fisheries Management Act 1991, together with other relevant Commonwealth agencies including the CSIRO and the Australian Institute of Marine Science, conduct discussions to establish a Commonwealth position on:

a. the concurrent operation of s301 of the EPBC Act and the Fisheries Management Act and seek endorsement of their respective Ministers to that position, and

b. establish a Commonwealth position in relation to exclusion of activities otherwise dealt with in regulations made under s301 of the EPBC Act from matters to be covered by future negotiated, or renegotiated arrangements with States and Territories under the Fisheries Management Act.

59. In the event that this is not possible or desirable, the Minister for the Environment and Heritage should consider amending the EPBC Act to ensure both Acts may operate concurrently and the distinction between action necessary for sustainable fisheries management and action necessary to regulate access to biological resources is clarified.

Existing fisheries management arrangements with States and Territories

8.118 I have also considered the implications of the various Commonwealth/State fisheries management arrangements. If operation of some of these arrangements is understood to mean the relevant State authority has responsibility to determine and regulate access to biological resources in the terms set out in this report, the practical effect may be to exclude the operation of regulations under s301 of the EPBC Act from the relevant Commonwealth waters.

8.119 Equally, it may be that some State authorities see their role under such arrangements as focused on the sustainable management of fisheries in its broader sense. They may not see management and regulation of bioprospecting as their role if this activity has no effect on the sustainable use of the resource. In such cases, s301 regulations may be framed to ensure no conflict arises.

8.120 It is not the Inquiry's intention to disturb the operation of the Offshore Constitutional Settlement as it relates to fisheries management. Rather, the Inquiry is looking at ways to achieve concurrent fisheries management and regulation of access to biological resources. To this end, there is a need for discussions between the Commonwealth and the States to obtain their views on regulating biological resources in light of the proposed Commonwealth scheme and development of access policy in each State.

8.121 The need for discussions was touched on in the Victorian Government's submission. In relation to the Offshore Constitutional Settlement, the submission said that the Inquiry should be aware of settlement arrangements between the States and the Commonwealth for harvesting wild fisheries resources and that 'any proposed recommendations by the Inquiry for changes to the current Settlement arrangements should be discussed with the States and Territories'.

8.122 While supporting such discussions, I consider they should be conducted a part of a broader discussion about development of a nationally consistent approach by the Commonwealth and the States and Territories to regulate access to biological resources.

8.123 Indeed, the current marine situation strongly illustrates the value of a broader approach. At present, if biotic material straddles the three-mile limit, access is determined by the adjacent State or perhaps the Commonwealth, depending on which side of the boundary it is found and on which set of legal instruments applies within each jurisdiction. If the material floats along the coast it may straddle the boundary between States or Territories with similar effect. The material is not affected by human boundaries but the rules under which it is accessed and under which benefit sharing is negotiated are. In such circumstances it may be equitabla for benefits derived from accessing material in the water column to be shared with an adjoining jurisdiction. These facts support the need for a consistent and cooperative approach across jurisdictions.

8.124 This latter need is supported by the Western Australian Government which makes the point that Commonwealth lands and waters should not be considered in isolation from the ecosystems and bioregions in which they are located and which will almost inevitably involve surrounding or adjacent areas under State jurisdiction. The existence of Commonwealth marine reserves adjacent to many of the States adds weight to this point.

Recommendation

60. That the Department of the Environment and Heritage discuss with State and Territory authorities the scope for concurrent operation of regulations under s301 of the EPBC Act in Commonwealth areas where States and Territories have arrangements under the Fisheries Management Act affecting access to biological resources.

61. That, with the concurrence of the State or Territory involved, the Australian Fisheries Management Authority be invited to participate in these discussions.

Ex situ collections

8.125 The CSIRO has helped the Inquiry through its active involvement in the process and with its comprehensive submission. This has given me a clearer picture of the complex issues facing holders of ex situ collections. I have also been assisted in my understanding by the contributions from the Chair of the Council of Heads of Australian Herbaria and the Australian National Botanic Gardens.

Ownership

8.126 A common concern of the holders of ex situ collections, and one raised by a number of submissions, is doubts about the ownership of elements of ex situ collections. Legal advice was sought in relation to this and has been discussed at Chapter 4. There is no single answer and the advice suggested that each collection would have to address this issue having regard to a range of factors, including the ownership, if any, of the material when it was in situ and the circumstances under which the material passed into the possession of the ex situ holder, including the terms and conditions of any relevant agreement, or any relevant legislation (including that governing the establishment and operation of the collection itself).

8.127 The CSIRO is particularly concerned with this issue as it houses major national collections, including the Australian National Herbarium, the Australian National Insect Collection and the Australian National Wildlife Collection. The CSIRO's view was:

> to have fair and proper benefit sharing, it is helpful to know who owns the title to a particular resource and who has the legitimate right to control the access to it.

8.128 In these circumstances, and given the cost and potential difficulty of the task, it may be worthwhile for the heads of Commonwealth ex situ collections to collaborate to formulate a single request for comprehensive legal advice which is applicable to the circumstances of each collection but which may be able to identify similar circumstances and common issues. This reduces costs and maintains some consistency of legal advice across common issues.

8.129 The CSIRO advanced a proposal to include, in the s301 regulations, a provision which would enable the biological resources, which were the subject of the contract, to be deemed the property of the holder of the collection, for the purposes of both the approval of an access permit and the making of a

benefit-sharing contract. This provision would only apply to elements of the collection about which there was insufficient evidence to establish its origins.

8.130 Legal advice suggests, however, that this is not possible under the s301 regulations. This does not mean that some form of legislative amendment might not be possible to vest ownership of the elements of the collection in the Commonwealth where there was no evidence of its origins.

8.131 For the Australian Institute of Marine Science the situation concerning ownership is much clearer. The Institute's collections differ from CSIRO's, because it has done all its own collecting. It does not receive material from others who 'lodge' or 'deposit' into its collection. Thus, there are no provenance questions, and applying the common law position, the Institute considers itself the owner of material in its collection, although there may be conditions of use of the material in access permits or benefit-sharing contracts to which it is party which affect its ability to deal with that material.

Recommendation

62. That the Minister ask the Department of the Environment and Heritage to discuss, with holders of ex situ collections, the value of a combined request for legal advice on ownership issues.

63. That, subject to the advice subsequently obtained, the Minister consider any recommendation from the holders of ex situ collections within his portfolio for legislative amendment to resolve outstanding ownership issues.

Asserting ownership

8.132 The suggestion has been made that the ownership issue could be resolved if the Commonwealth were to assert ownership or vest ownership of all biological resources in its possession. This suggestion has been made informally and formally, for example in Recommendation 1 of the CSIRO submission. Putting aside legal issues over the Commonwealth's capacity to take this step in all areas, the Inquiry believes a decision that Commonwealth has ownership (and therefore complete control over uses and conditions) would be unnecessarily inflammatory and could result in controversy over an action which might well be seen as high-handed and result in compensation claims.

8.133 Additionally, it might deter potential providers of material to national collections if they believed providing the material would result in a loss of rights, ie no scope for negotiation over uses and conditions. Indeed, would it mean that in future cases, material obtained by the Commonwealth (by legal means) automatically becomes the property of the Commonwealth, with no room for negotiations, eg for both parties to have rights in the material.

Biological material covered by existing international agreements

8.134 A second issue raised was whether ex situ collections ought to be covered by the access scheme. Agriculture, Fisheries and Forestry--Australia recommended against coverage of ex situ collections, in part on the basis that negotiations on the Food and Agricultural Organization International Undertaking on Plant Genetic Resources were as yet unresolved.

8.135 Other submissions have raised the issue of how exotic material, held in ex situ collections, might be covered. I have noted these points but am conscious that ex situ collections, especially living collections, may be attractive, from a biodiscovery point of view, because their representative nature makes them a potentially attractive alternative to in situ collecting.

8.136 At a time of constraints on public expenditure, overtures to holders of such collections may be difficult to resist. Indeed, consideration of any such offer may be responsible and prudent. There is a need, therefore, for guidelines to ensure benefit sharing and biodiversity conservation.

8.137 The Chair of the Council of Heads of Australian Herbaria put the position succinctly:

> With the advent of new and cheap technology enabling the extraction of DNA and other substances from dead herbarium specimens as well as from live plants, an increase may be expected in the frequency of approaches to herbaria for commercial sampling.

8.138 The ability of bioprospectors to sample ex situ collections of native species instead of surveying in situ resources means that, to ensure the integrity of any approach to regulating access to biological resources found in situ, ex situ resources must also be provided for.

8.139 It may be that the terms of establishment and operation of some ex situ collections allow them to consider biodiscovery requests; or that existing collection management policy would not permit it; or that the terms under which its holdings are kept might prevent collections from dealing in the material. Indeed some collections may be seen as existing for research or reference purposes and do not expect any involvement in commercial arrangements. Nevertheless, should an ex situ collection allow such sampling and be able to deal with its material in that way, there should be a framework in which that action takes place and which protects the public interest.

8.140 It has also come to my attention that the extent of Commonwealth ex situ holdings is not well known. Accordingly, action will be needed to identify the extent of all relevant collections so Environment Australia may take action to help holders introduce the access scheme.

8.141 At the same time, reflecting Agriculture, Fisheries, Forestry -- Australia's concerns, I have recommended that material which is the subject of existing international agreements (such as the Food and Agricultural Organization

International Undertaking on Plant Genetic Resources) should be excluded from the ambit of the regulations. In this regard I have already indicated that the access scheme does not extend to non-native species. This is to accord with the requirements of Articles 3 and 15 of the Convention on Biological Diversity.

8.142 The Chair of the Council of Heads of Australian Herbaria discusses, in detail, development of a nationally consistent approach to access and benefit sharing among their constituent ex situ collections as part of the Council's participation in developing the Common Guidelines for participating Botanic Gardens on access to genetic resources and benefit sharing (see Appendix 6).

8.143 I have considered the implications of this work. In my view it would be appropriate for the Minister to consider deferring application of the scheme to those Commonwealth organisations involved, pending the outcome of development of these Common Guidelines. This would only be an option if, in the Minister's view, deferral would, in this instance, help progress to a common Australian position and if there was no undue delay in establishing the Common Guidelines. This step would also contribute to the momentum towards a nationally consistent approach by the Commonwealth, States and Territories.

Recommendations

64. That, to the extent possible, Commonwealth ex situ collections of native species be included in the access scheme to be introduced by regulations under s301 of the EPBC Act.

65. That action be taken to identify ex situ collections and that the Department of the Environment and Heritage provide advice about the introduction of the access scheme.

66. That material which is the subject of existing international agreements, such as the Food and Agricultural Organization International Undertaking on Plant Genetic Resources, be excluded from the ambit of the regulations.

67. That the Minister for the Environment and Heritage consider deferring application of the regulations to participating Botanic Gardens and other ex situ organisations if, in his view, deferral would aid progress to a common Australian position and if there was no undue delay in establishing the Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit Sharing.

68. That, in settling an Australian position in relation to the terms of the Common Guidelines for participating institutions on access to genetic resources and benefit sharing, the Council of Heads of Australian Herbaria be asked to consider the relationship between the provisions of the access scheme to be introduced under s301 of the EPBC Act and the Common Guidelines.

Export of biological resources

Micro-organisms

8.144 Access to Australia's biological resources is currently partly regulated by the Wildlife Protection (Regulation of Exports and Imports) Act 1982, where there is the intent of exporting some or all of that biological material. In particular, where there is potential for commercial gain, access is regulated by either s10 or s10a of that Act. The Act helps discharge Australia's responsibility under the CITIES Convention.

8.145 These provisions were used to regulate harvesting of marine biological resources where the purpose was export of extracts of marine organisms harvested from marine waters of Australia by the Australian Institute of Marine Science.

8.146 In its submission, the Australian Institute of Marine Science commented that:

> there is great irony in the current restrictive export regulations with respect to finite amounts of raw sample or extract (which is unreproducible) of macro-organisms.

8.147 The Institute noted that the Wildlife Protection Act allows for export of micro-organisms, such as bacteria and microbes, without an export permit and recommended that the Act should be revised to ensure it covers all Australian wildlife.

8.148 ExGenix also commented on the need to have a consistent approach across biological resources, noting that micro-organisms are rarely considered in discussions about access and conservation of biological resources.

8.149 The Inquiry recognises the merit of controlling the export of micro-organisms to ensure adequate benefit sharing for Australia in the event that a commercially-valuable substance is developed from them.

8.150 The current controls, under the Wildlife Protection Act, were developed in the early 1980s when wildlife conservation focused on higher organisms. How applicable these controls are for the export of micro-organisms requires further consideration. Considering that most micro-organisms can be readily reproduced in very large numbers in the laboratory, rather than harvested from the wild, it is questionable why such controls would be necessary from a biodiversity conservation point of view.

8.151 But biodiversity conservation is only half the access story -- the other half is benefit sharing which is more relevant to the export of micro-organisms than it is to macro-organisms. This is because the culture for screening research and

development is exported, the means of large-scale long-term supply is also exported, potentially without ever having to refer back to Australia.

8.152 In such situations it is therefore important to ensure the material has been collected according to laws providing for access to biological resources and which ensure benefits from its use are shared by the exporting country.

8.153 The Inquiry is aware that the Wildlife Protection Act is currently being amended with the intention that its provisions will be incorporated into the EPBC Act. These amendments should consider the implications of placing export controls on micro-organisms. Options could range from controlling exports of all micro-organisms and products derived from them, through to limiting the control only to samples collected for biodiscovery purposes. While this latter proposal has the advantage of being administratively manageable and addresses Australian Institute of Marine Science and Ex-Genix concerns, it exposes a potential loophole: non biodiscovery-related export could result in the culture being deposited into a collection overseas, and then used for biodiscovery research.

8.154 Once a viable culture is exported without control, it becomes difficult to secure any downstream benefits from use of that culture which is infinitely reproducible. By contrast, an extract or compound from a macro-organism, is exported but without an inherent means of large-scale reproduction.

8.155 A further consideration is the role that closing the gaps in regulating the export of biodiscovery samples plays in acting against biopiracy.

8.156 There is growing international pressure to find ways to ensure biological resources of provider countries have been obtained in accordance with the articles of the Convention on Biological Diversity. One suggestion is to amend the system of intellectual property to require evidence that the biological material on which a patent application is based was obtained on terms consistent with the Convention. Another proposal is that countries into which biological source material is being imported require evidence that the material has been lawfully obtained. The Inquiry understands arguments in favour of such proposals were strongly advanced at COP5 in May.

8.157 The existence of a valid export permit, a precondition of which is that the material was collected in accordance with appropriate Commonwealth or State law, would provide a measure of such reassurance to the importing country. I am informed that the potential value of this approach to industry was demonstrated to members of the Australian delegation to the recent Conference of the Parties to the Convention on Biological Diversity. At that meeting a senior representative of a major pharmaceutical company and member of his national delegation explained that evidence of legality and certainty of title were very important to major firms (such as his) which bought the bulk of their product development leads from small, to medium companies.

8.158 He explained that to devote upwards of $700 million dollars and 10 years development work on a new product meant certainty about the company's rights to the source material was very important. In such circumstances to acquire 'pirated' material could put the company at risk. In this regard, the more countries do to add to marketplace confidence in the origins of biological resources the better.

b. Australian can play a positive role by closing any gaps in regulating the export of Australian biota used for genetic and biochemical research.

Recommendations

69. That the Department of the Environment and Heritage undertake further research to determine the extent of the export of micro-organisms and products derived from them.

70. That, in light of this information, export controls on such organisms be extended.

A tiered system for biodiscovery collecting

8.160 The Inquiry noted that some commercial organisations have entered into arrangements with State herbariums or museums to collect samples for biodiscovery purposes. In these cases, the herbarium or museum collects samples for their own collections and at the same time collects samples for the commercial organisation, in accordance with relevant State, Territory or Commonwealth legislation. Should either organisation wish to export these samples, the Wildlife Protection Act controls would apply as outlined in the Wildlife Protection (Regulation of Exports and Imports) Act 1982 Information Sheet No. 5 Scientific Transactions (at Appendix 13).

8.161 If the herbarium or museum wishes to send their samples to an approved overseas organisation or body for non-commercial purposes, they can do this under the Facilitated Scientific Exchange System. However, samples belonging to the commercial body could not be exported unless the original collecting regime had been in accordance with an approved management program or a controlled specimen declaration under s10 or s10A of the Wildlife Protection Act.

8.162 The Australian Institute of Marine Science noted, in their submission, that they obtained a controlled specimen declaration for their entire biodiversity collection and that the process took six months to complete. This example highlights the need to have a more streamlined approach which ensures protection of biodiversity yet provides an administrative framework appropriate for the proposed activity. The inquiry notes that the Institute and

the Great Barrier Reef Marine Park Authority are developing a tiered approach for allowing collection of samples for biodiscovery programs.

8.163 It would be desirable to amend the Wildlife Protection Act export provisions to allow recognition of such a model to ensure any approval process is appropriate to the scale of the collecting activity.

Recommendation

71. That the export provisions of the Wildlife Protection (Regulation of Exports and Imports) Act 1982 be amended to allow the s301 scheme and other similar systems, such as the tiered model being developed by Australian Institute of Marine Science and the Great Barrier Reef Marine Park Authority, to be taken into account when export approvals are sought or that this be reflected when proposed amendments to the EPBC Act incorporate the provisions of the Wildlife Protection Act.

APPENDICES

1. Excerpts from the *Environment Protection and Biodiversity Conservation Act 1999*
2. Public Inquiry Terms of Reference
3. Press Release
4. List of Submissions
5. Hearings, Consultations and Reference Group Meetings
6. Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit Sharing
7. Process for assessing access permits and benefit-sharing contracts under s301 of the EPBC Act
8. Convention on Biological Diversity Conference of the Parties 5, Nairobi May 2000 Decisions V/16 and V/26
9. Overseas examples of Access and Benefit Sharing Schemes
10. Indigenous interest in biological resources in Commonwealth areas - synthesis of submissions and related information, by Henrietta Fourmile
11. What the Inquiry is about and what it means for Indigenous communities
12. Legal and Constitutional Framework of Australia's Marine Areas
13. Scientific Transactions

14. Acronyms
15. Bibliography

Appendix 1: Excerpts from the Environment Protection and Biodiversity Conservation Act 1999

Section 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; and
    d. the granting of access to such resources and the terms and conditions of such access.

Section 525 Commonwealth areas

What is a **Commonwealth area**?

1. Each of the following, and any part of it, is a Commonwealth area:

    a. land owned by the Commonwealth or a Commonwealth agency (including land owned in Norfolk Island) and airspace over the land;

    b. an area of land held under lease by the Commonwealth or a Commonwealth agency (including an area held under lease in Norfolk Island) and airspace over the land;

    c. land in:

        i. an external Territory (except Norfolk Island); or

        ii. the Jervis Bay Territory;

    and airspace over the land;

    d. the coastal sea of Australia or an external Territory;

e. the continental shelf, and the waters and airspace over the continental shelf;

f. the waters of the exclusive economic zone, the seabed under those waters and the airspace above those waters;

g. any other area of land, sea or seabed that is included in a Commonwealth reserve.

Territory Land in the ACT is not a Commonwealth area.

2. Despite paragraph (1)(a), an area of land that is Territory Land, within the meaning of the Australian Capital Territory (Planning and Land Management) Act 1988 is not a Commonwealth area merely because of that paragraph, unless it is held under lease by the Commonwealth or a Commonwealth agency.

   Coastal waters of States and the Northern Territory are not Commonwealth areas.

3. Despite paragraphs (1)(d), (e) and (f), none of the following areas (or parts of them) are Commonwealth areas:

   a. the seabed vested in a State under section 4 of the Coastal Waters (State Title) Act 1980; and

   b. the seabed vested in the Northern Territory under section 4 of the Coastal Waters (Northern Territory Title) Act 1980; and

   c. the subsoil under the seabed described in paragraph (a) or (b); and

   d. any water and airspace over seabed described in paragraph (a) or (b).

Section 528 Definitions

animal means any member, alive or dead, of the animal kingdom (other than a human being).

biodiversity means the variability among living organisms from all sources (including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part) and includes:

   a. diversity within species and between species; and

   b. diversity of ecosystems.

Biodiversity Convention means the Convention on Biological Diversity done at Rio de Janeiro on 5 June 1992, as in force for Australia immediately before the commencement of this Act. Note: The English text of this Convention is set out in Australian Treaty Series 1993 No 32.

biological resources includes genetic resources, organisms, parts of organisms, populations and any other biotic component of an ecosystem with actual or potential use or value for humanity.

Commonwealth area has the meaning given by section 525.

Commonwealth land has the meaning given by section 27.

Commonwealth marine area has the meaning given by section 24.

Commonwealth reserve means a reserve declared under Division 4 of Part 15.

genetic resources means any material of plant, animal, microbial or other origin that contains functional units of heredity and that has actual or potential value for humanity.

native species means a species:

a. that is Indigenous to Australia or an external Territory; or

b. that is Indigenous to the seabed of the coastal sea of Australia or an external Territory; or

c. that is Indigenous to the continental shelf; or

d. that is Indigenous to the exclusive economic zone; or

e. members of which periodically or occasionally visit:

    i. Australia or an external Territory; or

    ii. the exclusive economic zone; or

f. that was present in Australia or an external Territory before 1400.

Note: A reference to Australia or an external Territory includes a reference to the coastal sea of Australia or the Territory. See section 15B of the Acts Interpretation Act 1901.

organism includes:

a. a virus; and

b. the reproductive material of an organism; and

c. an organism that has died.

plant means a member, alive or dead, of the plant kingdom or of the fungus kingdom, and includes a part of a plant and plant reproductive material.

plant reproductive material means:

a. a seed or spore of a plant; or

b. a cutting from a plant; or

c. any other part, or product, of a plant from which another plant can be produced.

precautionary principle has the meaning given by subsection 391(2).

Section 356 Regulations controlling activities relating to Commonwealth reserves

1. The regulations may:

a. regulate or prohibit the pollution of soil, air or water in a manner that is, or is likely to be, harmful to:

i. people, biodiversity or heritage in Commonwealth reserves; or

ii. the natural features of Commonwealth reserves; and

b. regulate or prohibit tourism in Commonwealth reserves; and

c. provide for the protection and preservation of Commonwealth reserves and property and things in Commonwealth reserves; and

d. provide for the protection and conservation of biodiversity in Commonwealth reserves; and

e. regulate or prohibit access to all or part of a Commonwealth reserve by persons or classes of persons; and

f. provide for the removal of trespassers from Commonwealth reserves; and

g. regulate or prohibit camping in Commonwealth reserves; and

h. provide for the safety of persons in Commonwealth reserves; and

i. regulate or prohibit the use of fire in Commonwealth reserves; and

j. regulate the conduct of persons in Commonwealth reserves; and

k. regulate or prohibit the carrying on of any trade or commerce in a Commonwealth reserve; and

l. regulate or prohibit the use of vehicles in Commonwealth reserves and provide for signs and road markings for those purposes; and

m. provide for:

    i. the removal of vehicles, aircraft or vessels from places in Commonwealth reserves where they have been left in contravention of the regulations or have been abandoned; and

    ii. the impounding of such vehicles, aircraft or vessels; and

n. provide that the person taken for the purposes of the regulations to be the owner of a motor vehicle involved in a contravention of a provision of the regulations relating to the parking or stopping of vehicles in a Commonwealth reserve is, except as provided otherwise, taken to commit an offence against the provision; and

o. provide for a person to be taken to be the owner of a motor vehicle for the purposes of regulations made under paragraph (n) (including a person in whose name the motor vehicle is registered under the law of a State or Territory); and

p. regulate or prohibit the use of vessels in, and the passage of vessels through, Commonwealth reserves; and

q. regulate or prohibit the landing and use of aircraft in, and the flying of aircraft over, Commonwealth reserves; and

r. provide for the giving of effect to management plans for Commonwealth reserves; and

s. regulate or prohibit the taking of animals or plants into or out of Commonwealth reserves; and

t. provide for the impounding, removal, destruction or disposal of animals found straying in Commonwealth reserves; and

u. regulate or prohibit the taking into Commonwealth reserves, and the use in Commonwealth reserves, of weapons, traps, nets, snares, fishing apparatus and other devices; and

v. regulate or prohibit the laying of baits and the use of explosives and poisons in Commonwealth reserves; and

w. provide for the collection of specimens and the pursuit of research in Commonwealth reserves for scientific purposes; and

x. provide for the issue of licences, permits and authorities relating to activities in Commonwealth reserves, the conditions subject to which they are issued and the charging of fees by the Commonwealth in respect of such licences, permits and authorities; and

y. provide for any matter incidental to or connected with a matter described in another paragraph.

2. A provision of the regulations regulating or prohibiting the flying of aircraft over a Commonwealth reserve does not have any effect so far as it is inconsistent with a law of the Commonwealth. For this purpose, a provision is not inconsistent with such a law if it can be complied with without contravention of the law.

3. A law of a Territory has effect so far as it is not inconsistent with a provision of the regulations having effect in that Territory. For this purpose, such a law is not inconsistent with the provision so far as it can operate concurrently with the provision.

Section 505A Establishment

1. The Indigenous Advisory Committee is established.

2. The Minister is to determine in writing the composition of the Committee, including the qualifications of its members.

3. The Minister is to appoint the members of the Committee on a part-time basis, and must appoint one of the members to chair the Committee.

Section 505B Functions of the Committee

1. The function of the Committee is to advise the Minister on the operation of the Act, taking into account the significance of Indigenous peoples' knowledge of the management of land and the conservation and sustainable use of biodiversity.

2. The Minister may give the Committee written guidelines about its function.

Section 391 Minister must consider precautionary principle in making decisions taking account of precautionary principle

1. The Minister must take account of the precautionary principle in making a decision listed in the table in subsection (3), to the extent he or she can do so consistently with the other provisions of this Act.

Precautionary principle

2. The precautionary principle is that lack of full scientific certainty should not be used as a reason for postponing a measure to prevent degradation of the environment where there are threats of serious or irreversible environmental damage.

3. The decisions are:

Decisions in which precautionary principle must be considered

Item	Section under which decision is made	Nature of decision
1	75	whether an action is a controlled action
2	133	whether or not to approve the taking of an action
3	201	whether or not to grant a permit
4	216	whether or not to grant a permit
5	237	whether or not to grant a permit
6	258	whether or not to grant a permit
7	269A	about making a recovery plan or adopting a plan as a recovery plan
7A	270A	whether or not to have a threat abatement plan for a key threatening process threat abatement plan
7B	270B	about making a threat abatement plan or adopting a plan as a
8	280	about approving a variation of a plan adopted as a recovery plan or threat abatement plan
9	285	about making a wildlife conservation plan or adopting a plan as a wildlife conservation plan
10	295	about approving a variation of a plan adopted as a wildlife conservation plan
11	316	about making a plan for managing a property that is included in the World Heritage List and is entirely within one or more Commonwealth areas
12	328	about making a plan for managing a wetland that is designated for inclusion in the List of Wetlands of International Importance

		kept under the Ramsar Convention and is entirely within one or more Commonwealth areas
13	338	about making a plan for managing a Biosphere reserve entirely within one or more Commonwealth areas
14	370	about approving a management plan for a Commonwealth reserve

Appendix 2: Public Inquiry Terms of Reference

The inquiry is to advise on a scheme that could be implemented through regulations under section 301 of the Environment Protection and Biodiversity Conservation Act 1999 to 'provide for the control of access to biological resources in Commonwealth areas'.

The scheme should take into account:

1. Australia's obligations under the Convention on Biological Diversity, including the obligation to encourage the equitable sharing of the benefits arising from the utilisation of biological resources. The scheme should particularly focus on the equitable sharing of benefits arising from the utilisation of traditional knowledge, innovations and practices (article 8(j)).

2. The objectives of the National Strategy for the Conservation of Australia's Biodiversity such as:

    - ensuring that the collection of biological resources for research and development purposes does not adversely affect the viability or conservation status of any species or population; and

    - ensuring that the social and economic benefits of the use of biological resources derived from Australia's biological diversity accrue to Australia.

The scheme should operate in a manner that promotes certainty for industry and facilities access to biological resources for environmentally sound uses.

Consistent with the objects of the EPBC Act, the scheme should:

- promote a cooperative approach to the protection and management of the environment involving governments, the community, land-holders and Indigenous peoples;

- recognise the role of Indigenous people in the conservation and ecologically sustainable use of Australia's biodiversity; and

- promote the use of Indigenous peoples' knowledge of biodiversity with the involvement of, and in cooperation with, the owners of that knowledge.

Inquiry Process

The inquiry is to be conducted by South Australian legal practitioner, Mr John Voumard.

Mr Voumard will be assisted by an Executive Officer. Mr Voumard will also seek advice from a Reference Group comprising:

- an environmental law specialist;

- a representative from industry with relevant expertise;
- an Indigenous representative with relevant expertise;
- an intellectual property specialist; and
- a representative of the scientific community with relevant expertise.

Additional support, including secretariat support, will be provided by Environment Australia.

Mr Voumard will report to the Minister for the Environment and Heritage by 30 June 2000. It is expected that the inquiry process will include:

- publication of a notice in relevant newspapers calling for public submissions; and
- public hearings in selected centres around Australia.

Submission details

Queries may be directed to the Inquiry's Executive Officer, Geoff Burton (telephone 6274 2528, fax 6274 2723 or geoff.burton@ea.gov.au) or to Sally Petherbridge, Assistant Director, Access Taskforce (telephone 6274 1568, fax 6274 2723 or sally.petherbridge@ea.gov.au).

Submissions are invited from interested parties by 3 March 2000 and may be made (in hard copy) to:

Geoff Burton, Director, Access Taskforce
Environment Australia
PO Box 787
Canberra ACT 2600

Or (in electronic form) to: geoff.burton@ea.gov.au, or

sally.petherbridge@ea.gov.au Unless marked confidential, all submissions will be regarded as public and may be placed on the Inquiry's web site. The Inquiry's preference is for submissions to be public; confidentiality should be reserved for material whose disclosure would be genuinely prejudicial to the party making the submission.

Appendix 3: Press Release

Inquiry to Examine Access to Biological Resources

Federal Environment Minister Robert Hill today initiated an inquiry into the key issues associated with access to Australia's biological resources in Commonwealth areas.

The inquiry is to advise on a scheme that could be implemented through regulations under section 301 of the Environment Protection and Biodiversity Conservation Act 1999 to provide for the control of access to biological resources in Commonwealth areas.

'The inquiry is an important initiative in the Federal Government's ongoing program to provide for the conservation and sustainable use of Australia's biological diversity. It will help deliver on Australia's responsibilities under the Convention on Biological Diversity and the goals of the National Strategy for the Conservation of Australia's Biological Diversity.

The inquiry will address some of the major environmental issues for the new millennium, including the ownership of biological resources and the terms on which access to such resources should be granted.

'Recognising the special knowledge held by Indigenous people in relation to our biodiversity, the inquiry will particularly focus on ensuring the equitable sharing of benefits arising from the utilisation of Indigenous knowledge and practices.
The inquiry will also report on mechanisms for ensuring that the collection of biological resources does not adversely affect the conservation status of any species.

'Access to biological and genetic resources for environmentally sound uses is of strategic importance to Australia's capacity to develop a biotechnology industry,' Senator Hill said.
'The inquiry will therefore look at options for implementing a streamlined access regime that, consistent with the principles of ecologically sustainable development, delivers certainty for industry.'

The inquiry is an important opportunity for everyone with an interest in these issues to contribute to a system which will ensure that the Australian community gets maximum benefit from the commercial and scientific potential of our diverse biological resources.'
South Australian legal practitioner Mr John Voumard will chair the inquiry. He will be supported by a reference group comprising specialists in environmental and intellectual property law, and representatives of the business, Indigenous and scientific communities.

The inquiry will consider public submissions and conduct hearings around Australia before reporting to Senator Hill by 30 June next year. The inquiry's terms of reference are available on the Environment Australia web site: www.environment.gov.au
22 December 1999

Contacts: Rod Bruem (Senator Hill's office) 02 6277 7640 or 0419 258 364

Con Boekel (Environment Australia) 02 6274 2894

Appendix 4: List of Submissions

1. James Balmer, Director, BMG Lab Technologies, Victoria
2. Associate Professor Anthony Weiss, Chair, University of Sydney Recombinant DNA (Biosafety) Committee
3. Biological Diversity Advisory Council
4. Australian Wildlife Protection Council
5. Brigitte Charron
6. Lucy Fish
7. DD Brown
8. National Native Title Tribunal
9. Dr David H Bennett, Executive Director, Australian Academy of the Humanities
10. Dr Charles Lawson, Visiting Fellow, Research School of Biological Sciences, Australian National University and Dr Catherine Pickering, Lecturer, School of Environmental and Applied Science, Griffith University
11. Professor Barry Conyngham, Vice-Chancellor, Southern Cross University
12. Professor Ronald J Quinn, Director, AstraAeneca R&D, Griffith University
13. Professor D Farrier, Centre for Natural Resources Law and Policy, Faculty of Law, University of Wollongong
14. Australian Wheat Board
15. Elizabeth Collins
16. John Henderson
17. Elen Shute
18. Tina Lesses
19. Peter Mirtschin, Venom Supplies Pty Ltd
20. John Ashe, Environment Institute of Australia
21. Dr Panos Ioannou, The Murdoch Children's Research Institute, Royal Children's Hospital, Melbourne (confidentiality requested)
22. Natalie Stoianoff, Faculty of Law, University of Wollongong
23. Commonwealth Attorney-General's Department
24. Ms Christine Morris, Research Fellow, Australian Key Centre for Cultural and Media Policy, Griffith University, Nathan Queensland
25. Dr David Mitchell, Parallel Biotechnologies Pty Ltd (confidentiality requested)
26. Dr John Keesing, Director, Division of Research and Development, Murdoch University
27. Dr Howard G Wildman, Manager, Biotic Resources, ExGenix
28. Dr Michael Mahony and others, Department of Biological Sciences, University of Newcastle
29. Mr Michael Anderson, for and behalf of the Euahlayi: Nyoongar Ghurradjong Murri Clan Group and Sovereign Union
30. Greg Eaton, Director of Science, Bio-Gene Bioprospecting Limited
31. Euroka Gilbert and Kathryn Looke
32. Mrs Juliet MacFarlane
33. Professor Helene Marsh, Professor of Environmental Science, James Cook University, Chair National Committee for the Environment
34. Environment ACT

35. Commonwealth Department of Transport and Regional Services
36. Professor Noel Dunn, Director, Cooperative Research Centre for Food Industry Innovation
37. Australian Biotechnology Association
38. Dr Jane Fromont, Curator of Marine Invertebrates, Department of Aquatic Zoology, Western Australian Museum
39. Dr David Newman, National Cancer Institute, Maryland
40. Australian Research Council
41. Commonwealth Department of Industry, Science and Resources
42. Council of Heads of Australian Herbaria
43. Commonwealth Department of Education, Training and Youth Affairs
44. IP Australia
45. Bureau of Meteorology
46. Australians against Commercialisation of Wildlife
47. University of Queensland
48. Professor Stephan Schnierer
49. University of New England
50. Australian Institute of Marine Science
51. Mr Peter J Whitehead, Key Centre for Tropical Wildlife Management, Northern Territory University
52. Northern, Central and Kimberley Land Councils
53. Australian Conservation Foundation
54. Tasmanian Conservation Trust Inc
55. Environmental Defenders Office Network
56. Aboriginal and Torres Strait Islanders Commission
57. Department of Premier and Cabinet, Victoria
58. Michael Davis, Research and Consultancies
59. Australian GeneEthics Network in association with Gunggalidda Association, Doomadge Aboriginal Association
60. Professor L R Webb, Vice-Chancellor, Griffith University
61. Kimberley Aboriginal Law and Culture Centre
62. Maxine Chi
63. Fisheries Division, Northern Territory Government
64. Council for Aboriginal Reconciliation
65. Commonwealth Scientific and Industrial Research Organisation
66. Great Barrier Reef Marine Park Authority
67. National Parks Association of New South Wales
68. University of Sydney
69. Wet Tropics Management Authority
70. Environment Australia
71. Department of Defence
72. Western Australia Ministry of the Premier and Cabinet
73. Department of Agriculture, Fisheries and Forestry--Australia
74. Queensland Government
75. Kakadu National Park Board of Management and Northern Land Council
76. Government of Norfolk Island
77. Department of Premier and Cabinet, Tasmania
78. Australian Institute of Aboriginal and Torres Strait Islander Studies
79. Council of Heads of Australian Botanic Gardens
80. Mr Clive A Evans

Appendix 5: Hearings, Consultations and Reference Group Meetings

Public Hearings

Public hearings were held in Canberra on 30 May and in Brisbane on 1 June 2000. Notices of the public hearings were placed in The Canberra Times, The Australian and The Courier Mail on Saturday 20 May 2000. Organisations which had made submissions to the Inquiry were sent letters inviting them to make presentations. Nine individuals or organisations made presentations. The Chair also held informal discussions with Dr Simon Hearn and Ms Kristiane Herrmann, from Agriculture, Fisheries, Forestry--Australia, about issues arising from that Department's submission to the Inquiry.

Witnesses at Canberra hearings

Mr Mikael Hirsch, Mr Stephen Midgley and Mr Stephen Trowell, CSIRO.

Mr Michael Davis, Canberra.

Ms Eleanor Gilbert on behalf of Mr Anderson of the Euahlayi: Nyoongar

Ghurradjong Murri Clan Group and Sovereign Union, NSW.

Mr Michael Kerr, Australian Conservation Foundation, Melbourne (by telephone).

Mr Don Anton, Environmental Defenders Office Network, Melbourne (by telephone).

Mr Peter McMahon, Mr Bob Phelps, Australian GeneEthics Network, Melbourne, in association with Gunggalidda Association, and Ms Wadjularbinna, Doomadgee

Aboriginal Association, Qld (by telephone).

Ms Jessica Wyers, IP Australia, Canberra.

Witnesses at Brisbane hearings

Ms Christine Morris, Australian Key Centre for Cultural and Media Policy, Griffith University, Brisbane.

Mr Charles Lawson, Brisbane.

Consultations by Chair

24-25 January 2000: Department of the Environment and Heritage, Canberra.

20 March 2000: Mr Leon Morris and Mr Peter Cooke, Northern Land Council, Darwin.

21 March 2000: Mr Fred Haala, Manager, Kakadu National Park.

22 March 2000: Mr Fraser Vickery, Manager Uluru-Kata Tjuta National Park; Mr Paul Josif, Office of Joint Management, and Ms Kathy Bannister, Assistant Coordinator; Mr Graham Lightbody and Mr Tony Keys, Central Land Council, Alice

Springs; Tony Tjamiwa and Ginger Wikilyiri, Traditional Owners of Uluru-Kata Tjuta; Leroy Lester, Park Ranger and interpreter.

23 March 2000: Mr Tony Keys, Central Land Council, Alice Springs.

5 April 2000: Ms Dawn Waddy, Chair, Board of Management, and Mr Scott Suridge, Manager, Booderee National Park, Jervis Bay Territory.

6 April 2000: Mr Reuben Ardler, Community Liaison Officer, Wreck Bay Aboriginal Community Council, Wreck Bay, Jervis Bay Territory.

26 April 2000: Mr Peter Rogers, President, Australian Biotechnology Association, Melbourne; Dr Howard Wildman, Manager, ExGenix, Melbourne.

3 May 2000: Queensland Department of State Development and Department of Premier and Cabinet, Brisbane.

4 May 2000: Professor Ron Quinn, AstraZeneca R&D Griffith University, Nathan Queensland.

9 May 2000: Mr Greg Eaton, Director of Science, Bio-Gene Bioprospecting Limited, West Perth; Western Australian Department of Premier and Cabinet, Perth; Ms Maxine Chi, Perth.

19 May 2000: Uluru-Kata Tjuta National Park Board of Management, Mutitjulu Community.

22 May 2000: Board of Management, Kakadu National Park.

16 June 2000: Ms Evelyn Scott, Chair, Council for Aboriginal Reconciliation .

Reference Group Meetings

1st meeting, 31 January 2000, Adelaide

2nd meeting, 27 and 28 April 2000, Melbourne

3rd meeting, 1 and 2 June 2000, Brisbane

4th meeting, 3 July 2000, Adelaide

Appendix 6: Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit Sharing [1]

PREAMBLE

The botanic gardens, subscribing to these common policy guidelines,

Recognising the vital role of botanic gardens world wide in conservation, research and education;

Affirming their commitment to cooperate fairly and equitably with Stakeholders for the benefit of humankind and the conservation and sustainable use of biological diversity;

Recognising the sovereign rights of States over their own biological resources and the authority of national governments to determine access to genetic resources, subject to national legislation;

Acknowledging the interests of other Stakeholders, including Indigenous and local communities and farmers, in biological resources and associated information;

Determined to honour the letter and spirit of the Convention on Biological Diversity, the Convention on International Trade in Endangered Species of Wild Fauna and Flora, and other international, regional, national and sub-national laws and policies concerning biodiversity; and Committed to honouring the terms and conditions under which they have acquired biological resources in the past;

Committed to honouring the terms and conditions under which they have acquired biological resources in the past;

have agreed as follows:

SECTION 1 - OBJECTIVES

The objectives are:

a. to ensure that the activities of the Participating Gardens involving access to genetic resources are consistent with the provisions of the Convention on International Trade in Endangered Species, the Convention on Biological Diversity and other international, regional, national and sub-national laws and policies concerning biodiversity;

b. to promote cooperation between botanic gardens, individuals, organisations, groups, and other Stakeholders dealing with genetic resources;

c. to establish conditions that facilitate access by others to the genetic resources within the collections held by the Participating Gardens and that may help each Participating Garden to access the genetic resources worldwide, whether found in in situ or ex situ conditions;

1. An explanatory note is being developed to accompany these Common Policy Guidelines

d. to promote the fair and equitable sharing of the benefits arising from the use of genetic resources, their progeny and derivatives, with the country of origin that provided the genetic resources and with other Stakeholders, as appropriate. The benefits to be shared arise both from the use of genetic resources, their progeny and derivatives, by the Participating Gardens and from the use by others of genetic resources, their progeny and derivatives, provided by Participating Gardens; and

e. to encourage other botanic gardens to become Participating Gardens and follow a harmonised system of access to genetic resources and benefit sharing.

SECTION 2 - DEFINITIONS

In this document, the following terms have the following meanings:

Accession means a sample or specimen of biological material held in a botanic garden or herbarium;

Access to genetic resources means the ability to acquire and use genetic resources; Acquisition means obtaining possession of a material or resource, through collection, receipt or other means;

Benefit sharing means sharing the benefits arising from the use, whether commercial or not, of genetic resources, their progeny and derivatives;

Biological material includes, but is not limited to, plants, plant parts or propagation material (such as seeds, cuttings, roots, bulbs, corms or leaves), fungi or other fungal material, and any other material of plant, animal, fungal, microbial or other origin and the genetic resources contained therein;

Biological resources include, but are not limited to, organisms or parts thereof, populations or any biotic component of ecosystems of actual or potential value, including genetic resources;

Botanic garden means, but is not limited to, an institution holding collections of documented and living plant accessions for the purposes of scientific research, conservation, display and education. For the purposes of this document, the term 'botanic garden' includes herbarium;

Commercialisation means the use or exploitation of genetic resources, their progeny or derivatives, with the object of, or resulting in, financial gain, and includes but is not limited to the following activities: sale, applying for, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or licence or in any other manner, commencement of product development, conducting market research, and seeking pre-market approval;

Country of origin of genetic resources means the country which possesses those genetic resources in in situ conditions;

Derivatives include, but are not limited to, modified or unmodified extracts and any compounds or chemical structures based on or derived from genetic resources and their progeny, including analogues;

Ex situ conservation means the conservation of components of biological diversity outside their natural habitats;

Genetic resources mean any material of plant, animal, fungal, microbial or other origin containing functional units of heredity of actual or potential value;

Herbarium means a reference collection of preserved and documented plant specimens, including those that are dried and pressed and those that are preserved in liquid;

In situ conditions mean conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties;

In situ conservation means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties;

Material acquisition agreement means an agreement between two or more organisations or individuals setting out the terms and conditions under which certain biological resources are acquired. A material acquisition agreement is a type of material transfer agreement;

Material supply agreement means an agreement between two or more organisations or individuals setting out the terms and conditions under which certain biological resources are supplied. A material supply agreement is a type of material transfer agreement;

Material transfer agreement means an agreement between two or more organisations or individuals setting out the terms under which one party will transfer biological materials, which may contain genetic resources, to or from another. Material transfer agreements can take many forms, ranging from the simple exchange of letters to specific contracts containing standard clauses such as the model material acquisition agreement and model material supply agreement set out in Annexes 2 and 3 hereto, respectively. Both material acquisition agreements and material supply agreements are types of material transfer agreements;

Model material acquisition agreement means the model material acquisition agreement developed to implement these Common Policy Guidelines, a pro forma of which is attached hereto as Annex 2;

Model material supply agreement means the model material supply agreement developed to implement these Common Policy Guidelines, a pro forma of which is attached hereto as Annex 3;

Participating Gardens means those botanic gardens listed in Annex 1 hereto which subscribe to the principles set out in this document and which have agreed to implement these Common Policy Guidelines;

Prior informed consent means the consent of the government and other Stakeholders which must be obtained prior to access to genetic resources and based on full disclosure of information, such as the intended use of the resources;

Provider means any individual or organisation, whether governmental or non-governmental, that provides genetic resources, their progeny or derivatives to a Participating Garden;

Recipient means any individual or organisation, whether governmental or non-governmental, that acquires genetic resources, their progeny or derivatives from a Participating Garden with its consent;

Stakeholder means an individual, organisation or group whether formal or informal, affected by, or with an interest in, the activities relating to the acquisition, use or supply of genetic resources, their progeny or derivatives. Stakeholders involved in conservation and the granting of collecting permits and prior informed consent for access may include relevant departments of government, local authorities, private individuals such as landowners, Indigenous peoples, local communities, farmers and non-governmental organisations. Stakeholders such as these are often described in law relating to access and benefit sharing;

Tracking means maintaining records of the location of specimens of genetic resources, their progeny and derivatives, following their distribution within an organisation or their supply to other organisations.

SECTION 3 - PRINCIPLES

Participating Gardens subscribing to these Common Policy Guidelines will, as far as possible and as appropriate:

- obtain prior informed consent for the acquisition of genetic resources from in situ conditions from the government of the country of origin and other Stakeholders;
- obtain the prior informed consent for the acquisition of genetic resources from ex situ conditions from the body governing the ex situ collection concerned, and such other consents as that body indicates are required;
- acquire and supply genetic resources, their progeny or derivatives under material acquisition and material supply agreements which satisfy these principles;
- maintain records and mechanisms to track the acquisition and supply of genetic resources, their progeny and derivatives, and the benefits that arise from their use; and
- share the benefits arising from the use of genetic resources, their progeny and derivatives fairly and equitably with the country of origin and other Stakeholders.

SECTION 4 - ACQUISITION

4.1 PRIOR INFORMED CONSENT

4.1.1 When it collects or otherwise gains access to genetic resources, each Participating Garden will abide by applicable law and best practice. When obtaining access to genetic resources from in situ conditions, each Participating Garden will obtain the prior informed consent of the government of the country of origin, in accordance with its applicable legislation, and will make reasonable and sincere efforts to obtain the prior informed consent of other Stakeholders, as appropriate. When obtaining access to genetic resources from ex situ conditions, each Participating Garden will obtain the prior informed consent of the body governing the ex situ collection, and such other consents as the body governing the ex situ collection requires.

4.2 PROVIDERS

4.2.1 The Participating Gardens recognise the importance of ensuring that Providers of genetic resources subscribe to the principles set out in Section 3 of this document. Each Participating Garden may accept genetic resources from any Provider which subscribes to these principles, and will endeavour, where practicable, to obtain from Providers confirmation of their acceptance of these principles, whether by signature of a material acquisition agreement or by some other means.

4.3 MATERIAL ACQUISITION AGREEMENTS

4.3.1 When obtaining access to genetic resources, each Participating Garden will make reasonable and sincere efforts to clarify the respective roles, rights and responsibilities of the Participating Garden, the country of origin and relevant Stakeholders in activities involving the utilisation of genetic resources.

4.3.2 When obtaining access to genetic resources from in situ conditions, each Participating Garden will:

a. where required, in accordance with applicable law, obtain, in writing, the prior informed consent of the government of the country of origin; and will make reasonable and sincere efforts to:

b. obtain and record the prior informed consent of other Stakeholders, as appropriate, for access to and use of the genetic resources concerned and associated knowledge;

c. ensure that any collection, import, export and other handling of the genetic resources has been in accordance with all applicable law; and

d. clarify, in writing, the terms and conditions under which the materials are acquired and can subsequently be used, particularly whether the materials, their progeny or derivatives may be supplied to third parties and/or commercialised.

4.3.3 When obtaining access to genetic resources from documented ex situ collections, each Participating Garden will:

a. obtain, in writing, prior informed consent from the officer authorised to agree terms of access on behalf of the ex situ collection, and such other consents required as indicated by that officer for access to the genetic resources concerned and for their use;

and will make reasonable and sincere efforts to:

b. obtain from the authorised officer of the ex situ collection a written undertaking that the genetic resources were acquired and are being supplied in accordance with all applicable law and that the ex situ collection is entitled to supply them to the Participating Garden;

c. ensure that the export of the genetic resources, their progeny or derivatives, from the country where the ex situ collection providing them is based, and import to the country where the Participating Garden is based, are in accordance with all applicable law; and

d. clarify, in writing, the terms and conditions under which the materials are acquired and can subsequently be used, particularly whether the materials, their progeny or derivatives may be supplied to third parties and/or commercialised.

4.3.4 When obtaining access to genetic resources from ex situ conditions other than those in section 4.3.3. above, for instance from commercial sources, each Participating Garden will ensure that the acquisition conforms with all applicable law, and, if appropriate, will make reasonable and sincere efforts to ascertain from the Provider that the materials were obtained in accordance with the Convention on Biological Diversity.

4.3.5 The Participating Gardens recognise the need to acquire genetic resources under material acquisition agreements. Where a Provider does not use a material transfer agreement, or where a Provider's material transfer agreement or the collecting permits currently in use in a particular country do not satisfy the requirements set out in Section 4.3.2 and Section 4.3.3, a Participating Garden may propose to the Provider that they enter into the model material acquisition agreement or another form of material acquisition agreement which contains those requirements.

SECTION 5 - RECORDS, TRACKING AND MANAGEMENT

5.1 RECORDS

5.1.1 Each Participating Garden acquiring genetic resources will make reasonable and sincere efforts to record and maintain data on their acquisition, including

information on the Provider; country of origin; collector; collection date and number; accession number; taxon; prior informed consent and conditions of use (for example as contained in permits and/or material acquisition agreements); and other relevant data associated with the acquisition of accessions in its collections in order to be able to implement these Common Policy Guidelines.

5.1.2 Each Participating Garden will make reasonable and sincere efforts to record and maintain information concerning the use of genetic resources, their progeny and derivatives, by that Participating Garden, and the benefits to that Participating Garden arising from such use.

5.1.3 Each Participating Garden will make reasonable and sincere efforts to record and maintain data on the supply of genetic resources, their progeny and derivatives, including information on the Recipient and the terms of access and benefit sharing under which they were supplied. When providing genetic resources, their progeny and derivatives to a Recipient, each Participating Garden will also provide relevant data on their acquisition to the Recipient, as described in Section 5.1.1, particularly information on prior informed consent and conditions of use.

5.2 TRACKING

5.2.1 In order to be able to fulfil its commitments under these Common Policy Guidelines now and in the future, each Participating Garden will develop and implement appropriate mechanisms to track the acquisition of genetic resources, the different uses of genetic resources, their progeny and derivatives held in its collections, their supply to Recipients, and the benefits that arise from their use.

5.3 MANAGEMENT

5.3.1 Each Participating Garden will establish systems of staff management and individual staff responsibilities for the implementation of and compliance with these Common Policy Guidelines.

5.3.2 Each Participating Garden will identify the members of its staff authorised to agree, on its behalf, the terms of access and benefit sharing associated with the acquisition and supply of genetic resources, their progeny and derivatives.

SECTION 6 - SUPPLY

6.1 Supply of Genetic Resources

6.1.1 Each Participating Garden may supply genetic resources, their progeny or derivatives, to other Participating Gardens and third parties for conservation, research, public display, education and other purposes.

6.1.2 At the time of supplying genetic resources, their progeny or derivatives, each Participating Garden will clarify with the Recipient whether the supply is for commercial or for non-commercial purposes.

6.1.3 When supplying genetic resources, their progeny or derivatives, each Participating Garden will honour any terms and conditions to which it committed when acquiring the genetic resources, such as any conditions set out in collecting permits or material acquisition agreements.

6.1.4 To the extent possible, when supplying genetic resources, their progeny or derivatives, each Participating Garden will treat genetic resources acquired prior to the entry into force of the Convention on Biological Diversity and those acquired after its entry into force in the same manner.

6.2 Recipients

6.2.1 The Participating Gardens recognise the importance of ensuring that Recipients of genetic resources, their progeny and derivatives, subscribe to the principles set out in Section 3 of this document. Each Participating Garden may supply genetic resources to any Recipient which subscribes to these principles, and will endeavour, where practicable, to obtain from Recipients confirmation of their acceptance of these principles, whether by signature of a material supply agreement or by some other means.

6.3 Material Supply Agreements

6.3.1 When supplying genetic resources, their progeny or derivatives, each Participating Garden will seek to use the model material supply agreement, or another material supply agreement which obliges each Recipient:

a. to share benefits arising from its use of the genetic resources, their progeny and derivatives, fairly and equitably with the Participating Garden providing them, who will then share them fairly and equitably with the country of origin and other Stakeholders, as appropriate, as set out in Section 7;

b. not to commercialise the genetic resources, their progeny or derivatives, without the explicit consent of the Participating Garden providing them; and

c. not to pass the genetic resources, their progeny or derivatives, on to third parties without ensuring that the third parties enter into written agreements containing terms that are no less restrictive.

SECTION 7 - BENEFIT SHARING

7.1 Commitment to Share Benefits

7.1.1 Each Participating Garden will make reasonable and sincere efforts to share the benefits arising from the use of genetic resources, their progeny and derivatives, fairly and equitably with the country of origin and other Stakeholders, as appropriate.

7.1.2 To the extent possible, each Participating Garden will share the benefits arising from the use of materials acquired prior to and after the entry into force of the Convention on Biological Diversity in the same manner.

7.2 Benefits

7.2.1 The object of sharing benefits is to achieve fairness and equity and to create incentives and provide resources for the conservation of biological diversity and the sustainable use of its components.

7.2.2 Benefits which Participating Gardens will share, depending upon what is fair and equitable in the circumstances, including commitments made in material acquisition and supply agreements, may include:

- taxonomic, biochemical, ecological, horticultural and other information and data, through research results, publications and educational materials;
- access to collections and databases;
- benefits in kind, such as augmentation of national collections in the country of origin and support of community development activities;
- the transfer of technology such as hardware, software and know-how;
- training in science, in situ and ex situ conservation and management, information technology and management and administration of access and benefit sharing;
- institutional development, strengthening and management;
- joint research and development, through collaboration in training and research programs, participation in product development, joint ventures and co-authorship of publications; and,
- in the case of commercialisation, also monetary benefits such as royalties.

SECTION 8 - IMPLEMENTATION

8.1 Progressive Implementation

8.1.1 The Participating Gardens will need to build their respective human and institutional capacities in order to be able to implement these Common Policy Guidelines fully. Therefore, each will develop measures such as procedural

manuals and instructions for staff, record keeping systems and mechanisms for sharing benefits.

8.2 Feedback and Development

8.2.1 Each Participating Garden recognises that this document will need to be revised periodically in order to reflect changes in international, national and other applicable law and acknowledged best practice. The Participating Gardens are committed to the continual development of these Common Policy Guidelines in response to feedback and suggestions.

8.3 Broadening Participation

8.3.1 The Participating Gardens subscribing to these Common Policy Guidelines are committed to working with the broader botanic gardens community and with individuals, organisations and groups dealing with genetic resources, in order to develop a harmonised system for access to genetic resources and benefit sharing.

MODEL MATERIAL ACQUISITION AGREEMENT

Note: This model agreement has been prepared for illustrative purposes in connection with the Botanic Garden Pilot Project on Access to Genetic Resources and Benefit sharing. The language of this draft agreement is appropriate to certain circumstances and to English law only. Consequently, no person should rely on the language of this draft without first consulting his or her own legal adviser.

MODEL MATERIAL ACQUISITION AGREEMENT BETWEEN [PARTNER INSTITUTION] AND [PARTICIPATING GARDEN]

An AGREEMENT made on the [ ] day of [ ] Two thousand between [Participating Garden] ([PG]) and [Partner Institution] ([Partner]).

WHEREAS:

[PG] is a [corporate description], whose mission is [mission statement];

In pursuit of this mission, [PG] exchanges Biological Material with other research institutes worldwide;

In its work, [PG] intends to honour the letter and spirit of the 1992 Convention on Biological Diversity, the 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora (including the relevant implementing European Community Regulations), and other regional, national and subnational laws and policies concerning biodiversity;

[PG] and [Partner] may establish a joint collecting and conservation program and may instigate collaborative research projects relating to the collection, study and conservation of plant biodiversity; and

[Partner] is interested in providing [PG] with certain Biological Materials;

NOW THEREFORE IT IS HEREBY AGREED AS FOLLOWS:

1. In this Agreement the following expressions shall have the following meanings:

1.1 'Biological material' includes, but is not limited to, plants, plant parts or propagation material (such as seeds, cuttings, roots, bulbs, corms or leaves), fungi or other fungal material, and any other material of plant, animal, fungal, microbial or other origin and the genetic resources contained therein;

1.2 'Commercialise' and 'Commercialisation' means the use or exploitation of genetic resources, their progeny or Derivatives, with the object of, or resulting in, financial gain, and includes but is not limited to the following activities: sale, applying for, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or licence or in any other manner,

commencement of product development, conducting market research, and seeking pre-market approval;

1.3 'Derivatives' include, but are not limited to, modified or unmodified extracts and any compounds or chemical structures based on or derived from genetic resources and their progeny, including analogues;

1.4 'Genetic Resources' mean any material of plant, animal, fungal, microbial or other origin containing functional units of heredity of actual or potential value;

1.5 'Material' shall mean the plant, animal, microbial or fungal biological material transferred from time to time under this Agreement;

1.6 'Third Party' shall mean any person other than [PG] and [Partner].

2.1 In consideration of the undertaking by [PG] in clause 3.1, below, [Partner] will transfer to [PG] the Material listed in each 'Notification of Material Transferred under the Material Acquisition Agreement between [Partner] and the [PG] (the 'Notification of Transfer') to be itemised and agreed by the parties for each material transfer under this Agreement. A pro forma copy of the Notification of Transfer is attached as Appendix A hereto.

2.2 The Material referred to in clause 2.1 will be transferred pursuant to the terms of this Agreement.

2.3 The signature of [Partner] on any Notification of Transfer will confirm **firstly** that [Partner] is satisfied that best efforts have been made by [PG] and/or by [Partner], as appropriate, to obtain all necessary permits, prior informed consents and licenses in connection with the acquisition by [PG] of the Material and **secondly** that [Partner] is authorised to acquire and supply the Material to [PG].

3.1 [PG] undertakes, where reasonably practicable, to provide [Partner] with a fair and equitable share of any benefits obtained by [PG] resulting from the use of any Genetic Resources, their progeny or Derivatives, including the results of processing, monitoring, research, development or other use of such Genetic Resources.

c. Research publications by [PG] resulting from the use of any Genetic Resources, their progeny or Derivatives, will acknowledge [Partner] as the source of such Genetic Resources.

4.1 In order to justify investment in the collaboration established by this Agreement, [PG] must ensure its future use of the Material. Consequently, subject to the terms of clause 4.2, below, [PG] shall own the Material and may use it for purposes consistent with its not- for-profit mandate.

4.2 [PG] will not Commercialise any Genetic Resources, their progeny or Derivatives, without having obtained the written permission of [Partner] prior to such Commercialisation. Any such Commercialisation to which [Partner]

agrees will be subject to a separate agreement with [Partner] consistent with [PG]'s policy on access to genetic resources and benefit sharing.

4.3 [PG] may supply any Genetic Resources, their progeny or Derivatives, to a Third Party and will use its best efforts to ensure that such Third Party has entered into a written agreement with [PG] containing conditions no less restrictive than those contained in this Agreement, including the conditions on benefit sharing, publication, Commercialisation and supply of Genetic Resources, their progeny or Derivatives, and providing that such Third Party shall not supply such Genetic Resources, their progeny or Derivatives, to any other Third Party (a 'Subsequent Recipient') unless such Subsequent Recipient has entered into a legally binding written agreement containing conditions no less restrictive than those contained in this Agreement, including the conditions on benefit sharing, publication, Commercialisation and supply of Genetic Resources, their progeny or Derivatives.

5.1 This Agreement shall be in effect from [date] and shall extend for a term of [ten (10)] years after such date unless the parties reach prior agreement to new terms. The obligations and rights contained in Clauses 1, 2.2, 2.3, 3, 4 and 5 herein shall survive the expiration or other termination of this Agreement.

5.2 Notwithstanding clause 5.1 above, either party to this Agreement may give six months notice to the other party to terminate this Agreement.

5.3 Neither party shall be liable to the other party for any delay or non-performance of its obligations under this Agreement arising from any cause beyond its reasonable control including, without limitation, any of the following: Act of God, governmental act, war, fire, flood, explosion, civil commotion or industrial disputes of a Third Party or impossibility of obtaining gas or electricity or materials. Subject to the affected party promptly notifying the other party in writing of the cause and the likely duration of the cause, the performance of the affected party's obligations, to the extent affected by the cause, shall be suspended during the period the cause persists.

5.4 Any dispute, difference or question between the parties arising under this Agreement shall be referred to an arbitrator to be agreed between the parties or, in default of agreement [insert appropriate arbitration provisions].

5.5 Any notice or other document to be served under this Agreement may be delivered or sent by prepaid air mail or by fax to the party to be served at the below address or at such other address as it may have notified to the other party in accordance with this clause. Any notice shall be marked for the attention of the person and at the address indicated below:

[Participating Garden]:	Name:	[Insert name]
	Position:	[Insert title]
	Address:	[Insert address]
[Partner Institution]:	Name:	[Insert name]
	Position:	[Insert title]
	Address:	[Insert address]

Any notice or document shall be deemed to have been served (a) if delivered, at the time of delivery; or (b) if posted by air mail, at 10:00 a.m. on the fifth business day after it was put in the post; or (c) if sent by fax at the expiration of two hours after the time of despatch if despatched before 3:00 p.m. (local time of destination) or at 10:00 a.m. (local time) on the next business day after despatch in any other case.

5.6 The provisions of this Agreement constitute the entire Agreement between the parties relating to the subject matter and the parties do not make any representations or warranties except those contained in this Agreement. The Agreement shall not be considered extended, cancelled or amended in any respect unless done so in writing signed on behalf of the parties hereto.

5.7 This Agreement is personal to the parties and none of the rights or the obligations under this Agreement may be assigned or transferred without the prior written consent of the other party.

5.8 The provisions contained in each clause and sub-clause of this Agreement shall be enforceable independently of each of the others and its validity shall not be affected if any of the others is invalid. If any of these provisions is void and would be valid if some part of the provision were deleted, the provision in question shall apply with such modification as may be necessary to make it valid.

5.9 Nothing contained in this Agreement shall constitute a partnership between [PG] and [Partner] or constitute either of them the agent of the other.

5.10 This Agreement is governed by and shall be construed in accordance with [insert appropriate nationality] law.

5.11 This Agreement may be executed in any number of counterparts, all of which, taken together, shall constitute one and the same agreement.

AS WITNESS the hands of the duly authorised representatives of the parties hereto.

SIGNED BY:
for and on behalf of [Partner]
Name: Date:
Title:

SIGNED BY:
for and on behalf of [Participating Garden]
Name: Date:
Title:

APPLICATION FOR THE SUPPLY OF PLANT MATERIAL FROM THE AUSTRALIAN NATIONAL BOTANIC GARDENS

I,.....(full name and position) being the legally authorised person representing
.....
.....
.....(name and address of institution or company)

agree that the plant material, including essentially derived* plant material or substances, supplied by the Australian National Botanic Gardens and listed below will not be supplied to any person or party not specifically named in this agreement and will not be used for any purpose other than that stated in this agreement. I will acknowledge the ANBG as the source of the material in all publications relating to its use and I shall supply a copy of these publications to the ANBG Library within 12 months of publication. I accept all responsibility for the security of the plant material and any damages resulting from the use, loss or escape of the material. I also accept responsibility and costs for compliance with any relevant laws, regulations , conventions or treaties. Any departure from these conditions will be subject to further negotiation and the agreement of ANBG. I also indemnify the Commonwealth of Australia, the Director of National Parks and Wildlife and servants and agents, against any liability and costs whatsoever arising out of any act of negligence of myself or servants or agents in the course of activities authorised by the permit granted in response to this application.

The plant material required is:

The purpose(s) for the which the material is requested is/are:

(Attach and initial additional pages if necessary)

Signed. .....
Date .....

Witnessed by .....
Date .....

Name of Witness .....

* 'essentially derived' means that the material or substance is determined by the expression of one or more genes or other heritable determinants originating from the plant material supplied under this agreement.

Note: The above material transfer agreement is preceded by a letter to the applicant as follows:

Dear .....

Thank you for your request of [date] for plant material from the Australian National Botanic Gardens (ANBG).

ANBG will only supply material to individuals or institutions that are prepared to enter into a formal agreement describing the purpose for which the material is required. Plant material will only be supplied if the stated purpose is consistent with the aims of ANBG, and normally material is only supplied for research or educational purposes. Material cannot be supplied if it may compromise research being conducted at ANBG or the Centre for Plant Biodiversity Research.

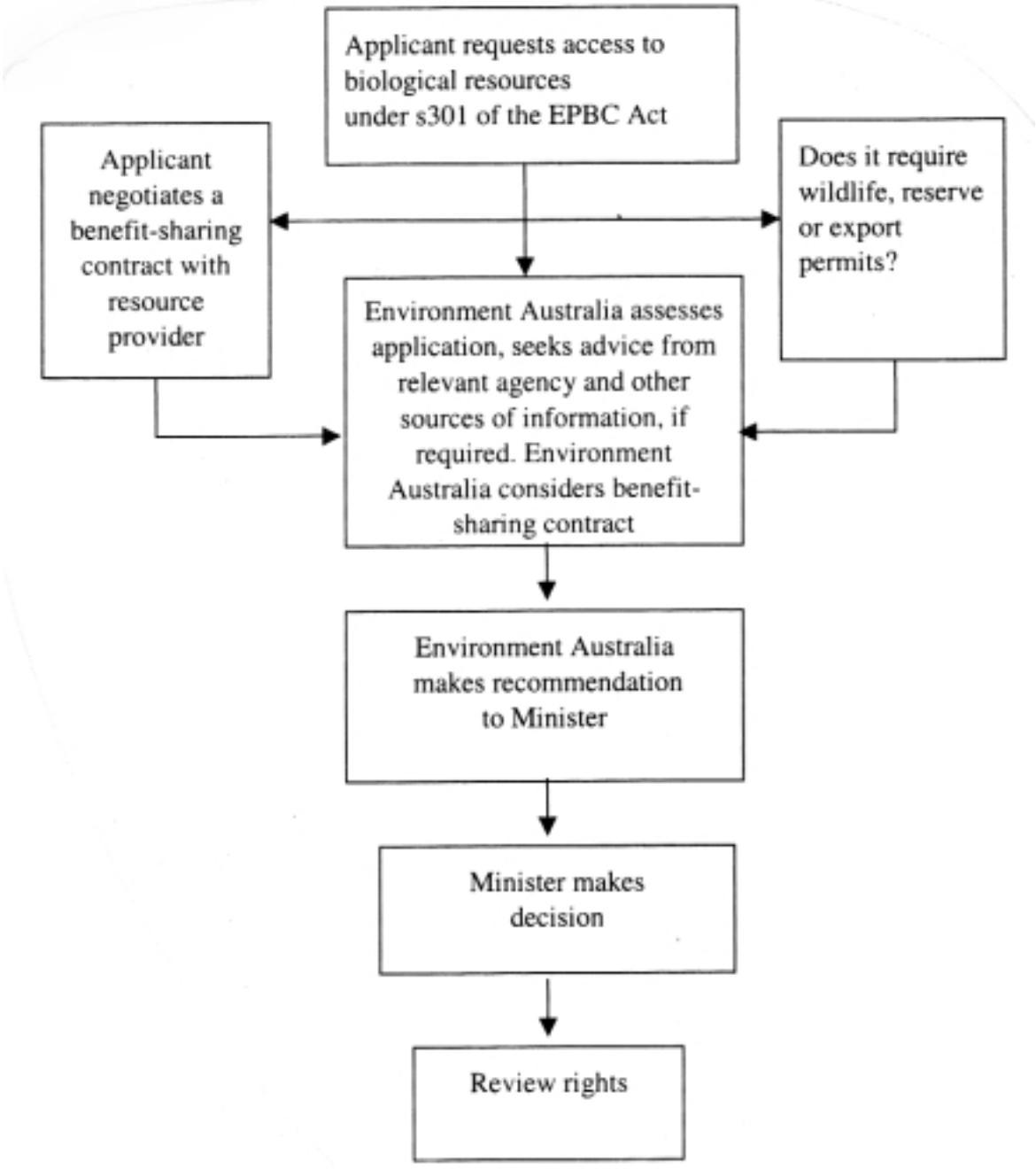
In addition, where material is requested for use outside Australia, it can only be supplied in compliance with the Convention on International Trade in Endangered Species (CITES). Also ANBG will only supply to countries which have ratified the international Convention on Biological Diversity. The Convention affirms national sovereignty over genetic resources and establishes a framework for the fair and equitable sharing of the benefits arising from the development of the world's genetic resources. The Convention also provides that access to genetic resources should be subject to prior informed consent and shall be on mutually agreed terms (see Attachment A). The mechanisms by which Australia will give effect to these provisions are currently being developed. Until the mechanisms for the supply of Australian genetic material are formalised Australian government organisations are adopting a conservative approach.

Accordingly, the ANBG has developed interim measures. Those wishing to obtain plant material from the Gardens are required to provide a full description of the purpose for which the material is required and sign an agreement accepting certain conditions. This forms part of the application form which is attached. Charges may be incurred depending on the use to which the material will be put. Some general information on ANBG policy is enclosed (Attachment B) but specific charges may need to be negotiated. Phytosanitary expenses and other permit fees are always the responsibility of the applicant. Approval for export may also require a separate permit under the terms of the Wildlife Protection (Regulation of Exports and Imports)Act 1982.

If these requirements are acceptable to you please provide the information requested and acknowledge your acceptance of our terms and conditions on the enclosed form. This form must be returned to ANBG before we will process your request.

Yours sincerely,

Appendix 7: Process for assessing access permits and benefit-sharing contracts under s301 of the EPBC Act



Appendix 8: Convention on Biological Diversity Conference of the Parties 5, Nairobi May 2000 Decisions V/16 and V/26 [2]

V/16 Article 8(j) and related provisions

The Conference of Parties,

Recalling its decision IV/9,

Recognizing the need to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application,

Noting the need for a long-term approach to the programme of work on implementation of Article 8(j) and related provisions of the Convention on Biological Diversity, within a vision to be elaborated progressively, in line with the overall objectives set out in Article 8(j) and related provisions,

Emphasizing the fundamental importance of ensuring the full and effective participation of indigenous and local communities in the implementation of Article 8(j) and related provisions,

Noting the importance of integrating with the full and effective participation of indigenous and local communities the work on Article 8(j) and related provisions into national, regional and international strategies, polices and action plans,

Recognizing the vital role that women play in the conservation and sustainable use of biodiversity, and emphasizing that greater attention should be given to strengthening this role and the participation of women of indigenous and local communities in the programme of work,

Further noting the linguistic and cultural diversity among indigenous and local communities as well as differences in their capacities,

Noting existing declarations by indigenous and local communities to the extent they relate to the conservation and sustainable use of biodiversity, including, inter alia, the Kari Oca Declaration, the Mataatua Declaration, the Santa Cruz Declaration, the Leticia Declaration and Plan of Action, the Treaty for Life Forms Patent Free Pacific, the Ukupseni Kuna Yala Declaration, the Heart of the Peoples Declaration on Biodiversity and Biological Ethics, the Jovel Declaration on Indigenous Communities, Indigenous Knowledge and Biodiversity, the Chiapas Declaration, other relevant declarations and statements of Indigenous Forums, as well as Convention 169 of the International Labour Organization, Agenda 21 and other relevant international conventions, Recognizing the role that the International

2. This document (UNEP/CBD/COP/5/23) can be found at www.bopdiv.org

Indigenous Forum on Biodiversity has played since the third meeting of the Conference of the Parties in addressing the Conference of the Parties on the implementation of Article 8(j) and related provisions,

Reaffirming the importance of making Article 8(j) and related provisions of the Convention and provisions of international agreements related to intellectual property rights mutually supportive,

Further noting that there are existing international agreements, intellectual property rights, current laws and policies that may have influence on the implementation of Article 8(j) and its related provisions,

Noting also that the methods of implementation of Article 8(j) and related provisions differ among regions and countries in approach and capacity,

1. Endorses the programme of work as contained in the annex to the present decision, which shall be subject to periodic review during its implementation;

2. Decides to implement the programme of work giving priority to tasks 1, 2, 4, 5, 8, 9 and 11, as well as 7 and 12, which shall be initiated following completion of tasks 5, 9 and 11;

3. Urges Parties and Governments in collaboration with relevant organizations, subject to their national legislation, to promote and implement this programme of work, and to integrate the tasks identified into their ongoing programmes as appropriate to national circumstances, taking into account the identified collaboration opportunities;

4. Requests Parties, Governments and relevant organizations to take full account of existing instruments, guidelines, codes and other relevant activities in the implementation of the programme of work;

5. Encourages the participation of indigenous and local communities in the work of the Ad Hoc Open-ended Working Group on Access and Benefit sharing on the development of guidelines and other approaches to ensure the respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity;

6. Takes into account the importance of the proposals for action on traditional forest- related knowledge of the Intergovernmental Panel on Forests/Intergovernmental Forum on Forests as an important part of this programme of work;

7. Requests Parties, Governments, and international, regional and national organizations to provide appropriate financial support for the implementation of the programme of work;

8. Requests the Executive Secretary to facilitate the integration of the relevant tasks of the programme of work in the future elaboration of the thematic programmes of the Convention on Biological Diversity and provide a report on the progress of the thematic programmes to the Ad Hoc Open-ended Inter-Sessional Working Group on Article 8(j) and Related Provisions of the Convention on Biological Diversity;

9. Decides to extend the mandate of the Ad Hoc Open-ended Inter-Sessional Working Group on Article 8(j) and Related Provisions of the Convention on Biological Diversity to review progress in the implementation of the priority tasks of its programme of work according to reports provided by the Executive Secretary, and the Parties to the meeting of the Working Group and recommend further action on the basis of this review. The Working Group should further explore ways for increased participation by indigenous and local communities in the thematic programmes of work of the Convention on Biological Diversity. The Working Group should report to the Conference of the Parties at its sixth meeting;

10. Requests Parties, Governments, subsidiary bodies of the Convention, the Executive Secretary and relevant organizations, including indigenous and local communities, when implementing the programme of work contained in the annex to the present decision and other relevant activities under the Convention, to fully incorporate women and women's organizations in the activities;

11. Invites Parties and Governments to support the participation of the International Indigenous Forum on Biodiversity, as well as relevant organizations representing indigenous and local communities, in advising the Conference of the Parties on the implementation of Article 8(j) and related provisions;

12. Urges Parties and Governments and, as appropriate, international organizations, and organizations representing indigenous and local communities, to facilitate the full and effective participation of indigenous and local communities in the implementation of the Convention and, to this end:

    a. Provide opportunities for indigenous and local communities to identify their capacity needs, with the assistance of Governments and others, if they so require;
    b. Include, in proposals and plans for projects carried out in indigenous and local communities, funding requirements to build the communications capacity of indigenous and local communities to facilitate dissemination and exchange of information on issues related to traditional knowledge, innovations and practices;

c. Provide for sufficient capacity in national institutions to respond to the needs of indigenous and local communities related to Article 8(j) and related provisions;

d. Strengthen and build capacity for communication among indigenous and local communities, and between indigenous and local communities and Governments, at local, national, regional and international levels, including with the Secretariat of the Convention on Biological Diversity, with direct participation and responsibility of indigenous and local communities through their appropriate focal points;

e. Use other means of communication in addition to the Internet, such as newspapers, bulletins, and radio, and increasing the use of local languages;

f. Provide case-studies on methods and approaches that contribute to the preservation of traditional knowledge, innovations and practices, including through their recording where appropriate, and that support control and decision-making by indigenous and local communities over the sharing of such knowledge, innovation and practices;

13. Emphasizes once again the need for case-studies developed in conjunction with indigenous and local communities requested in paragraphs 10 (b) and 15 of its decision IV/9, to enable a meaningful assessment of the effectiveness of existing legal and other appropriate forms of protection for the knowledge, innovations and practices of indigenous and local communities;

14. Recognizes the potential importance of sui generis and other appropriate systems for the protection of traditional knowledge of indigenous and local communities and the equitable sharing of benefits arising from its use to meet the provisions of the Convention on Biological Diversity, taking into account the ongoing work on Article 8(j) and related provisions, and transmits its findings to the World Trade Organization and the World Intellectual Property Organization, as suggested in paragraph 6 (b) of recommendation 3 of the Inter-Sessional Meeting on the Operations of the Convention (UNEP/CBD/COP/5/4, annex);

15. Invites Parties and Governments to exchange information and share experiences regarding national legislation and other measures for the protection of the knowledge, innovations and practices of indigenous and local communities;

16. Recognizes that the maintenance of knowledge, innovations, and practices of indigenous and local communities is dependent on the maintenance of cultural identities and the material base that sustains them and invites Parties and Governments to take measures to promote the conservation and maintenance of such identities;

17. Requests Parties to support the development of registers of traditional knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity through participatory programmes and consultations with indigenous and local communities, taking into account strengthening legislation, customary practices and traditional systems of resource management, such as the protection of traditional knowledge against unauthorized use;

18. Invites Parties and Governments to increase the participation of representatives of indigenous and local community organizations in official delegations to meetings held under the Convention on Biological Diversity;

19. Emphasizes the need for arrangements controlled and determined by indigenous and local communities, to facilitate cooperation and information exchange among indigenous and local communities, for the purposes of, inter alia, helping to ensure that such communities are in a position to make informed decisions on whether or not to consent to the release of their knowledge, and, in this respect:

    a. Requests the Executive Secretary, to fully utilize the clearing-house mechanism, to cooperate closely with indigenous and local communities to explore ways in which such needs may best be addressed;

    b. Invites Parties to consider ways and means of providing the necessary resources to enable the Secretariat to undertake the above-mentioned tasks;

20. Further requests Parties and international financial institutions to explore ways of providing the necessary funding for these activities.

Annex: Programme of Work on the Implementation of Article 8(J) and Related Provisions of the Convention on Biological Diversity

Objectives

The objective of this programme of work is to promote within the framework of the Convention a just implementation of Article 8(j) and related provisions, at local, national, regional and international levels and to ensure the full and effective participation of indigenous and local communities at all stages and levels of its implementation.

I. GENERAL PRINCIPLES

1. Full and effective participation of indigenous and local communities in all stages of the identification and implementation of the elements of the

programme of work. Full and effective participation of women of indigenous and local communities in all activities of the programme of work.

2. Traditional knowledge should be valued, given the same respect and considered as useful and necessary as other forms of knowledge.

3. A holistic approach consistent with the spiritual and cultural values and customary practices of the indigenous and local communities and their rights to have control over their traditional knowledge, innovations and practices.

4. The ecosystem approach is a strategy for the integrated management of land, water and living resources that promotes conservation and sustainable use of biological diversity in an equitable way.
5. Access to traditional knowledge, innovations and practices of indigenous and local communities should be subject to prior informed consent or prior informed approval from the holders of such knowledge, innovations and practices.

II. TASKS OF THE FIRST PHASE OF THE PROGRAMME OF WORK

Element 1. Participatory mechanisms for indigenous and local communities

Task 1. Parties to take measures to enhance and strengthen the capacity of indigenous and local communities to be effectively involved in decision-making related to the use of their traditional knowledge, innovations and practices relevant to the conservation and sustainable use of biological diversity subject to their prior informed approval and effective involvement.

Task 2. Parties to develop appropriate mechanisms, guidelines, legislation or other initiatives to foster and promote the effective participation of indigenous and local communities in decision-making, policy planning and development and implementation of the conservation and sustainable use of biological diversity at international, regional, subregional, national and local levels, including access and benefit sharing and the designation and management of protected areas, taking into account the ecosystem approach.

Task 4. Parties to develop, as appropriate, mechanisms for promoting the full and effective participation of indigenous and local communities with specific provisions for the full, active and effective participation of women in all elements of the programme of work, taking into account the need to:

a. Build on the basis of their knowledge,

b. Strengthen their access to biological diversity;
c. Strengthen their capacity on matters pertaining to the conservation, maintenance and protection of biological diversity;

d. Promote the exchange of experiences and knowledge;

e. Promote culturally appropriate and gender specific ways in which to document and preserve women's knowledge of biological diversity

Element 2. Status and trends in relation to Article 8(j) and related provisions

Task 5. The Executive Secretary to prepare, for the next meeting of the Ad Hoc Working Group, an outline of a composite report on the status and trends regarding the knowledge, innovations and practices of indigenous and local communities, a plan and a timetable for its preparation, based, inter alia, on advice submitted by Parties, Governments, indigenous and local communities and other relevant organizations regarding sources and availability of information on these matters. Parties, Governments and indigenous and local communities and other relevant organizations to submit the information and advice to address the requirements of this task and to Parties include in their national reports the current state of implementation of Article 8(j).

Element 4. Equitable sharing of benefits

Task 7. Based on tasks 1, 2 and 4, the Working Group to develop guidelines for the development of mechanisms, legislation or other appropriate initiatives to ensure: (i) that indigenous and local communities obtain a fair and equitable share of benefits arising from the use and application of their knowledge, innovations and practices; (ii) that private and public institutions interested in using such knowledge, practices and innovations obtain the prior informed approval of the indigenous and local communities; (iii) advancement of the identification of the obligations of countries of origin, as well as Parties and Governments where such knowledge, innovations and practices and the associated genetic resources are used.

Element 5. Exchange and dissemination of information

Task 8. Identification of a focal point within the clearing-house mechanism to liaise with indigenous and local communities.

Element 6. Monitoring elements

Task 9. The Working Group to develop, in cooperation with indigenous and local communities, guidelines or recommendations for the conduct of cultural, environmental and social impact assessments regarding any development proposed to take place on sacred sites and on lands or waters occupied or used by indigenous and local communities. The guidelines and recommendations should ensure the participation of indigenous and local communities in the assessment and review.

Element 7. Legal elements

Task 11. The Working Group to assess existing subnational, as appropriate, national and international instruments, particularly intellectual property rights instruments, that may have implications on the protection of the knowledge, innovations and practices of indigenous and local communities with a view to identifying synergies between these instruments and the objectives of Article 8(j).

Task 12. The Working Group to develop guidelines that will assist Parties and Governments in the development of legislation or other mechanisms, as appropriate, to implement Article 8(j) and its related provisions (which could include sui generis systems), and definitions of relevant key terms and concepts in Article 8(j) and related provisions at international, regional and national levels, that recognize, safeguard and fully guarantee the rights of indigenous and local communities over their traditional knowledge, innovations and practices, within the context of the Convention.

III. TASKS OF THE SECOND PHASE OF THE PROGRAMME OF WORK

Element 1. Participatory mechanisms for indigenous and local communities

Task 3. On the request of the Executive Secretary, Parties and Governments, with the full participation of indigenous and local communities, would establish a roster of experts based on the methodologies used by the Conference of Parties, to allow the experts to support the implementation of this programme of work.

Element 3. Traditional cultural practices for conservation and sustainable use

Task 6. The Ad Hoc Working Group to develop guidelines for the respect, preservation and maintenance of traditional knowledge, innovations and practices and their wider application in accordance with Article 8(j).

Task 13. The Ad Hoc Working Group to develop a set of guiding principles and standards to strengthen the use of traditional knowledge and other forms of knowledge for the conservation and sustainable use of biological diversity, taking into account the role that traditional knowledge can play with respect to the ecosystem approach, in situ conservation, taxonomy, biodiversity monitoring and environmental impact assessments in all biodiversity sectors.

Task 14. The Ad Hoc Working Group to develop guidelines and proposals for the establishment of national incentive schemes for indigenous and local communities to preserve and maintain their traditional knowledge, innovations and practices and for the application of such knowledge, innovations and practices in national strategies and programmes for the conservation and sustainable use of biological diversity.

Task 15. The Ad Hoc Working Group to develop guidelines that would facilitate repatriation of information, including cultural property, in accordance with Article 17, paragraph 2, of the Convention on Biological Diversity in order to facilitate the recovery of traditional knowledge of biological diversity.

Element 5. Exchange and dissemination of information

Task 16. The Executive Secretary to identify, compile and analyse, with the participation of indigenous and local communities, existing and customary codes of ethical conduct to guide the development of models for codes of ethical conduct for research, access to, use, exchange and management of information concerning traditional knowledge, innovations and practices for the conservation and sustainable use of biological diversity.

Element 6. Monitoring elements

Task 10. The Ad Hoc Working Group to develop standards and guidelines for the reporting and prevention of unlawful appropriation of traditional knowledge and related genetic resources.

Task 17. The Executive Secretary to develop, in cooperation with Governments and indigenous and local communities, methods and criteria to assist in assessing the implementation of Article 8(j) and related provisions at the international, regional, national and local levels, and reporting of such in national reports in conformity with Article 26.

IV. WAYS AND MEANS

In developing and implementing the programme of work, the Executive Secretary shall solicit information from Parties, Governments, indigenous and local communities and other relevant organizations, and consult with the liaison group on Article 8(j) and related provisions. The Executive Secretary to develop, in consultation with indigenous and local communities, Parties, Governments, and relevant international organizations, a questionnaire, as a basis for the provision of information concerning: (i) existing instruments and activities relevant to the tasks of the programme of work; (ii) gaps and needs concerning the guidelines referred to in task 6 above; and (iii) priorities for the further development of the programme of work. The Executive Secretary to consult with and invite relevant international organizations to contribute to the implementation of this programme of work, also with a view to avoiding duplication and to encouraging synergies. This programme of work shall, as relevant, take into account the work of the Ad Hoc Open-ended Working Group on Access and Benefit sharing, and, as far as possible, be carried out in collaboration with other relevant organizations, including the World Intellectual Property Organization (WIPO). Parties, Governments, and international, regional and national organizations to provide appropriate financial support for the implementation of the programme of work.

V/26. Access to genetic resources

A. Access and benefit-sharing arrangements

The Conference of the Parties

1. Requests Parties to designate a national focal point and one or more competent national authorities, as appropriate, to be responsible for access and benefit-sharing arrangements or to provide information on such arrangements within its jurisdiction;

2. Requests Parties to notify the Executive Secretary of the names and addresses of its focal points and competent authorities;
3. Urges Parties to ensure that national biodiversity strategies as well as legislative, administrative or policy measures on access and benefit sharing contribute to conservation and sustainable-use objectives;

4. Recognizing the importance for Parties to promote trust-building and transparency in order to facilitate the exchange of genetic resources, particularly with regard to the implementation of Article 15 of the Convention:

   a. Urges Parties to pay particular attention to their obligations under Articles 15, 16 and 19 of the Convention, and requests them to report to the Conference of the Parties on the measures they have taken to this effect;

   b. Notes that legislative, administrative or policy measures for access and benefit sharing need to promote flexibility, while recognizing the need for sufficient regulation of access to genetic resources to promote the objectives of the Convention;

   c. Notes that all countries are providers and recipients of genetic resources, and urges recipient countries to adopt, appropriate to national circumstances, legislative, administrative or policy measures consistent with the objectives of the Convention that are supportive of efforts made by provider countries to ensure that access to their genetic resources for scientific, commercial and other uses, and associated knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant to the conservation and sustainable use of biological diversity, as appropriate, is subject to Articles 15, 16 and 19 of the Convention, unless otherwise determined by that provider country;

   d. Recognizing the complexity of this issue, with particular consideration of the multiplicity of prior informed consent considerations, invites Parties to cooperate further to find practical and equitable solutions to this issue;

5. Notes that the promotion of a comprehensive legal and administrative system may facilitate access to and use of genetic resources and contribute to mutually agreed terms in line with the aims of the Convention;

6. Notes that, in the absence of comprehensive legislation and national strategies for access and benefit sharing, voluntary measures, including guidelines, may help ensure realization of the objectives of the Convention, and to that end invites the Parties to consider promotion of their use;

7. Stresses that it is important that, in developing national legislation on access, Parties take into account and allow for the development of a multilateral system to facilitate access and benefit sharing in the context of the International Undertaking on Plant Genetic Resources, which is currently being revised;

8. Notes the report of the Chairman of the Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations (UNEP/CBD/COP/5/INF/12) and urges the Commission to finalize its work as soon as possible. The International Undertaking is envisaged to play a

crucial role in the implementation of the Convention on Biological Diversity. The Conference of the Parties affirms its willingness to consider a decision by the Conference of the Food and Agriculture Organization of the United Nations that the International Undertaking become a legally binding instrument with strong links to both the Food and Agriculture Organization of the United Nations and the Convention on Biological Diversity, and calls upon Parties to coordinate their positions in both forums;

9. Notes the common understandings of the Panel of Experts on Access and Benefit Sharing with respect to prior informed consent and mutually agreed terms as contained in paragraphs 156 to 165 of its report (UNEP/CBD/COP/5/8);

10. Decides to reconvene the Panel of Experts on Access and Benefit Sharing with a concrete mandate and agenda. The Panel will conduct further work on outstanding issues from its first meeting, especially:

    a. Assessment of user and provider experience in access to genetic resources and benefit sharing and study of complementary options;

    b. Identification of approaches to involvement of stakeholders in access to genetic resources and benefit-sharing processes; and will include additional expertise. The Panel will submit its report to the Ad Hoc Open-ended Working Group on Access and Benefit sharing referred to in paragraph 11 below;

11. Decides to establish an Ad Hoc Open-ended Working Group, composed of representatives, including experts, nominated by Governments and regional economic integration organizations, with the mandate to develop guidelines and other approaches for submission to the Conference of the Parties and to assist Parties and stakeholders in addressing the following elements as relevant to access to genetic resources and benefit sharing, inter alia: terms for prior informed consent and mutually agreed terms; roles, responsibilities and participation of stakeholders; relevant aspects relating to in situ and ex situ conservation and sustainable use; mechanisms for benefit sharing, for example through technology transfer and joint research and development; and means to ensure the respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity, taking into account, inter alia, work by the World Intellectual Property Organization on intellectual property rights issues. The above-mentioned elements should, in particular, serve as inputs when developing and drafting:

    a. Legislative, administrative or policy measures on access and benefit sharing; and

    b. Contracts or other arrangements under mutually agreed terms for access and benefit sharing. The results of the deliberations of the Working Group, including draft guidelines and other approaches, shall

be submitted for consideration by the Conference of the Parties at its sixth meeting. The work of the Working Group shall take into account the reports of the Panel of Experts on Access and Benefit Sharing and other relevant information. The Working Group will be open to the participation of indigenous and local communities, non- governmental organizations, industry and scientific and academic institutions, as well as intergovernmental organizations. The Working Group shall maintain communication and exchange of information with the Working Group on Article 8(j) and Related Provisions of the Convention on Biological Diversity. In order to build capacity for access and benefit sharing, the Open-ended Working Group shall consider issues of capacity-building, including those needs identified in paragraphs 14 (a), (b), (c) and (d) below;

12. Notes that information is a critical aspect of providing the necessary parity of bargaining power for stakeholders in access and benefit-sharing arrangements, and that, in this respect, there is a particular need for more information regarding:

    a. User institutions;

    b. The market for genetic resources;

    c. Non-monetary benefits;

    d. New and emerging mechanisms for benefit sharing;

    e. Incentive measures;

    f. Clarification of definitions;

    g. Sui generis systems; and

    h. 'Intermediaries';

13. Requests the Executive Secretary to compile the information referred to in paragraph 12 above and disseminate it through the clearing-house mechanism and relevant meetings, and requests Parties and organizations to provide such information to assist the Executive Secretary;

14. Notes that further development of capacities regarding all aspects of access and benefit- sharing arrangements is required for all stakeholders, including local governments, academic institutions, and indigenous and local communities, and that key capacity- building needs include:

    a. Assessment and inventory of biological resources as well as information management;

    b. Contract negotiation skills;

c. Legal drafting skills for development of access and benefit-sharing measures;
d. Means for the protection of traditional knowledge associated with genetic resources;

15. Noting that the Panel of Experts on Access and Benefit Sharing was not able to come to any conclusions about the role of intellectual property rights in the implementation of access and benefit-sharing arrangements, and that the Panel developed a list of specific issues that require further study (UNEP/CBD/COP/5/8, paras. 127-138):

a. Invites Parties and relevant organizations to submit to the Executive Secretary information on these issues by 31 December 2000;

b. Requests the Executive Secretary, on the basis of these submissions and other relevant material, to make available for the second meeting of the Panel, or the first meeting of the Ad Hoc Open-ended Working Group, a report on these specific issues;

c. Recalls recommendation 3 of the Inter-Sessional Meeting on the Operations of the Convention, and requests the Executive Secretary to prepare his report in consultation with, inter alia, the Secretariat of the World Intellectual Property Organization;

d. Invites relevant international organizations, including the World Intellectual Property Organization, to analyse issues of intellectual property rights as they relate to access to genetic resources and benefit sharing, including the provision of information on the origin of genetic resources, if known, when submitting applications for intellectual property rights, including patents;

e. Requests relevant international organizations, for example, the World Intellectual Property Organization and the International Union for the Protection of New Varieties of Plants, in their work on intellectual property rights issues, to take due account of relevant provisions of the Convention on Biological Diversity, including the impact of intellectual property rights on the conservation and sustainable use of biological diversity, and in particular the value of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity;

f. Requests the Executive Secretary to explore experience and possibilities for synergistic interactions resulting from collaboration in research, joint development and the transfer of technology following access to genetic resources.

B. The relationship between intellectual property rights and the relevant provisions of the Agreement on Trade-related Aspects of Intellectual Property Rights and the Convention on Biological Diversity

The Conference of the Parties,

Noting recommendation 3 of the Inter-Sessional Meeting on the Operations of the Convention, concerning the relationship between intellectual property rights and the relevant provisions of the Agreement on Trade-related Aspects of Intellectual Property Rights and the Convention,

1. Reaffirms the importance of systems such as sui generis and others for the protection of traditional knowledge of indigenous and local communities and the equitable sharing of benefits arising from its use to meet the provisions of the Convention, taking into account the ongoing work on Article 8(j) and related provisions;

2. Invites the World Trade Organization to acknowledge relevant provisions of the Convention and to take into account the fact that the provisions of the Agreement on Trade-related Aspects of Intellectual Property Rights and the Convention on Biological Diversity are interrelated and to further explore this interrelationship;

3. Requests the Executive Secretary to transmit the present decision to the secretariats of the World Trade Organization and the World Intellectual Property Organization, for use by appropriate bodies of these organizations, and to endeavour to undertake further cooperation and consultation with these organizations;

4. Renews its request to the Executive Secretary of the Convention to apply for observer status on the Council for the Trade-related Aspects of Intellectual Property Rights, and requests him to report back to the Conference of the Parties on his efforts.

C. Ex situ collections acquired prior to the entry into force of the Convention and not addressed by the Commission on Genetic Resources for Food and Agriculture

The Conference of the Parties

1. Decides to continue the information-gathering exercise on ex situ collections acquired prior to the entry into force of the Convention and not addressed by the Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations initiated by decision IV/8;

2. Requests the Executive Secretary to gather available information of the type described in the annexes to the present decision, as appropriate, from Parties, Governments and relevant organizations and forums through questionnaires;

3. Invites relevant organizations and forums already involved in consideration of these issues to provide this information to the Executive Secretary;

4. Invites Parties, Governments and other organizations to provide capacity-building and technology development and transfer for the maintenance and utilization of ex situ collections;

5. Requests the Executive Secretary to report to the Conference of the Parties at its sixth meeting on the implementation of the present decision.

Annex I: Elements for a questionnaire on ex situ collections

A questionnaire to solicit the relevant information may contain the following elements:

1. Number, types and status, including legal status and institutional links, of relevant collections;

2. Approximate number of accessions acquired prior to the entry into force of, or not in accordance with, the Convention on Biological Diversity (<100; >100; >1000; other);

3. Whether the following information is likely to be available: country of origin; name of depositor; date of deposit; terms of access under which the material is available (All available; Some available; None available);

4. Any relevant policies regarding collections that are not addressed by the FAO Commission on Genetic Resources for Food and Agriculture, where appropriate, in particular those addressing the issue of access to the relevant collections, including matters relating to repatriation of information and repatriation of duplicates of germplasm collections;

5. Information regarding the number of requests for information and the exchange of germplasm;

6. Details of the benefits from shared germplasm and information on costs of maintaining such collections;

7. Any other relevant information.

Annex II: Questionnaire on ex situ collections

Objective

To inform consideration of the implementation of the Convention on Biological Diversity by ex situ collections.

1. Information on collections

Number of accessions
Pre-Convention on Biological Diversity
Post-Convention on Biological Diversity
Public
Private
Public
Private

PLANT GENETIC RESOURCES

seed gene banks:
field collections: (e.g. botanic gardens and arboreta)
other: (e.g. DNA, pollen in cold storage, tissue cultures, herbaria)

ANIMAL GENETIC RESOURCES

Whole animal collections: (e.g. zoological gardens; rare breed collections)
other: (e.g. DNA, semen, ova in cold storage)

MICROBIAL GENETIC RESOURCES

culture collections:
other:

2. Information on pre-Convention on Biological Diversity collections (Information to be differentiated between plant genetic resources, animal genetic resources and microbial genetic resources.)

   Is information available on:

   For all accessions
   For most accessions
   For some accessions
   For few accessions
   For no accessions
   country of origin
   name of depositor
   date of deposit
   user institution/country

3. Conditions/restrictions on access and use (Information to be differentiated between plant genetic resources, animal genetic resources and microbial genetic resources.)
   a. Description of the main conditions/restrictions (including those contained in national law, those set by the collections themselves and those set by depositors) on access to and use of genetic resources identified separately, if appropriate, for pre-Convention on Biological Diversity and post-Convention on Biological Diversity material.

b. What limitations, if any (legal or practical), are there on applying the provisions of the Convention on Biological Diversity to the supply of pre-Convention on Biological Diversity materials for collections in your country?

4. Use of collections (Information to be differentiated between plant genetic resources, animal genetic resources and microbial genetic resources.) Information on the number of requests for genetic resources and for information differentiated by type of collection (public/private) and by the source of the request (national/foreign; public/private).

5. Additional information (Information to be differentiated between plant genetic resources, animal genetic resources and microbial genetic resources.)

Any additional relevant information on other key characteristics of collections, for example:

Focus on medicinal plants, certain families/genera/species, emphasis on economic importance, certain ecosystems (e.g. drylands);

Whether the accessions are duplicated elsewhere (for conservation purposes and to determine the genetic diversity of collections world-wide).

Appendix 9: Overseas Examples of Access and Benefit Sharing Schemes

The following descriptions of access and benefit-sharing arrangements are summarised from case studies in the Columbia University School of International and Pacific Affairs, Environmental Policy Studies Working Paper No 4, *Access to Genetic Resources: an Evaluation of the Development and Implementation of Recent Regulation and Access Agreements*, prepared for the Biodiversity Action Network by Environmental Policy Studies Workshop, 1999.

COSTA RICA

INBio-Merck Research Agreement

Background

INBio is a Costa Rican non-government, non-profit, scientific research institute. Merck is a United States multinational pharmaceutical products and services company. Their agreement was signed in 1991 and renewed in 1994 and 1996.

Sustainable use and conservation

The INBio-Merck agreement does not explicitly address sustainability.

However, INBio has a cooperation agreement with the Ministry of Environment and Energy which states that 'INBio's gathering of specimens will cause no harm or alteration that may imply or become a threat to the biodiversity of the site where the specimen was removed'.

This agreement allows INBio to collect biological samples for the purpose of bioprospecting, states that the equivalent of at least 10 per cent of each bioprospecting venture's budget is to support the management and protection of conservation areas, and establishes that 50 per cent of any economic and material benefits INBio receives through bioprospecting are to be transferred to MINAE (and used for conservation purposes). To date, MINAE has received $100,000 for these purposes.

Benefit sharing

Under the agreement, Merck provided $1 million during the first two years to purchase laboratory equipment and materials to operate INBio's processing laboratory; the original agreement provides that Merck is to provide additional funding in an agreed amount for the extension period. The agreement applies to the sharing of a predetermined (confidential) number of plant, insect and environmental (micro-organism) samples. Samples are initially extracted and processed by INBio, and their properties are explored at Merck facilities in Spain and the United States.

The division of royalties between INBio and Merck is not known, being confidential to the agreement. However, INBio stipulates that 50 per cent of any royalties it

receives are destined for MINAE, in accordance with their agreement. No royalties have yet been derived from INBio samples.

The agreement includes a confidentiality article which prevents either party from disclosing any confidential information to third parties for seven years from the expiration of the agreement.

Although the standard INBio agreement specifies the non-exclusivity of the arrangement, the contract with Merck prevents INBio from supplying other organisations interested in human and animal health or agriculture with the samples it provided Merck for a two-year initial evaluation period. After this period, Merck may extend the exclusive evaluation period indefinitely for up to 1 per cent of the total number of samples provided to them. INBio is free to offer all other samples to other parties and may enter into agreements with other parties.

Prior informed consent

Although prior informed consent is not referred to explicitly in the INBio-Merck agreement, the agreement requires that virtually all developments be reported to the other party.

Law 7788 addresses prior informed consent in several ways. For example, if access to Indigenous lands is sought, prior informed consent must be obtained from the authority of the Indigenous community and the Director of the Conservation Area. The law recognises local and Indigenous communities' right to oppose the access to resources and associated knowledge for cultural, spiritual, social, economic or any other reason.

Property rights

The INBio-Merck agreement stipulates that samples will be collected from the conservation areas of Costa Rica and other areas of the private domain. INBio, and subsequently Merck, appears to have access to all biological resources found in Costa Rican territory. However, no mention is made of the 'owner' of the physical resources in either Costa Rica's legislation or the INBio-Merck agreement.

Intellectual property

The INBio-Merck agreement authorises each party to independently prepare, submit, follow-up and maintain all patents, provided they consult the other party on all plans and developments.

Indigenous issues/sui generis community intellectual property rights

Law 7788 deals with intellectual and industrial property rights. The mechanisms of protection include patents, commercial secrets, plant improvement rights, sui generis community intellectual property rights, and agricultural rights.

A significant exception is inventions derived from knowledge associated with traditional or cultural biological practices in the public domain. This exception

juxtaposes with the article on sui generis community intellectual property rights which stipulates that the State expressly recognises and protects the practices and innovations of Indigenous peoples and local communities. The purpose of the article is to prevent any form of protection of intellectual or industrial property rights from affecting historical practices; it does not constitute a recognition of any property rights per se or mandate compensation.

Other articles call for examination, determination, and registration of sui generis community intellectual property rights via a participatory process. Another article calls for determination of how sui generis community property rights will be used and who will hold their title, and will identify the recipients of any benefit derived therefrom.

However, no specific measures have yet been taken to ensure that local and Indigenous property rights are enforced and communities compensated.

THE PHILIPPINES

1995 Philippines Executive Order 247

Outline/key points

Section 1 states that it is state policy 'to regulate the prospecting of biological and genetic resources so that these resources are protected and conserved, are developed and put to the sustainable use and benefit in the national interest'.

Bioprospecting is permitted 'within the ancestral lands and domains of Indigenous cultural communities' only with their prior informed consent, 'obtained in accordance with the customary laws of the community' (Section 2).

Section 3 provides for research agreements, ie Academic Research Agreements (ARAs) and for commercial agreements, ie Commercial Research Agreements (CRAs) where collection is intended, directly or indirectly, for commercial purposes.

Applicants for these agreements are required to submit an application to the Inter-Agency Committee on Biological and Genetic Resources through the Protected Areas and Wildlife Bureau (an agency of the Department of the Environment and Natural Resources). A copy of the proposal must be submitted to the recognised head of the local or Indigenous cultural community or communities that may be affected (Section 4).

Section 5 provides for the following minimum terms for research agreements:

- There is a limit on samples that may be obtained and exported.

- A complete list of all samples collected will be deposited with the national museum or a designated government body.

- Access to this material will be allowed to all Filipino citizens and government bodies when they are deposited abroad.

- The collector must inform the Government and relevant Indigenous communities of all discoveries from the activity, if a commercial product is derived.

- Agreements will include provision for payment of royalties where commercial use is derived from the resource (other forms of compensation may be negotiated where appropriate).

- The Government may unilaterally terminate an agreement where the collector has violated any of its terms.

- Status reports of the research and the ecological state of the area and/or species will be submitted to the Inter Agency Committee regularly, as agreed.

- If the collector is a foreign identity, scientists who are citizens of the Philippines must be actively involved in the research and collection process.

- A fixed fee must be paid in accordance with a schedule of fees determined by the Inter Agency Committee.

- The maximum term for a Commercial Research Agreement will be three years, renewable on review by the Inter Agency Committee.

Provisions for Academic Research Agreements

- The collector is required to apply for a commercial research agreement when the work is being done for commercial projects.

- A minimal fee must be paid to the Government in accordance with a schedule of fees set by the Inter Agency Committee.

- The maximum term for the Academic Research Agreement will be for five years, renewable on review by the Inter Agency Committee.

Section 6 sets out the composition and functions of the Inter Agency Committee on Biological and Genetic Resources.

The Inter Agency Committee on Biological and Genetic Resources is attached to the Department of Environment and Natural Resources. Its membership is as follows:

- Undersecretaries of Department of Environment and Natural Resources and the Department of Science and Technology (co-chairs);
- representatives of the Departments of Agriculture, Health and Foreign Affairs with specified expertise; and
- representatives from the science community (2), the National Museum, non-government organisations active in biodiversity protection selected by that community, and a People's Organisation with membership consisting of Indigenous communities and/or organisations selected by themselves.

Membership terms are for three years, renewable for a further three. A technical secretariat, headed by the Protected Areas and Wildlife Bureau, supports the work of the Inter Agency Committee.

Section 7 sets out the powers and functions of the Inter Agency Committee. These include meeting at least quarterly, process applications and recommend for approval to the relevant department head; ensure the conditions of research agreements are strictly observed; and ensure the rights of Indigenous and local communities are protected.

Section 8 provides that the Protected Areas and Wildlife Bureau will be the lead agency in monitoring the implementation of research agreements. Section 9 provides for decisions of the Secretary of the relevant government department to be appealed to the President.

Department Administrative Order No 20 (DAO 96-20)

The Executive Order is supplemented by the Department of Environment and Natural Resources' Department Administrative Order (DAO) which was issued in 1996. DAO 96-20 sets out the rules and regulations governing implementation of EO 247, provides details about the application and review process for parties seeking access to genetic resources and established the Inter Agency Committee on Biological and Genetic Resources.

Agreements under EO 247

The Philippines government has approved only two of 37 applications to date. They are a commercial research agreement between the Marine Science Institute of the University of the Philippines, (the co-collector) the Department of Agriculture and the University of Utah (the collector) signed in 1998 (CRA 98); and an academic research agreement between the University of the Philippines and the Philippines Government signed in 1999.

The CRA 98 allows parties to collect marine organisms as a source of extracts and compounds with potential anti-cancer activity which are exported to the United States for evaluation.

Sustainable use and conservation

Under the CRA 98, the potential impact of the proposed activities on the environment is considered to be minimal. Only the kind and quantity of materials listed in the attachments to the agreement can be collected, and collection carried out only in designated areas.

Property rights

The ownership of all the materials remains with the Republic of the Philippines and a complete set of all specimens is to be deposited at the University of the Philippines/Marine Science Institute. When materials collected under the agreement are transferred to third parties, ownership is defined explicitly by CRA 98 and must be accompanied by a standard Material Transfer Agreement. Data documents and other materials are required by law to remain confidential for purposes of acquiring intellectual property rights, and cannot be disclosed until after the rights of the inventions become vested and are protected.

Prior informed consent

Section 7 of the DAO 96-20 provides detailed procedures for obtaining prior informed consent for both ARAs and CRAs. Chapter VI of The Indigenous People's Rights Act 1997 states that 'access to Indigenous knowledge related to the conservation, utilization and enhancement of biological and genetic resources shall be allowed in ancestral lands and domains only with a free and prior informed consent of the communities, obtained in accordance with customary laws of the community'.

CRA 98 sets out requirements and time lines for obtaining prior informed consent from Indigenous communities in each year of the agreement. For Material Transfer Agreement under the agreement, third parties must obtain written consent from the University of Utah/ University of the Philippines/Marine Science Institute for the intellectual property rights to inventions developed from the materials and before attempting to licence or otherwise develop the intellectual property.

Benefit sharing

Under the agreement, co-collectors must pay a bioprospecting fee, in the amount of ten thousand pesos, to the Inter Agency Committee on Biological and Genetic Resources for the duration of the agreement. A minimal performance bond is payable, to be returned at the end of the agreement, providing there has been no violation of the agreement (this reflects the expectation that there will not be a significant impact on the environment). All product discoveries (improvements and use) must be made available to the Government and local communities concerned.

Intellectual property

Either the co-collectors or the third party can obtain intellectual property rights and/or commercialise materials and/or technology derived from them. Where such rights

exist, a separate agreement must be made among the co-collectors and the third party for sharing the royalties, other benefits and technology derived from the collected materials.

With any invention, license, royalty or commercialisation of any material occurs, 5 per cent of the net revenue will be paid to the Department of Agriculture (the Integrated Protected Areas Fund if the materials come from a protected area; the concerned Indigenous people or local community who gave the prior informed consent; or persons who provided such materials from private property).

THE UNITED STATES

1997 The Yellowstone-Diversa Agreement

In the United States, access to biological resources in public lands is regulated under pre-existing legal instruments which were not specifically designed to comply with the Convention on Biological Diversity. Although the practice of bioprospecting on public land is well established in the United States, the Yellowstone-Diversa agreement is the first bioprospecting contract. The agreement relies primarily on the National Park Service Organic Act and the Federal Technology Transfer Act.

Sustainable use and conservation

The National Environmental Protection Act requires that any federal action 'significantly affecting the quality of the human environment' be subject to a prior environmental impact assessment or environmental assessment. However, exclusion from this requirement is possible and in order to claim this exclusion, Yellowstone defines Diversa's bioprospecting activities as resource management.

It would appear that sampling of bacterial organisms is not an ecologically detrimental activity. From the Park's perspective, the sampling process does not affect conservation efforts.

Property rights

Yellowstone is administered by the National Park Service under the authority of the federal government's Department of the Interior. The National Park Service Organic Act governs the collection of research specimens on national park land. Issue of permits (by park superintendents) is subject to the submission of a Statement of Work which describes in detail the objectives and methods of collection activities. Permits do not transfer ownership of specimens to the collector. In the case of the Yellowstone-Diversa agreement, ownership of the physical material collected remains park property.

Prior informed consent

In the Yellowstone-Diversa agreement, prior informed consent between the parties may not be a major issue as it was the park service that initiated the process with the

intention of discovering applications for products derived through research on thermophilic organisms.

Benefit sharing

The contract provides for annual payments from Diversa to Yellowstone of US$100,000 for five years for sample collecting and collaborative research with the Yellowstone research facility as well as in-kind services and resources valued at US$375,000. The exact terms regarding the sharing of royalties earned by Diversa through eventual commercialisation remain confidential, but the corporation and the park have referred to figures of á5 per cent to 10 per cent from proceeds. All proceeds are to go to the park for the purposes of conservation and enhancement of research facilities.

Intellectual property

The Federal Technology Transfer Act 1986 was enacted in response to concern that research funded by federal agencies did not result in the return of commercial benefits from the laboratories of origin. Application of the Act to Yellowstone relies on the interpretation of the term 'laboratory' to include national parks and possibly all federal lands.

In the Yellowstone-Diversa agreement, the Federal Technology Transfer Act was invoked to allow the results of research to be used for commercial purposes.

BRAZIL

Proposed federal legislation

National Bill No 306 was introduced in 1995. This bill addresses:

- the issue of national sovereignty over genetic resources;
- regulation of access to these resources and their derived products;
- protection of traditional knowledge associated with genetic resources; and
- sharing of benefits derived from the outcome of access to genetic resources.

Bill No 306 would ensure that access and benefit sharing would be controlled by a single national agency which would have the power to grant authorisation for access; monitor requests for and activities of access; grant authorisation for and monitor the export of samples; and maintain a database of information and requests for access and remittance.

A second bill was introduced in 1998 to address some concerns about Bill No 306. This bill (the Wagner bill) affords stronger rights to Indigenous peoples and

communities by referring to laws which enable other entities to act in defence of these groups' rights.

A third bill was prepared by the Interministry Group on Access to Genetic Resources. This group was established to review and analyse Bill No 306. A major difference between the Interministry Group on Access to Genetic Resources bill and first two bills is that the Group's proposal leaves the specific details of regulation to be developed and implemented through regulatory mechanisms to be established.

Sustainable use and conservation

The three federal bills establish that the regulations are relevant to the conservation and sustainable use of the nation's genetic resources. The protocol for access requests in Bill No 306 requires applicants to provide information on the environmental sustainability of collection and the risks that may arise from access. The competent authority may also require an environmental impact study and report on the activities being carried out. The No 306 and Wagner bills call for the government to 'adopt measures to prevent serious and irreparable damage deriving from activities carried out under the terms of the Act', citing eight potential threats similar to those in the Sao Paolo bill (see below).

Property rights

Bill No 306 states that 'genetic resources and derived products are considered public property for special use of the Brazilian nation' and recognises national sovereignty over genetic resources.

The Interministry Group on Access to Genetic Resources bill recognises the different land property types, including Indigenous lands, protected areas, private property and areas indispensable for national security, each of which has an organising body which must be a party to the contract for access.

Intellectual property

Bill No 306 recognises traditional knowledge held by Indigenous people and communities as a protected right of these groups. Holders of 'possible intellectual property rights' are required to be determined in the access contract. It is also stipulated that 'depositors of intellectual creations subject to protection by copyright, industrial property, crops, or any other mode of intellectual property' based on any genetic resource of traditional knowledge must present a certificate of approval by the groups of origin before requesting legal protection of the property.

The Interministry Group on Access to Genetic Resources bill does not specifically mention intellectual property rights but recognises the special status of traditional knowledge.

Prior informed consent

In the No 306 and Wagner bills prior informed consent is required for any request of

access to genetic resources or traditional knowledge. The Interministry Group on Access to Genetic Resources bill does not address prior informed consent, leaving this to regulations.

Benefit sharing

The 306 and Wagner bills refer to benefit sharing as the 'distribution of outcomes, whether economic or not, of research, development, commercialisation or licensing derived from the access to genetic resources'. In addition, 'a fair compensation [must be] ensured to the State, in the form of money or commercialisation rights' and shall be used for conservation, research and inventory of genetic resources, and project support, as decided by the competent authority.

The Sao Paulo bill

Sao Paulo State drafted a bill in 1999. It is currently under public discussion and a final draft has not yet been presented to the State government.

Under the bill, research permits are issued primarily for non-commercial collection of material. Any potential for commercial development must be addressed in a further agreement with the State. The bill also establishes that authorisation for access to genetic resources, derived products and traditional knowledge will only be granted to a Brazilian institution, public or private, conducting biological research. Foreign researchers will be authorised to conduct research only in conjunction with an authorised supervising Brazilian institution.

Sustainable use and conservation

Guaranteeing the sustainability of native genetic resources and the preservation of the environment are the explicit goals of the Bill. The bioprospector will be solely responsible for any damage inflicted on the environment and traditional communities.

The Bill specifically authorises the State Environmental Secretariat to require an environment impact assessment together with a given access request, and to deny access based on any of the following circumstances:

- extinction risk of the species;
- subspecies or varieties;
- high rarity or endemism;
- ecosystem vulnerability;
- adverse effects on human health or the quality of life, the cultural identity, of the local or traditional communities;
- risk of genetic erosion; and

- use of these resources to goals contrary to national interest and the treaties signed by Brazil.

Property rights

According to the State bill, regulation of resources on private property are to be dealt with under federal provisions on property rights, and the regulation of access to lands owned by Indigenous populations is deferred to specific legislation and is explicitly excluded from the state law provisions. It further states that it does not intend to interfere with the rights of the owners of that land where the resources are found. Under its premises, private owners are free to negotiate payments (compensatory or royalty-derived) directly with the users, federal procedures and fees notwithstanding.

Intellectual property

Permission to patent any product or process obtained from the access to resources in State Conservation Units is to be regulated by the State; in private areas, however, intellectual property rights are to be regulated by specific federal patent legislation.

Prior informed consent

Several articles of the Bill state that prior informed consent is required for any request of access to genetic resources or traditional knowledge.

Benefit sharing

The bill establishes that state authorisation for the commercial use of products or processes resulting from access will be formulated as a 'Contract on the Use and Sharing of Benefits'. Some of the major elements that must be included in a contract are the mechanisms by which the equitable sharing of the benefits will be achieved; the pertinent intellectual property rights, and the sanctions and mechanisms for solving conflicts among the parties. The parties to this contract must consist of the state government, the owner of the land (public or private) or representative of traditional or Indigenous community; the institution requesting access, and when applicable, the institution receiving the samples.

National Cancer Institute-Universidade Paulista Agreement

The National Cancer Institute is the primary agency for cancer research and training for the United States government. In 1997 the National Cancer Institute and the Universidade Paulista (a private educational institution in the state of Sao Paulo, Brazil) signed an agreement following the standard format of the National Cancer Institute's Memorandum of Understanding. Universidade Paulista has also submitted a request for access to genetic resources to the Environment Secretariat of Sao Paulo State in association with two other public associations. If this goes ahead, the group will obtain collecting permits for the State Park.

Sustainable use and conservation

The Memorandum of Understanding establishes that the National Cancer Institute wishes to 'promote the conservation of biological diversity' and 'that it recognises the need to compensate source country organisations and peoples in the event of commercialisation of a drug developed from an organism collected within their borders'. Clause 13 specifies that if the source country cannot provide the desired product to a licensee in adequate quantity or price, the licensee is to pay the source country a negotiated amount that is to be spent in cultivation of endangered medicinal plant species.

Property rights

Provisions regarding property rights of the land or biota where the genetic resources are to be collected are not provided for in the Memorandum of Understanding. Instead, property rights are addressed in the agreement between the Universidade Paulista and the Environment Secretariat of Sao Paulo State. Universidade Paulista has requested access only for random collection of plants; thus property rights pertaining to state land apply, according to the proposed state law.

Intellectual property

The Memorandum of Understanding provides for joint patent protection for all inventions developed collaboratively by the National Cancer Institute and source country employees. If a compound isolated in the source country merits advancement to pre-clinical development, the source country can elect to apply for patent protection as the sole owner of the invention. The Memorandum of Understanding seems to rely on the source country's internal arrangements for regulation of traditional knowledge.

Prior informed consent

Prior informed consent of the source country organisation is required for transferring materials collected to their parties and for publication of results. The Memorandum of Understanding does not directly acknowledge the intellectual property rights of traditional communities.

Benefit sharing

The main benefit-sharing provisions of the Memorandum of Understanding include:

- monetary benefits are to be negotiated directly between the source country and the potential licensee of a patented product;
- joint patent protection is sought for all inventions developed collaboratively;
- facilities being available, the source country undertakes primary screening and later fractionalisation of compounds, with staff training and bioassay materials provided if these are non-existent;

- results of National Cancer Institute-based advanced screens must be repatriated within 90 days;

- licensee is to resupply from the source country or provide monetary compensation; and

- distribution of material to third parties from the National Cancer Institute is subject to prior informed consent from the source country.

Andean Pact Decision 391

The following is a summary of key provisions of the Andean Pact Decision 391. A copy of the decision was included as an attachment to ATSIC's submission to the Inquiry.

The Andean Pact decision is an agreement between Bolivia, Columbia, Ecuador, Peru and Venezuela.

The objective of the decision is to regulate access to the genetic resources of the Member Countries in order to (among other things):

- create the conditions for fair and equitable sharing of benefits;

- establish a basis for recognition and appreciation of genetic resources, particularly where Indigenous, afro-American and local communities are involved; and

- encourage conservation of biological diversity and sustainable use of biological resources containing genetic resources.

The agreement sets out various principles which include Member Countries' sovereignty over their genetic resources, recognition of traditional practices, knowledge and innovations, and support for training, research, development and transfer of technology.

Access procedure

All access procedures must include the presentation, admission, publication and approval of an application, signature of a contract, issue and publication of the corresponding resolution and a declaratory record of actions linked with such access.

Applications for and contracts of access must include conditions such as:

- participation by nationals of the region in research activities into genetic resources;

- support for research contributing to the conservation and sustainable use of biological diversity;

- strengthening of mechanisms for the transfer of knowledge and technologies, including biotechnologies, which are culturally, socially and environmentally safe and healthy;

- provision of information on antecedents, scientific progress or of any other nature likely to contribute to greater knowledge of matters relating to the genetic resources for which the Member Country is the country of origin;

- strengthening and development of capacities of Indigenous, afro- American and local communities with regard to the intangible components associated with genetic resources;

- obligatory deposit of duplicates of all material collected;

- obligation to inform the Competent National Authority of the results of research; and

- terms under which material may be transferred to third parties.

Documents relating to the access procedure must be included on a public record file kept by the Competent National Authority.

The Competent National Authority will keep a public record of, among other things, the resolution dismissing the application, dates of signature, modification, suspension and termination of the access contract; date and number of the resolution delivering or cancelling the contract, date and number of the decision leading to the annulment or imposing conditions, etc.

Delivery of access is determined by the legally correct, complete and trustworthy information provided by the applicant. The applicant must therefore present the Competent National Authority with all the information concerning the genetic resource with which he is familiar or in a position to know at the time of presenting the application.

The application should contain the following:

- identification of the applicant;

- identification of the supplier of the resources;

- identification of the national support institution or individual;

- identification and curriculum vitae of the project manager and working group;

- nature of the access activity being requested;
- location or area in which access will be made; and
- a project proposal.

The Competent National Authority will give a date for its presentation or establishment and register it in the official record.

Within five working days of its inscription in the public record an extract of the application shall be published so that any person may submit information to the Competent National Authority.

The Competent National Authority shall evaluate the application within 30 working days of its registration (extension to 60 days on its discretion).

The Competent National Authority shall then either accept or reject the application.

Once the application and project proposal have been accepted, the applicant will be notified within five working days and may proceed to the negotiation and drafting of the access contract.

The applicant should comply with the applicable environmental regulations in cases where this is required under the legislation of the Member Country of if the Competent National Authority deems it necessary to do so.

The Access Contract is covered as follows:

Parties: the State represented by the Competent National Authority and the applicant are the parties to the contract.

The access contract shall include an annex providing for the fair and equitable distribution of the benefits.

Once the contract has been signed, the corresponding resolution shall be published in the official journal or gazette or in a daily newspaper.

The Member Countries may establish limitations on access in the following cases:

- endemism, rarity or threat of extinction of species;
- conditions of vulnerability or fragility in the structure or function of ecosystems, likely to be aggravated by access activities;
- adverse effects of access activities on human health or on essential elements of the inhabitants' cultural identify;
- access activities likely to have undesirable or hard-to-control environmental impacts on ecosystems;

- danger of genetic erosion due to access activities;
- regulations governing biosafety; or
- genetic resources or geographical areas classified as strategic.

Other provisions cover infractions and penalties, notifications among Member countries, the Competent National Authority and the Andean Committee on Genetic Resources.

Appendix 10: Indigenous interests in biological resources in Commonwealth areas -- synthesis of submissions and related information by Henrietta Fourmile

13 June 2000

Introduction

The need to respect the particular relationship between Indigenous people, their ancestral territories and the species to be found in those territories is widely acknowledged in the submissions to the Inquiry, as is the need to respect any traditional knowledge associated with their territories and species.

Many submissions strongly supported recognition of Indigenous cultures in maintaining Australia's biological diversity.1 The basic framework for the definition and recognition of Indigenous rights to lands, species and knowledge has been evolving for more than a decade in various international fora, including that provided by the Convention on Biological Diversity, and has been well summarised by Posey and Dutfield (1996) in the concept of 'traditional resource rights'. A number of submissions2 have drawn attention to this fact. For example, the Australian Research Council points out that:

An essential framework for the recognition of the rights of Indigenous peoples to their traditional knowledge and to the natural resources upon which they have relied for their subsistence has emerged over the last decade. These rights include the right to manage such natural resources, and to be involved in any decisions regarding those resources.3

It is anticipated there will be increased respect for the role that traditional biodiversity-related knowledge has in land and biodiversity management. This increased respect will stem from:

- Commonwealth obligations under various international agreements, such as the Convention on Biological Diversity; and

- national policy instruments, such as the National Strategy for Ecologically Sustainable Development and the National Strategy for the Conservation of Australia's Biological Diversity;

which are reflected in the various requirements in Bilateral Agreements between the Commonwealth and the States and Territories under Chapter 3 of the Commonwealth's Environment Protection and Biodiversity Conservation Act 1999.

1 For example, Australian Biotechnology Association, Sub.37:p.2; Environmental Defenders office, Sub.55:p.1.
2. ATSIC, Sub.56; Bennet, Sub.9; Australian Research Council, Sub.40.
3.Sub.40:p.21-2.

With the prior informed consent and involvement of the knowledge-holders, it is expected that traditional biodiversity-related knowledge will play an increasing part in activities and processes regarding, for example:

- protected area, water catchment, forest management and land management generally;
- development plans;
- environmental and social/cultural impact assessments;
- species monitoring and recovery plans;
- rehabilitation of degraded lands;
- taxonomy; and
- alien species eradication programs.

It is, therefore, to be expected that there will be an increasing need to take account of traditional biodiversity-related knowledge in a range of activities and processes sanctioned by Commonwealth and State and Territory governments.

There is also considerable commercial interest in Indigenous traditional knowledge of plant and animal species for food, medicine and other purposes. Much of this knowledge has already been recorded and has been published in books readily available to the public as well as in scientific journals. Such knowledge is useful in helping to locate species that could be used, for example, by:

- the pharmaceuticals industry for developing new drugs;
- herbalists and the medical profession in developing natural therapies and neutriceuticals;
- the bushfood industry, for new herbs, spices, flavours and food staples;
- agricultural, aquaculture and floriculture industries;
- industries based on development of personal care products, ie cosmetics, soap, shampoo, fragrance, sun-screen, aromatic oil, etc; and
- biotechnology industries, in which products associated with any of the above industries are developed, as well as industrial products such as adhesives, cleansing agents, etc, and processes.

When Indigenous traditional knowledge is used to develop any new products, submissions widely acknowledged that Indigenous holders or owners of such knowledge should have the right to:

- determine conditions of use and access;
- be involved in the application of their knowledge, if they so wish; and
- an equitable share in any benefits which arise from use of their knowledge.

All these rights are recognised in Article 8(j) of the Convention on Biological Diversity.

A wide perception exists, among Indigenous peoples, that their knowledge has been ripped-off. The evidence can be readily seen, for example, in any government or ABC bookshop, where publications, such as the 'Bush Tucker Man' series, on bush tucker and Indigenous use of plants (particularly) can be readily purchased. In some cases these publications have been undertaken in collaboration with traditional knowledge-holders, who are duly acknowledged. A prime motivation in many of these collaborations is to ensure their traditional biodiversity-related knowledge is recorded and preserved. In other cases, Indigenous sources are not acknowledged, and the non-Indigenous author (or the institution for which he or she works) holds the copyright over this information.

While such 'rip-offs' cause grave cultural offence and harm, in considering this issue in the context of access and benefit sharing there is also need to reckon with the economic or monetary value of traditional knowledge within the research and development process.

A number of submissions4 drew attention to the recently released ATSIC report, Our Culture: Our Future, prepared by Terri Janke. The report deals with a number of mechanisms and options which can be used or developed to protect Indigenous cultural and intellectual property. Such options include:

- amendments to existing intellectual property rights laws;
- development of sui generis legislation and codes of ethics; and
- common law remedies.

Relevant findings and recommendations of the Our Culture: Our Future report will be referred to in this synthesis.

There may be a number of matters (because of the complexities involved and the need to respect Indigenous sensitivities and/or customary laws) which may lie outside the ambit of the regulations and be best left to the Indigenous community to resolve. Such matters may include:

- establishing an Indigenous biodiversity trust;
- developing capacity-building measures (as sought in the ATSIC submission); and
- distributing benefits between Indigenous stakeholders (how they should be distributed, what form they should take, etc.).

4. Attorney General's Department, Sub.23; ATSIC, Sub.56; Northern, Central and Kimberley Land Councils, Sub.52.

Inquiry terms of reference

The inquiry is to advise on a scheme that could be implemented through regulations under s301 of the Environment Protection and Biodiversity Conservation Act 1999 to 'provide for the control of access to biological resources in Commonwealth areas'.

The scheme is to take into account:

1. Australia's obligations under the Convention on Biological Diversity, including the obligation to encourage equitable sharing of the benefits arising from the use of biological resources. The scheme should particularly focus on the equitable sharing of benefits arising from the use of traditional knowledge, innovations and practices (Article 8(j)).

2. The objectives of the National Strategy for the Conservation of Australia's Biodiversity, such as:

    - ensuring the collection of biological resources for research and development does not adversely affect the viability or conservation status of any species or population; and

    - ensuring the social and economic benefits from the use of biological resources derived from Australia's biological diversity accrue to Australia.

The scheme should operate in a manner that promotes certainty for industry and facilitates access to biological resources for environmentally-sound uses.

Consistent with the objects of the EPBC Act, the scheme should:

- promote a cooperative approach to protecting and managing the environment and involve governments, the community, land-holders and Indigenous people;

- recognise the role of Indigenous people in the conservation and ecologically sustainable use of Australia's biodiversity; and

- promote the use of Indigenous peoples' knowledge of biodiversity with the involvement of, and in cooperation with, the owners of that knowledge.

Section 301 'Control of access to biological resources', of the EPBC Act states:

- The regulations may provide for the control of access to biological resources in Commonwealth areas.

- Without limiting subsection (1), the regulations may contain provisions about all or any of the following:

    - the equitable sharing of the benefits arising from the use of biological resources in Commonwealth areas;

- the facilitation of access to such resources;

- the right to deny access to such resources; and

- the granting of access to such resources and the terms and conditions of such access.

Principles of a scheme to control access

A number of submissions[5] indicated the need for a set of principles to provide a framework for developing a regime for accessing biological resources. They recommended:

> that the Commonwealth adopt, as the basis for access to biological resources in Commonwealth areas, a simple, comprehensive, effective and consistent system, founded on the basic principles identified by the Commonwealth State Working Group on Access to Biological Resources in its October 1996 discussion paper, Managing Access to Australia's Biological Resources: Developing a Nationally Consistent Approach (see p.11).

In its submission, Environment Australia[6] pointed to four over-arching principles, or desirable features, of an access scheme/regime, namely, that such a regime should:

- provide effective protection of biological diversity and important natural heritage sites;
- provide incentives for conservation and sustainable use of biological resources;
- is equitable and transparent; and
- is simple and efficient to administer.

To these principles could be added:

- provide certainty, not only to industry, but to all stakeholder groups including Indigenous stakeholders;
- be cost effective;
- avoid duplication; and
- have international credibility.[7]

With regard to this last point, the CSIRO[8] explains the principle that:

> ... consistency with international developments is of paramount importance. Australian agriculture has a net dependency on overseas biological resources, and consequently any access management regime should seek to ensure both Australians and overseas parties have access to Australian biological resources on similar terms as we would like to have to other biological resources kept overseas.

5. For example, CSIRO, Sub.65:p.8;Environmental Defenders Office (Vic), Sub.55:p.3-4; Commonwealth Department of Education, Training and Youth Affairs, Sub.43;Commonwealth Department of Industry, Science and Resources, Sub.41.
6. Sub.70
7.Department of Training, Education and Youth Affairs, Sub.43; CSIRO, Sub.65:p.8
8. Sub.65:p.8.

The issue of international credibility also has other dimensions, particularly with regard to enforcement. International consistency in legislation governing access to biological resources with regard to enforcement clauses will make it easier for Indigenous stakeholders, for example, to pursue actions against those who have infringed access conditions where Indigenous interests are concerned. This issue has been dealt with further in 'Illicit use of traditional knowledge in the international arena' below.

Environment Protection and Biodiversity Conservation Act 1999

The Act puts into law many of Australia's obligations under international environment-related treaties, such as the:

- Convention on Biological Diversity;
- Ramsar Convention on Wetlands of International Importance Especially as Waterfowl Habitat;
- Convention on the International Trade in Endangered Species of Wild Fauna and Flora (CITES);
- World Heritage Convention (Convention for the Protection of the World Cultural and Natural Heritage); and
- bilateral agreements with China and Japan regarding migratory birds: ie the China-Australia Migratory Birds Agreement and the Japan-Australia Migratory Birds Agreement.

It replaces the National Parks and Wildlife Conservation Act 1975 and contains many provisions of direct relevance to Indigenous peoples in Australia. The Act does not affect operation of the Native Title Act 1993 [s8].

Most importantly, in many of its provisions, the Act reflects Australia's obligations to Indigenous peoples under the Convention on Biological Diversity. For example, amongst the objects of the Act [s3] occur the following:

d. to promote a cooperative approach to the protection and management of the environment involving governments, the community, land- holders and indigenous peoples; and

f. to recognise the role of indigenous people in the conservation and ecologically sustainable use of Australia's biodiversity; and

g. to promote the use of indigenous peoples' knowledge of biodiversity with the involvement of, and in cooperation with the owners of the knowledge.

In order to achieve its objects, the Act, under s3(2)(g)(iii) promotes a partnership approach to environmental protection and biodiversity conservation through 'recognising and promoting Indigenous peoples' role in, and knowledge of, the conservation and ecologically sustainable use of biodiversity'.

Recognition and protection of Indigenous interests provisions occur many times in the Act. For example, under s49A, one of the prerequisites for making bilateral agreements between the Commonwealth and the States and Territories is that the Minister may enter into such an agreement only if he or she:

c. has considered the role and interests of indigenous peoples in promoting the `conservation and ecologically sustainable use of natural resources in the context of the proposed agreement, taking into account Australia's relevant obligations under the Biodiversity Convention.

This, of course, means the obligations specified in Articles 8(j), 10(c), 17.2 and 18.4 in particular. The Minister, as long as other requirements are satisfied in relation to listed threatened species and ecological communities [s201(3)(c)], may issue permits, for example, for hunting, fishing and gathering in a Commonwealth area, as long as he or she is satisfied that 'the specified action is of particular significance to indigenous tradition and will not adversely affect the survival or recovery in nature of the listed threatened species or listed threatened ecological community concerned'.

Similar provisions also occur in relation to migratory species [s216(3)(c)] and listed marine species [s258(3)(c)]. Within the Act, 'indigenous tradition means the body of tradition, observances, customs and beliefs of indigenous persons generally or of a particular group of indigenous persons' [s201(4)]. In the content of recovery plans [s270(3)(e)], in the making of a recovery plan, regard must be had to 'the role and interests of indigenous people in the conservation of Australia's biodiversity'. Similar wording also occurs in relation to threat abatement plans [s271] and wildlife conservation plans [s287(3)(e)].

The Minister, under s305, may enter into conservation agreements (subject to a number of other provisions) with an Indigenous entity, which is legally binding [s307]. The relevant paragraphs of s305 state that:

5. Under subsection (1), the Minister may enter into a conservation agreement covering land with one of the following persons who has a usage right relating to the land:

    a. an indigenous person;

    b. a body corporate wholly owned by indigenous persons;

    c. a body corporate established by or under an Act for the purposes of holding, for the benefit of indigenous persons, land vested in it by or under the Act; and

    d. the trustee of a trust that holds land for the benefit of Indigenous persons.

This does not limit subsection (1)

6. The Minister must take account of the following when entering into a conservation agreement as described in subsection (4):

    a. paragraph (j) of Article 8 of the Biodiversity Convention;

    b. paragraph (c) of Article 10 of the Biodiversity Convention;

    c. paragraph 4 of Article 18 of the Biodiversity Convention;

    d. objective 1.8.2 of the National Strategy for the Conservation of Australia's Biological Diversity, published by the Commonwealth in 1996.

Importantly, the Act recognizes a role for Indigenous peoples in administering the Act. Three committees are established with their membership by ministerial appointment:

- the Threatened Species Scientific Committee [s502 and s503], the principal committee under the Act and also referred to in many of its provisions as the Scientific Committee;

- the Biological Diversity Advisory Committee [s504 and s505];

- the Indigenous Advisory Committee [s505A and s505B].

While membership of the Scientific Committee is determined by the Minister [s502(2)], the Biological Diversity Advisory Committee must have a representative of 'indigenous peoples' [s504(4)(ea)]. With regard to the Indigenous Advisory Committee, as with the other committees, the Minister is to determine in writing the composition of the Committee, including the qualifications of its members. The members are appointed on a part-time basis, and the Minister must appoint one of the members to chair the Committee. Under s505B:

1. the function of the Committee is to advise the Minister on the operations of the Act, taking into account the significance of indigenous peoples' knowledge of the management of land and the conservation and sustainable use of biodiversity;

2. the Minister may give the Committee written guidelines about its function.

While the provisions summarised above have important implications throughout the Act and are an important recognition of Australia's obligations to Indigenous peoples with respect to the Convention on Biological Diversity, it should be remembered that many will only apply where the Act applies only to Commonwealth areas [s525].

However, in the context of bilateral agreements between the Commonwealth and a State or Territory, with respect to s49A(c) and s50(a), in the latter instance the Minister may only enter into a bilateral agreement if satisfied the agreement accords

with the objects of the Commonwealth Act (the Minister is obliged to ensure Indigenous interests are fully taken into account in such agreements). Such bilateral agreements, within the overall context of the Act, will be the principal instruments through which the Commonwealth can ensure the States and Territories comply with the various obligations entered into under the Convention on Biological Diversity.

Consideration of the role of the Indigenous Advisory Committee

Some consideration should be given to the role and function of the Indigenous Advisory Committee established by s505A of the EPBC Act. As noted above, the Minister is to determine the composition of committee and may provide written guidelines about its function. Because of the wide range of issues and international obligations covered by the EPBC Act which affect the interests of Indigenous peoples in Australia, membership of the Committee should be large enough to enable it to adopt a 'portfolio approach' in covering these issues and to be able to provide informed and quality advice to the Minister. Indigenous biodiversity-related issues are now being addressed in a number of international fora in addition to the Convention on Biological Diversity. These include the:

- Ramsar Convention on Wetlands,
- Convention to Combat Desertification,
- Intergovernmental Forum on Forests,
- World Heritage Convention,
- Convention on the International Trade in Endangered Species (CITES),
- World Intellectual Property Organization,
- World Trade Organization (in relation to the TRIPs Agreement),
- Commission on Human Rights Working Group on Indigenous Populations,
- United Nations Commission on Trade and Development,
- United Nations Food and Agriculture Organization, and
- International Labour Organization Convention 169.

As with the Convention on Biological Diversity, meetings are held regularly under these Conventions and international processes and decisions are being made which directly affect the interests of Indigenous peoples in Australia: yet Indigenous Australians are not being represented at these meetings (with the exception of some recent World Intellectual Property Organization meetings).

For example, the Conference of the Parties (COP) to the Ramsar Convention, at its seventh meeting in Costa Rica in May 1999, adopted guidelines for involving local and Indigenous people in wetland management. Australia was among the first to sign

this convention when it entered into force in 1975 and has emerged as one of the most significant signatories: ranking third in the world in its number of designated wetlands (42), and third in terms of their total area (4, 659,282 ha). While many of Australia's designated wetlands are clustered in Tasmania and southern Australia, other sites include Kakadu National Park, the Coongie Lakes in South Australia, Coburg Peninsula (Northern Territory), Shoalwater Bay (Queensland) and the Lake Argyle-Kununurra wetlands (Western Australia) which are all areas owned, inhabited and/or used by Indigenous communities. While Australia regularly sends delegations of five or six members to most of these meeting, Indigenous representation is absent.

To keep Indigenous communities and the Minister informed and to provide input into the meetings held in these various fora, sufficient funding should be provided so members of the Indigenous Advisory Committee, in accordance with their portfolio responsibilities, can attend relevant meetings.

Recommendation

To provide effective and informed advice to the Minister, the Minister should consider appointing members to the Indigenous Advisory Committee with experience and expertise in intellectual property rights and protection of traditional biodiversity-related knowledge; access and benefit sharing; conservation and sustainable use of biodiversity; international trade; forests; fisheries; wetlands and arid lands.

The Indigenous Advisory Committee should also have representation from ATSIC, Australian Institute of Aboriginal and Torres Strait Islander Studies and the Indigenous Biodiversity Trust (if established).

National strategy for conserving Australia's biological diversity

The National Strategy for the Conservation of Australia's Biological Diversity contains a number of references to Aboriginal and Torres Strait Islander peoples. Of the principles which have been adopted as a basis for the Strategy's objectives and actions, and which should be used as a guide for implementation, the final principle states:

The close, traditional association of Australia's Indigenous peoples with components of biological diversity should be recognised, as should the desirability of sharing equitable benefits arising from the innovative use of traditional knowledge of biological diversity.9

With regard to the objectives, the goal of Objective 1.8 is to: 'Recognise and ensure the continuity of the contribution of the ethnobiological knowledge of Australia's Indigenous peoples to the conservation of Australia's biological diversity.'10 One of the actions designed to implement this objective concerns access to information through:

9. National Strategy for the Conservation of Australia's Biological Diversity, p6
10.op.cit., p.14.

[The provision of] resources for the conservation of traditional biological knowledge through cooperative ethnobiological programs [; and The provision of] access to accurate information about biological diversity for Aboriginal and Torres Strait Islander peoples, and involve them in research programs relevant to the biological diversity and management of lands and waters in which they have an interest.

The Strategy also identifies the need to improve our knowledge and understanding of Australia's biological diversity essential for its effective conservation and management. With regard to the ethnobiological knowledge of Aboriginal and Torres Strait Islander peoples, it is necessary to:

> Recognise the value of the knowledge and practices of Aboriginal and Torres Strait Islander peoples and incorporate this knowledge and those practices in biological diversity research and conservation programs by:
>
> a. encouraging the recording (with the approval and involvement of the Indigenous peoples concerned) of Indigenous peoples' knowledge and practices;
>
> b. assessing the potential of this knowledge and these practices for nutritional and medical uses, wildlife and protected areas management and other purposes;
>
> c. applying the knowledge and practices in ways that ensure equitable sharing of the benefits arising from their use.11

In implementing the Strategy, it is stated that, by the year 2000, Australia will have, among other things,

implemented cooperative ethnobiological programs, where Aboriginal and Torres Strait Islander peoples see them to be appropriate, to record and ensure the continuity of ethnobiological knowledge and to ensure that the use of such knowledge within Australia's jurisdiction results in social and economic benefits to Aboriginal and Torres Strait Islander peoples.12

These references, in their various wordings, reflect the requirements of the Convention on Biological Diversity with respect to Articles 8(j), 10(c), 17.2 and 18.4, but also reflect the need to involve the nation's Indigenous peoples in the work of other provisions, such as Article 7 (identification and monitoring) and the whole of Article 8 (in situ conservation).

Convention on Biological Diversity

In the Convention on Biological Diversity the world has formally recognised the critical role that Indigenous and local communities and their traditional biodiversity-related knowledge have to play in sustainably managing critical components of biodiversity.

11. op. Cit., p.35.
12. op. Cit., p.41.

The official wording of the phrase 'Indigenous and local communities embodying traditional lifestyles' primarily refers to those communities which have not adopted western industrialised forms of agriculture and who remain responsible, in no small way, for the world's food and medicinal security because of the custodial and innovative role they play in nurturing and developing genetic resources essential to modern food and agricultural production. It is estimated that such communities number some 1.5 billion people,13 making Article 8(j), because of the sheer numbers of people involved and because of the critical genetic resources for which they are responsible, one of the most important provisions for the in situ conservation of biological diversity.

Thus consideration for Article 8(j) is embedded in virtually all the work programs being carried out under the decisions made at the various meetings of the Conference of the Parties (COP)14. Consequently, Indigenous and local communities world-wide are increasingly looking upon the Convention on Biological Diversity as the most important international instrument through which to protect natural resources, knowledge, technologies, traditions and lifestyles.

Among its provisions are those that require that:

- traditional knowledge, innovations and practices be respected, preserved and maintained [Article 8(j)];

- such knowledge should only be used with the approval and involvement of its holders [Article 8(j)];

- where it is used, the holders of such knowledge should equitably share in the benefits arising from its use [Article 8(j)];

- customary uses of biological resources in accordance with traditional practices should be protected and encouraged [Article 10(c)]; and

- traditional knowledge and technologies should be accorded the same treatment as other forms of knowledge and technologies that can contribute to the conservation and sustainable use of biodiversity [Articles 17.2 and 18.4].

Importantly, the COP has recognized that 'traditional knowledge should be given the same respect as any other form of knowledge in the implementation of the Convention'. This recognition was given further elaboration at COP5 in Nairobi in May 2000, whereby one of the general principles guiding the program of work adopted to further implement Article 8(j), states that:

'Traditional knowledge should be valued, given the same respect and considered as useful and necessary as other forms of knowledge.'15

13. Food and Agriculture Organisation, 1998:p.25.
14. To implement the provisions of the Convention meet approximately every two years to review progress and make decisions about how to further the work being carried out under the Convention. These meetings are referred to as the Conference of the Parties or COP.
15. COP5, Decision V/16, Annex.

Application of traditional biodiversity-related knowledge also is one of the essential elements making up the ecosystem approach which has been adopted by the COP as a framework for analysis and implementation of the objectives of the Convention on Biological Diversity and in elaborating and implementing the various thematic and cross-cutting work programs under the Convention.16

However, the requirements to 'respect, preserve and maintain' traditional knowledge, and to secure the approval of its holders can only take place within the context of acknowledging and protecting the intellectual property rights of Indigenous communities in their knowledge, innovations and practices. This can be achieved by either adapting and using existing patent and plant breeder's rights regimes, or through using other alternative mechanisms by which to negotiate access to such knowledge, and which will guarantee its acknowledgment and protection. Amendments to both the Patents Act and the Plant Breeder's Rights Act are discussed in Our Culture: Our Future.

Implementation of Article 8(j) and related provisions (Articles 10(c), 17.2 and 18.4) has been considered as a separate agenda item at the last three COP meetings, giving rise to decisions III/14 (COP3 in Buenos Aires, Argentina in 1996), IV/9 (COP4 in Bratislava, Slovakia, May 1998) and V/16 (COP5 in Nairobi Kenya, May 2000), and will be considered again at COP6 at The Hague in 2002.

Decision III/14 authorised a Workshop on Traditional Knowledge and Biological Diversity, which took place in Madrid, Spain in November 1997. This workshop recommended establishing an Ad Hoc Open-ended Intersessional Working Group to address Article 8(j) and related provisions and provided options for a program of work for consideration by COP4. COP4 duly established the Ad Hoc Working Group on Article 8(j) and mandated it to develop the program. The first meeting of the Ad Hoc Working Group took place in Seville, Spain in March 2000 and its recommendations to COP5 have resulted in adoption of a program of work for implementing Article 8(j).

The Secretariat of the Convention on Biological Diversity prepares a number of documents for the meetings held under the Convention by its various bodies (the COP; its principal advisory body, the Subsidiary Body on Scientific, Technical and Technological Advice; the Ad Hoc Working Group on Article 8(j); and various meetings of panels of experts). These documents include reports and background documents which help COP make its decisions, information documents and compilations of case studies, technical and national reports, and so on -- most of which are available to the public through the Convention's clearing house mechanism.

Of particular relevance to this Inquiry is the Report of the Panel of Experts on Access and Benefit Sharing17 and the decisions of COP5 which are available, at this stage, as a pre-publication release through the clearing house mechanism. These documents are also sent to the national focal points for the Convention to help Parties prepare for meetings. The documents, as a whole, contain much information that is of the utmost

16. COP4, 1(B):3
17. UNEP/CBD/COP/5/8, 2 November 1999

relevance to Indigenous communities and are essential if they are to achieve the best out of their negotiations with governments and their agencies.

The Parties consider implementation of Article 8(j) and related provisions to be a cross-cutting issue virtually affecting all sectoral and thematic areas, and work programs dealt with under the Convention on Biological Diversity (eg forests, agro-biodiversity, inland waters, coastal and marine ecosystems, incentive measures, access and benefit sharing, in situ conservation, public education and awareness, environmental impact assessment, and so on). Thus references to 'Article 8(j)' ('traditional knowledge, innovations and practices' and 'involvement of Indigenous and local communities') occur in no less than 11 of the 19 decisions made at COP4. In addition to the Ad Hoc Working Group on Article 8(j) the Executive Secretary of the Convention's secretariat has established a liaison group, comprising representatives of Indigenous and local communities, to act as an informal reference group to provide advice on preparation of documents for the various meetings. Indigenous peoples in Australia have representation on this liaison group.

Representatives of Indigenous and local communities have had a very direct input into the whole Convention process and have had a direct bearing on the outcomes of all the decisions referred to above. In fact the COP, in its meetings, has been very concerned to explore ways and means of increasing the direct and effective participation of Indigenous and local communities in the work of the Convention. Indigenous peoples from Australia have generally been well-represented at the above-mentioned meetings, and because of continuity of attendance, provide considerable leadership at the international level when dealing with issues being addressed by the COP under the Convention.

Recommendation

In order to promote the full and effective participation of Indigenous peoples in Australia in the work of the Convention on Biological Diversity and other international environment-related agreements, the national focal points for these agreements should disseminate the relevant information, forwarded by the respective secretariats, to relevant Indigenous organisations for their consideration.

Ownership of biological resources

In any consideration of ownership of biological resources, the Indigenous position should be respected. Generally, Indigenous peoples in Australia have a particular spiritual connection with the native flora and fauna in their territories as expressed through their totemic relationships with various species. This relationship has been widely acknowledged in the submissions. In this relationship, which is a feature of many Indigenous and local cultures around the world, Indigenous people see themselves as custodians or stewards of biodiversity as distinct from having ownership in the form of a property right over particular species, whether exercised through a system of intellectual property rights (via patents or plant breeder's rights)

or through statutes which might assign particular rights to landowners with regard to native animals and plants found on their land.

It is widely believed, amongst Indigenous peoples both in Australia and overseas (and as evidenced in their many declarations and statements made over the last decade), that all life, even in its tiniest forms and components, is sacred and therefore cannot be owned as property.18 This presents a huge ethical dilemma for traditional owner groups who may wish to profit commercially from native species found on their lands by undergoing, for example, plant breeding activities, and who may wish to take out plant breeder's rights over new varieties they have developed, in order to secure their commercial interests.

There are many religious, philosophical and ethical dimensions to the issue of ownership of biological resources. Many oppose, in particular, use of intellectual property rights to gain control over traditionally used varieties of food, medicinal and other useful species.19 For example, the Environmental Defenders Office:

> ... strenuously objects to patent laws that allow the patenting of components or modification of living organisms. Our objection is based on the following reasons, inter alia:
>
> > The Patent system favours larger corporations over traditional users of biological resources. Patenting systems around the world are littered with examples of major corporations patenting components or variations of living organisms that have been used by traditional breeders or Indigenous peoples for thousands of years.'20

Similarly the Australian GeneEthics Network submits that: 'Patents on life forms, including organisms, genes, primary or secondary compounds are inconsistent with ethical principles and with the beliefs and customs of many Indigenous peoples. ... Patents may apply to specific commercial products as long as they are not living organisms.'21

Patents over genes, genetic processes, etc., can be seen as a way for (some) countries to thwart the principle of national sovereignty over biological resources as contained in Article 15.1 of the Convention on Biological Diversity.

Some concern was also expressed about access to human genetic material (eg through extraction of DNA from Indigenous remains excavated in Commonwealth areas).22 The biological resources referred to under s528 of the EPBC Act do not include human biological/genetic material which is covered under separate legislation (see, for example, the Aboriginal and Torres Strait Islander Heritage Protection Act 1984 (Cwth)). Human genetic resources are also not included within the framework of the Convention on Biological Diversity (see decision II/11, paragraph 2, arising from COP2 in Jakarta, November 1995). Research involving the human genome is, instead, covered under the UNESCO Universal Declaration on the Human Genome and Human Rights.

18. See for example, Michael Anderson, Sub.29; and Attachment 5.
19. See for example, Australian Conservation Foundation, Sub.53.
20. Sub.55:p.3.
21. Australian GeneEthics Network, Sub.59:p.3.
22. Christine Morris, Sub.24; Euroka Gilbert and Kathryb Looke, Sub.31.

Broadly speaking, issues of ownership of biological resources with regard to Indigenous traditional owners revolve around ownership of:

- the biological resource itself;
- land on which a biological resource is found; and
- any knowledge associated with the particular biological resource for which access is being sought.

It will only be in rare instances that ownership of land, a particular biological resource and associated knowledge will coincide. Such instances are likely to be confined to cases in which a particular species is endemic to a particular area of land owned by an Indigenous traditional owner group and over which they hold native title rights, particularly species found on their lands to which their cultural, social and economic rights, associated with the species, are recognised.

On the other hand, a situation more likely to arise is where Indigenous traditional owner groups have neither title to land nor can they claim, or have yet to establish, (native title) rights to traditionally used species, but possess traditional knowledge associated with a particular species which is the subject of an access request. In such situations, traditional knowledge may be important, from a conservation and sustainable use perspective, or it may have benefits in terms of taxonomic knowledge. As the CSIRO points out:

In considering the issues surrounding access to biological resources, it is necessary to distinguish between the physical biological resource itself (ie the living organisms, specimens, or accessions) and the associated knowledge about the resource itself (including embodied intellectual property), or further knowledge gained from the use thereof.23

Ownership of biological resources

A number of submissions noted that long-standing issues of ownership of biological resources needed to be satisfactory resolved, particularly where two or more jurisdictions were involved. It was also pointed out that resource managers were not necessarily owners, and that their right to claim a share of any benefits arising from use of a biological resource was open to question. The resolution of ownership is essential, particularly in relation to benefit sharing.24

The Australian Institute of Marine Science argued that only owners of biological resources should share the benefits from using such resources and not those whose role is confined to one of management (which may include the role of issuing permits for access, as is frequently the case with regard to statutory authorities charged with administering natural resources on Crown lands). In its first recommendation, the CSIRO:

> ... recommended that the regulations under the EPBC Act vest ownership and title to biological resources in its possession to the Crown.25

23. CSIRO, Sub.65:p.5
24. ATSIC, Sub.56:p.9; Australian Institute of Marine Science, Sub.50:p.14; CSIRO, Sub.65:pp.13-14; Department of Industry, Science and Resources, etc.
25. Sub.65:p.3.

However, such an action would have to take into account native title considerations and recent court decisions, like the High Court's decision in *Yanner v Eaton*.26 See also 'Native title considerations' below.

Land ownership considerations

In some Commonwealth areas, under Aboriginal land legislation, traditional owner groups manage access to their lands through a permit system. Normally, anyone wishing to access Aboriginal lands for whatever purpose must lodge a permit application with the relevant land council and, on the basis of information supplied, the traditional owner group(s) concerned can grant or refuse access. This regime will have practical implications for anyone wishing to access biological resources on Aboriginal lands and therefore must be taken into consideration in any access procedures.

Native title considerations

The National Native Title Tribunal makes the following points:

The Inquiry will need to consider the effect of any proposed regulations on the common law of native title, which is that native title in any area may include rights and interests in relation to biological resources in the area. The Native Title Act 1993 confirms the common law of native title which is that this form of title is held by one or more people for the benefit of the members of their group and their descendants. Native title is an underlying right which continues to exist in some areas of land or water. It is not a right which is granted by any operation of law. Consistent with this position at common law, one of the objects of the Act is to recognise and protect native title where it continues to exist.

Under the Act people can apply to the Federal Court to have their native title recognised by a determination of the Court. Native title applications can be made in respect of land and waters other than private freehold land, including Crown land, reserve land, leasehold land and land affected by a range of other interests such as permits and licences.

Applicants seeking recognition of their native title, are required to specify the native title rights and interests they seek to be determined. Often applicants claim a native title right to manage and protect natural resources within the claim area, including biological resources.

All persons with an interest in an area of a claim, which interest may be affected by a determination of native title may become a party to an application. Through mediation the parties may reach agreement about the existence of native title and/or the existence of particular native title rights and interests. If parties do reach agreement the Federal Court may ratify the agreement as a determination of native title or it may make a decision after trial about whether native title exists and if so, what native title rights and interests are held by the native title holders.

26. ATSIC, Sub.56:pp.9-10.

If the Commonwealth has an interest in the land or waters the subject of an application, it may become a party and participate in mediation. Any native title right concerning access to and management and use of biological resources would therefore be considered in the mediation process.

Parties in the Tribunal's arbitral process in relation to certain future dealings in land may also reach agreement about access to that land and use of resources derived from that land, including biological resources. The relevant State or Territory may be a party to an agreement reached in the course of an arbitral process.

Further, under the Act Indigenous people and other persons may enter Indigenous Land Use Agreements. These may be developed in the course of, or independently of, an application for a determination of native title. These agreements can deal with a range of issues in relation to access to and use of land, including extraction and use of natural resources. Parties to the agreement can request the Native Title Registrar to register the agreement on the Register of Indigenous Land Use Agreements. Upon registration an agreement takes effect as a contract between the parties. Therefore, even if a native title application has not been filed or finalised, parties are able to reach agreements about access to land and use of resources derived from that land, including biological resources. Local, state, territory and Commonwealth governments may be party to an Indigenous Land Use Agreement.

Applicant groups may be represented and/or legally aided by native title representative bodies. These bodies are established under the Native Title Act to assist applicants and potential applicants within designated areas. They operate under the auspices of the Aboriginal and Torres Strait Islander Commission.27

Protection of customary access/use of biological resources

Among Australia's obligations under the Convention on Biological Diversity, the Commonwealth Attorney-General's Department mentions 'an obligation to protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements'.28 That is a direct reference to Article 10(c) of the Convention. At COP5 in May 2000, the Conference of the Parties of the Convention on Biological Diversity recognized that:

> ... the maintenance of knowledge, innovations and practices of Indigenous and local communities is dependent on the maintenance of cultural identities and the material base that sustains them and invites Parties and Governments to take measures to promote the conservation and maintenance of such identities.29

A number of submissions30 highlighted the importance of continued access to traditionally-used biological resources for maintaining traditional lifestyles and traditional knowledge, and that access to any particular biological resource for whatever purpose should not impede traditional/customary usage of that resource.

27. National Native Title Tribunal, Sub:8.
28. Commonwealth Attorney-General's Department, Sub.23.
29.COP5 paragraph 16 of Decision V/16.
30. ATSIC, Sub.56:p.7; Bruce Rose 1995 Land management issues: Attitudes, Central Land Council; Northern, Central Kimberley Land Coucils, Sub.52; Professor Stephan Schnierner, Sub.48.

While access regimes (subject to conservation and sustainable use requirements) should not impede traditional usage, some consideration needs to be given to traditional owner groups wishing to access biological resources for commercial purposes, either by harvesting the species in the wild, or by commercial farming. For a number of Indigenous communities, access to the biological resources on their traditional lands and associated knowledge for commercial purposes may be their only hope for a long-term economic and sustainable future.

The Tasmanian Conservation Trust submits that:

> Article 10(c) of the Convention on Biological Diversity requires Australia to 'protect and encourage customary use of biological resources in accordance with traditional cultural practices ...' This obligation, taken with Article 8(j) and 18(4), should be regarded as establishing a binding obligation to confer ownership of intellectual property rights over populations of native animals and plants customarily used by Aboriginal and Torres Strait Islander communities in Australia to those communities. These rights should include the right to control access to and use of all characteristics and parts of members of relevant species and populations of plants and animals within Australian national jurisdiction.31

Some concern was also raised that any access regime which allows for continued access to biological resources for customary purposes should not condone any cruelty or inhumane practices towards any fauna. Lucy Fish 'does not feel traditional Aboriginal methods of hunting and killing should be encouraged ... as many of these are incredibly inhumane and are not justified in the society we live in today'.32 M Wilson submits that the 'Terms of Reference fail to take into consideration animal welfare issues'.33 Particular reference is made to turtles and dugong: 'Indigenous people should be held accountable under the same laws of prevention of cruelty as the rest of the community is held responsible.' '... These issues must be addressed before you talk about rights or control over or ownership of our biological resources.'

Intellectual property rights

In its submission, the CSIRO argues that:

> Managing knowledge is just as important as managing the biological material, as knowledge may actually be of greater value than the physical resource. ... The knowledge management issues are as complex as those involved with managing physical resources.34

Intellectual property is an important aspect of managing knowledge, but it should also be pointed out that intellectual property can be used to gain control over certain genetic resources and the species of which they are a part,35 and can therefore have a considerable bearing on access and benefit-sharing arrangements.

31. Sub.54:p.10.
32. Sub.6.
33. Australian Wildlife Protection Council, Sub.4:p.2.
34. Sub.65:p.5
35. See also Crucible Group, 1999 report.

The World Bank has pointed out that: 'Today knowledge is perhaps the most important factor determining a nation's standard of living -- more than land, than tools or labour.'36 It also points out that: 'Eighty per cent of the world's commercial research and development and a similar share of its scientific publications come from the more industrialised nations. World Bank vice- president Ismail Serageldin warns of an 'emerging scientific apartheid'.37 In the global economy, creation of intellectual property is becoming an increasingly important factor in wealth generation as new ideas, new research and innovation form the basis of much modern-day commerce.

This source of wealth creation also requires protection of the intellectual property on which it relies. This is particularly so with regard to the life industries with their heavy reliance on genetic engineering and other forms of biotechnology. Not only do biological resources provide much of the raw materials for such industries, but traditional biodiversity-related knowledge of such resources can also provide vital clues to industry researchers, saving valuable time and money in the research and development process.

It is also important for long-term economic security and sustainable development that Indigenous communities in Australia secure a stake and participate in this and any other industries based on Australia's biological wealth and its management. Indeed, for many of Indigenous communities, their long-term sustainable economic development may depend on their capacity to generate new intellectual property from their traditional knowledge; to create new products derived from their natural resources. In this context, Indigenous communities might, therefore, need to focus on such forms of intellectual property protection as plant breeder's rights, patents, trade secrets, and creation and protection of economic advantage through trademarks, product certification, labelling and geographic indicators. It is also relevant to consider various forms of contractual means for protecting traditional knowledge, such as biodiversity contracts, non-disclosure clauses to protect certain kinds of information, and licensing agreements.

Many Indigenous, institutional, non-governmental and industry groups have expressed concern about the need to find some form of adequate protection of Indigenous traditional knowledge as (Indigenous) intellectual property.38 For, example, in the view of the CSIRO:

> ... it would appear that the traditional means of capturing benefit from knowledge-generation through the usual intellectual property regimes does not always work well in those situations where Indigenous knowledge about particular biological resources are of significance. The existing regimes, such as patents, copyrights, plant variety rights etc, are not geared to capture such 'background Indigenous'.39

In referring to its 1994 Workshop Report, Access to Australia's Genetic Resources, the Australian Research Council pointed out that:

> The 1994 Workshop consideration of intellectual property issues went wider than just the technical interpretation of patents, trademarks, design, copyright and plant variety rights. It also included the rights of Indigenous people to protect the 'intellectual

37. Crucible Group, 1996:6 fn 6.
38. Professor Stephan Schnierer, Sub.48; Michael Anderson, Sub.29; ATSIC, Sub.56
39. Sub. 65:p.11.

> property' or knowledge derived from living organisms that they have supplied to researchers. Participants felt that this alternative interpretation of intellectual property needed to be carefully distinguished from the more conventional understanding of the term and that these rights also require protection.40

It should also be pointed out that issues concerning protection of traditional knowledge have been receiving considerable attention and have been the subject of a number of inquiries and reviews over the last two and a half decades with no effective response by government. Traditional knowledge of biodiversity represents a considerable economic asset for Indigenous knowledge-holders, but an asset upon which they have been unable to capitalise, the benefits of such knowledge, instead going to others. It is clear from submissions received that the matter needs to be dealt with. Pires de Carvalho, Intellectual Property Division, World Trade Organization Secretariat, Geneva, argues that:

> Indigenous (knowledge) holders might very well be seen as potential technology providers for the western pharmaceutical and agro-chemical industries -- provided the legal mechanisms exist that allow transactions to take place within a framework of legal security. Contract law, for instance, may apply. But the parties to a contract have obligations only to each other, and they have no rights enforceable erga omnes. A framework of legal security undoubtedly means proprietary rights.
>
> If Indigenous communities' interests are to prevail in the relations with companies, then there must be a set of laws that allows stable legal relations between the economic agents to be set forth. We should then look for an enabling system for the protection of Indigenous knowledge. 'Enabling' means that the system should enable knowledge holders to have their rights protected and enforceable, and, on the other side of the equation, it should allow companies to conclude negotiations within a legal framework that they could understand. Furthermore, the adopted system should enable courts to feel comfortable with the rules they will apply.41

For traditional knowledge-holders to effectively realise their knowledge as an economic asset and to enter into partnerships with research institutions and industry groups, their traditional knowledge must be given recognition and protection in a way that provides legal certainty for both knowledge-holders and those with whom they wish to share it. Such certainty will also enable traditional knowledge holders and research/industry groups to more confidently negotiate terms of access to traditional knowledge and benefit- sharing arrangements a situation that will also further the cause of reconciliation.42

Legislative recognition and protection of traditional knowledge should not, however, preclude traditional knowledge holders from building on their knowledge and having recourse to other (standard) forms of intellectual property rights such as plant breeder's rights and patents.

In his detailed legal analysis, de Carvalho argues that patent law systems can be used in a number of circumstances to protect traditional knowledge and the rights of its

40. Sub.40:p.6.
41.nd:51-2
42. Council for Aboriginal Reconciliation, Sub.64.

holders, either by stopping the grant of a patent because of the existence of such knowledge as prior art (as in the case of turmeric in the United States), or by knowledge-holders themselves applying for patent protection over their knowledge. While this is an option few Indigenous groups anywhere have tried, it is also relevant to point out that the costs of applying for and defending a patent are way beyond the means of most communities.

For example, to obtain patent protection for an invention in an appropriate range of countries can cost as much as US$100,000 - 200,000 (A$150,000 - 300,000), and up to double that per litigation to protect the patent from illegal use or challenge.43 While this might represent small change for a major biotechnology corporation, and is no doubt factored into their overall research and development and operational budgets, fees like this represent insurmountable obstacles for Indigenous traditional knowledge holders in Australia.

CSIRO has put forward two options that ... 'could be considered further in order to appropriately recognise the value of Indigenous knowledge about biological resources, although we acknowledge that the policy challenges could be significant:'

1.Either a new property right is created for all Indigenous knowledge attached to biological resources naturally occurring in Australia and a formula is negotiated and applied to facilitate benefit sharing. It may be possible to strike some standardised ratio as the basis for benefit sharing. CSIRO is aware that the Australian Institute of Marine Science has used this approach as applied to Indigenous knowledge.

2.Alternatively, Indigenous knowledge is declared and validated similar to the declaration of background intellectual property when commercial technology relationships are created. The existence of Indigenous knowledge could be demonstrated by reference to linguistic or ceremonial studies. Under this model a more specific benefit sharing arrangement could be negotiated on a case-by- case basis recognising the value of the specific, embodied Indigenous knowledge.44

Accordingly, the CSIRO has recommended that the Commonwealth consider in more depth the intellectual property issues surrounding Indigenous knowledge, including options for declaration and validation of intellectual property rights.45

ATSIC also addresses the matter, referring to recommendation 11.5 of the Our Culture: Our Future report in which:

> A new class of proprietary rights for traditional knowledge should be considered, or the creation of a transfer agreement for the adoption of procedures which ensure that:
>
> Indigenous people are informed of patent applications or plant breeder's rights applications that include Indigenous material or relate to Indigenous species; Prior informed consent to use such material and species has been obtained from any relevant Indigenous group or groups; and

43. Biotechnology Australia 1999:26.
44. Sub.65:pp.11-12
45. Sub.65:p.17.

> Indigenous people have a right to negotiate the types of use permitted and to share in any economic benefits that might accrue. Where possible, rights should be effected in written agreements.[46]

Granting of plant breeder's rights and patents over, for example genes of certain species, may compromise Indigenous customary rights to those species or, if such rights are protected, it may compromise their rights to the commercial application of those species, ie they may only use such species for commercial gain under license to the company holding the patent or plant breeder's rights.

Traditional knowledge in the public domain

There is world-wide concern over commercial interests exploiting the knowledge of Indigenous communities. Such commercial interests have, thus far, sought free access to what they consider to be public domain knowledge of plant resources and their uses, modifying this public property superficially, and transferring it into the private domain of intellectual property rights. This is particularly the case in regard to patenting of life forms and recognition of plant breeder's rights.

This so-called 'public domain knowledge', defined according to criteria laid out in standard intellectual property law, is in fact the communally-owned knowledge of Indigenous peoples, governed and regulated by their customary laws with regards to its access, use, and dissemination. But because much traditional knowledge cannot be attributed to a single community, much less to an individual, and is frequently shared in accordance with cultural practices, it is regarded as being in the public domain and therefore, for example, unprotectable under patent law.

One of the main consequences of the incompatibility of 'western' systems of intellectual property rights laws and local customary systems can be seen in the way in which corporations gain access to, use, benefit from, and ultimately control components of traditional knowledge.

Typically, anthropologists, ethnobiologists, or their like, visit Indigenous communities, collect traditional biodiversity-related knowledge from the Elders and acquire copyright protection for their compilations of this knowledge, whether or not they acknowledge the intellectual contributions of their local informants. Company researchers may then read this work, investigate a certain piece of information in it, add knowledge of their own, and patent the result. This process is well advanced in Australia: traditional biodiversity-related knowledge has largely been exploited by others, with benefits accruing to those who have acquired and disseminated that knowledge. While to many the Bush Tucker Man is the very public face of that process, many non-Indigenous people and institutions are involved.

A considerable amount of traditional knowledge about Indigenous use of plant and animal species for food and medicine is already published, with the copyrights to such information held by non-Indigenous collectors and institutions.

46. Sub.56:pp.12-13

The sui generis option

While the EPBC Act addresses the important provisions contained in Articles 8(j), 10(c) and 18.4 of the Convention on Biological Diversity, it falls short of providing intellectual property-style protection for communally-held traditional knowledge. While prior informed consent procedures and contractual provisions can give a degree of legal certainty to protecting traditional knowledge, recognition of such knowledge as intellectual property will provide a higher degree of certainty for all parties and attract greater recognition in court proceedings.

Pires de Carvalho argues that:

> ... Indigenous knowledge presents some characteristics that make it irremediably unsuitable to fit within one or two specific intellectual property rights. Those peculiar characteristics derive from the fact that there are cultural, philosophical and religious components that are intrinsically connected to the scientific and technical knowledge of traditional communities that no intellectual property system can cover entirely.47

Dr David Bennett also points out that '... reforms may not be sufficient, rather a new sui generis regime is needed'48 and refers to subsection 26.4(b) of Agenda 21 which states that one measure governments could take is to:

> Adopt or strengthen appropriate policies and/or legal instruments that will protect Indigenous intellectual and cultural property and the right to preserve customary and administrative systems and practices.

He concludes that: 'The important point made here is that any form of intellectual property rights regime adopted should 'preserve customary and administrative systems and practices'. That is, the regime should conform to traditional practices rather than attempt to force traditional practices into a Western legalistic mould.'49

ATSIC refers to the Our Culture: Our Future report's recommendations 18.1-21 concerning introduction of specific, sui generis laws to protect Indigenous cultural and intellectual property. As the ATSIC submission concludes: 'These measures would enable a more 'holistic' approach to protection and management of Indigenous cultural and intellectual property, that includes biodiversity-related traditional knowledge, innovations and practices.'50

Recommendation

That the Commonwealth Government commission a study, to be carried out in conjunction with the Indigenous community, to draft sui generis legislation to protect Indigenous intellectual and cultural property. Such a study should take particular account of recommendations 18.1-21 of the Our Culture: Our Future report, as well as existing models developed for this purpose together with sui generis laws in force in other countries.51

47. nd:51
48. Sub.9:p.7
49. Sub.9:p.5
50. Sub.56:p.13
51. A list of models and other national sui generis laws is in Attachment 5.

Protecting traditional biodiversity-related knowledge under Native Title

The possibility of using native title as a means of providing protection for traditional biodiversity-related knowledge as intellectual property has, to date, not been thoroughly explored. For example, Bryan Horrigan and Simon Young do not deal with it in the book they edited concerning the Commercial Implications of Native Title, and yet, from the evidence presented so far, the commercial implications for both Indigenous and non-Indigenous Australians regarding protecting and using traditional biodiversity-related knowledge are far-reaching.

In the context of both protecting traditional biodiversity-related knowledge and regulating access to it, in cases where it has not been extinguished, native title may hold the key and warrants further critical examination. As Dr David Bennett argued in his 1996 paper, 'Native Title and Intellectual Property':

> ... native title rights and interests are based on Indigenous intellectual property. Therefore a loss, diminution, or impairment of the intellectual property that underlies native title rights and interests would in effect be wholly or partly inconsistent with the continued existence, enjoyment or exercise of native title rights and interests, and therefore could entitle the owner of traditional knowledge to compensation under the Native Title Act. If this is so, then the Native Title Act could be a form of protection for communal intellectual property of Aboriginal and Torres Strait Islander peoples.

He suggests that use of traditional biological knowledge in the scientific, commercial and public domains without the cooperation and control of the traditional owners of that knowledge, and without ensuring the use and collection of such knowledge results in social and economic benefits to the traditional owners, '... could lead to extinguishing a communal, group or individual native title right or interest or be otherwise wholly or partly inconsistent with the continued existence, enjoyment or exercise of native title rights and interests.' If an action were successful in such circumstances, compensation could be payable for the extinguishment or impairment of that native title right.

Shelley Wright also argues that the absence of statutory instruments extinguishing Indigenous intellectual property rights (and numerous Federal Court judgements recognising the presence of communal interests in Indigenous designs) supports the continued operation of common-law intellectual property rights. As Wright notes, such rights as Indigenous 'cultural rights' would 'transcend the normal boundaries between and within intellectual property regimes and protection of cultural heritage'.52 She believes such cultural rights would only arise in relation to traditional forms of Indigenous culture related to occupation and guardianship of land. In pursuing this line of argument, Terri Janke concludes that:

> Under Indigenous customary laws, cultural heritage is an integrated whole way of life and thinking which connects Indigenous people with all aspects of their inherited cultural heritage, including arts and cultural expression, cultural objects, land and knowledge. So it follows that native title is incidental to the protection of other aspects [of] Indigenous cultural and intellectual property such as knowledge, cultural objects and stories, songs and designs associated with land and the environment.53

52. Wright S, 1994:p.169
53. Janke T, 1998:p.169

However, as Janke points out in the Our Culture: Our Future report, this area of law requires further testing and analysis, particularly in view of the government's amendments to the Native Title Act 1993, and recommends that:

> Support should be given for native title actions which test and expand the meaning of native title rights and interests to other areas of Indigenous cultural heritage including stories, biodiversity knowledge and cultural objects.

Illicit use of traditional knowledge in the international arena

In a submission that has important implications for holders of traditional biodiversity-related knowledge, John Henderson points out that:

> ... some Australian biological specimens are being illegally removed from the country for the sole purpose of scientific research. ... The inquiry into the examination of access to biological resources does not appear to address the problem of 'illegal access' to biological resources, or legal access gained for what may well turn out to be the illegal export and subsequent research work and exploitation of native biological specimens.54

He then asks a number of questions:

2. Has consideration been given to the implications relating to the intellectual ownership consequent on the illegal removal and scientific exploitation of native biological specimens taken from Commonwealth areas by foreign nationals?

3. In the event of the foreign development of Australian biological resources derived by illegal means, what arrangements are made to ensure that social and economic benefits from such developments accrue to Australia?

4. In the event of the foreign development of Australian biological resources derived by illegal means, what arrangements are made to promote the use of Indigenous peoples' knowledge of biodiversity with the involvement of, and in cooperation with, the owners of that knowledge?55

Legal pursuit of those who have illicitly used traditional biodiversity-related knowledge outside of Australia is likely to be prohibitively expensive with little prospect of a guaranteed result so other means may need to be investigated. One strategy advocated by the Scientific, Technical and Research Commission of the 53-member Organization of African Unity in its Draft 'Legislation on Community Rights and Access to Biological Resources',56 is to provide for a scale of sanctions and penalties which include publicising any violations through national and international media, and reporting to the secretariats of relevant international agreements/treaties and regional bodies (see Article 10.2). Presumably the Secretariat of the Convention on Biological Diversity would be one such body.

54. Sub:16
55.Sub:16.
56. Organisation of African Unity/Scientific, Technical and Research Commission, 1998.

It may be that an international facility, such as the proposal for a Global Biodiversity Information Facility, put forward at the OECD Global Science Forum, may also be able to undertake a policing role with regard to illicit use of traditional biodiversity-related knowledge.57 As envisioned, the Global Biodiversity Information Facility would encompass:

> ... the creation of a world-wide electronic information network. ... Scientists hope the Global Biodiversity Information Facility will become the single database that pools all the recorded, but widely scattered, data about the earth's animals, plants and micro-organisms. The database is to be made accessible via the Internet.
>
> The Global Biodiversity Information Facility is needed to coordinate the standardisation, digitisation and world-wide dissemination, within appropriate property rights conditions, of the data collected world wide on organisms, genomes, species and ecosystems. Opportunities in health, resource and environmental management, agriculture, industry as well as education and research increasingly depend on it. It will also contribute to information management for the Convention on Biological Diversity.

Setting up such a facility raises issues as to whether information should also include that concerning traditional knowledge of species and would, therefore need to consider protocols for lodging such information as well as access and use. Such a database could be beneficially accessed by national intellectual property offices, for example, with respect to traditional knowledge as prior art.

COP5 directed that, as one of the tasks in the program of work it adopted, the Working Group on implementing Article 8(j) and related provisions, '... develop standards and guidelines for the reporting and prevention of unlawful appropriation of traditional knowledge and related genetic resources'.

However, as this falls into the second phase of the program of work it is unlikely that the Working Group will address this until after COP6 in 2002. Nevertheless, the Commonwealth Government, in conjunction with the Indigenous community, should give thought to this matter and present findings and recommendations as a case study to the Secretariat of the Convention on Biological Diversity under paragraph 13 of decision V/16. See also 'Developing an Indigenous code of ethics' below.

Recommendation

The Commonwealth Government, in conjunction with the Indigenous community, undertake a study of ways and means of preventing the illicit use of traditional biodiversity-related knowledge overseas and of addressing instances of such use where it has occurred.

57. Australian Research Council, Sub.40:p.8.

Applying principles of prior informed consent

In its submission, Environment Australia points to:

> Prior informed consent [as] the central procedural device which enables the provider to negotiate the terms of access and benefit-sharing agreement with the prospective user of the biological resource or related knowledge. It is desirable that prior informed consent on a number of issues is reached between the providers and prospective users of the biological resource.58

For the CSIRO '... the principle of prior informed consent, [constitutes] the explicit agreement to the end purpose of granting access.'59

Prior informed consent is essentially an administrative procedure or device which engenders considerable flexibility. It enables providers of biological resources and users of those resources to put all their concerns on the table and discuss any issues before the provider(s) decide whether to give their consent. The bottom line, is of course, that providers must retain the right to refuse consent (and should be empowered to do so by the regulations) or withhold consent until certain conditions are met by the access seeker(s).60 For traditional owners it offers the possibility to exercise customary law in the decision-making processes, and to impose certain conditions, based on customary law, as part of the mutually-agreed terms governing access.61 Such terms can form the essential conditions of any contracts between traditional owners as providers of a biological resource and the access seeker(s).

In the absence of more formal recognition of Indigenous systems of customary law within the legal framework of the Australian State, a prior informed consent regime can give practical effect to the exercise of customary law, albeit within the limits of a regime governing access to biological resources over which traditional owners can exercise a range of rights. This becomes particularly important in terms of being able to enforce intellectual property rights over traditional knowledge in accordance with customary law.

In order to provide basic minimum protection to traditional owner groups regarding biological resources in which they are stakeholders and associated traditional knowledge, the proposed regime should involve an administrative process based on achieving the prior informed consent of traditional owners. A prior informed consent procedure should involve the full and legally accurate disclosure of information regarding, among other things:

- the nature of the proposed activity (eg academic research, taxonomic studies, bioprospecting);
- the duration of the access activity;

58. Sub. 70:p.6.
59. Sub.65:p.5
60. See also Michael Anderson, Sub.29; DD Brown, Sub.7
61. cf the Phillipines EO 247, OAU Draft Legislation.

- the locality of areas of access (including the traditional owner groups and Indigenous communities likely to be affected);
- an assessment of the impact of the access activity on conservation and sustainable use, and particularly the continued customary access to and use of the biological resource(s) for which access is being sought;
- the reasons for the activity (eg site identification, preparation of an environmental/cultural impact assessment for a proposed development, or whether it is for commercial/non-commercial purposes);
- the purpose of the research, expected results, and benefit-sharing arrangements;
- personnel likely to be involved (including research institutes, sponsors, commercial interests, and partners - as possible third parties - in the research and development process);
- specific procedures the activity would entail (desk-top research, sample collecting, random surveys, field trials, archaeological excavation);
- kinds of materials and their quantity to which access is sought;
- potential risks involved (eg entry into sacred areas, partial destruction of an Aboriginal site);
- the full implications that can realistically be foreseen (eg commercial, environmental, cultural); and
- conditions for third party transfer.

Provision of misleading or false information could result in a penalty or the cancellation of any agreements entered into on the basis of the information originally provided.

While it might be possible to formulate national guidelines for the information required in a prior informed consent procedure, some land councils/Native Title Representative Bodies may wish to devise their own checklists and guidelines. In their joint submission, the Northern, Central and Kimberley Land Councils pointed out that: 'Research and consultation is required to ensure current and comprehensive information is gathered and provided to the Boards and traditional owners in a form which is both accessible and understandable to Aboriginal people. This is a necessary precondition to prior informed consent.'62

62. Sub.52:p.3.

The proposed administrative processes regarding the prior informed consent of the relevant traditional owners, and which would be governed by regulation, could entail a number of steps. For example:

- A standard application form would be administered by a competent national authority -- to be filled out for any activities proposed to be carried out under s301 of the EPBC Act;

- A 'trigger mechanism' -- not all research applications would involve Indigenous community interests, therefore there should be a question(s) in the application form, the answer(s) to which would determine whether the applicant has to seek prior informed consent of the relevant traditional owner group(s). The question(s) should
- Does the applicant propose to carry out activities on land over which Indigenous people have title, or is subject of a native title claim?

- Does the biological resource(s) for which access is sought have known (or is likely to have) customary uses or be otherwise of significance to Indigenous people?

- Is access to any traditional biodiversity-related knowledge being sought?

- If the answer is 'yes' to any of these questions, the applicant would be required to obtain prior informed consent from the relevant Indigenous group(s).

- An Applications Assessment Committee - one submission calls for establishment of an Access Forum 'to regulate biotechnology industry activities with regard to access and use of native biological resources'63 with Indigenous representation. Such a Committee should be established for overall administration of the process. Indigenous representation could be provided from the Indigenous Advisory Committee established by s505A of the EPBC Act.

- A further two-step referral process -- where prior informed consent of the relevant Indigenous traditional owner group(s) would be needed, namely:

- the Applications Assessment Committee would refer the application to the relevant competent Indigenous organisation (eg a land council, particularly if there are likely to be a number of traditional owner groups involved);

- the Indigenous organisation would then forward the application to the relevant traditional owners;

- An approval process -- after due consideration of their own interests and concerns, and consultation with other (Indigenous) groups likely to be affected by the proposed access activity, the traditional owners would either approve or refuse the application.

63. Tina Lesses, Sub.18.

- Where the application is approved, the traditional owners may set certain conditions regarding use of their knowledge (eg with respect to confidentiality, publication, or that before the activity proposed in the application form is to proceed, a legally-binding contract with the traditional owners must be signed).

- Where the application is refused, reason(s) for refusal would be attached.

- Applicant notification -- the traditional owners would return the application form to the Applications Assessment Committee via the relevant Indigenous organisation. The applicant would then be notified as to whether the application has been approved or refused.

The administrative process should also include an appeal process for cases where applications are refused, or to enable other Indigenous groups to appeal an application if they believe their interests have not been adequately considered. The overall process should also be set within a realistic timeframe (eg six months from date of lodgement), and with appropriate timeframes for each stage. Adequate time (two to three months) must be given for the traditional owners to assess the application. This must particularly be the case where the biological resource for which access is being sought is found over a wide geographic range and there are a number of traditional owner groups for whom the resource has traditional significance.

Some consideration might be given to a process whereby access applications are dealt with twice a year. Rather than dealing with a constant trickle, a number of applications can be assessed at the one time by the various affected traditional owners with recourse to the necessary technical advisers (legal, scientific and anthropological) who will also need to be assembled. In this way the likely environmental and cultural impacts of a number of proposed access activities can be assessed and, if needs be, coordinated so as to minimise disturbance to the communities involved and to their lands.

The basis of such an approach governing prior informed consent procedures already exists, for example, in the Australian Institute of Aboriginal and Torres Strait Islander Studies' application process for research grants.

Recommendation

To protect the interests of traditional owners in their lands, biological resources and associated traditional knowledge, any access procedure instituted under s301 of the EPBC Act should contain requirements which make the approval of access conditional upon receipt of prior informed consent from the traditional owners and/or knowledge holder(s) in the relevant circumstances.

Benefit-sharing arrangements

Submissions widely support the view that the Commonwealth should develop an approach to benefit-sharing that, among other things, recognises the role of Indigenous peoples.64

Indigenous traditional owner groups, as providers of biological resources, however, will need to bear in mind that the value of genetic resources and associated traditional knowledge may vary enormously according to the needs of particular industries, availability of the genetic resource itself, whether there is a need for ongoing supply, and the usefulness of their knowledge. For example, the main value of genetic resources to the pharmaceutical industry is less in the genetic resource than in the intellectual property that can be generated from that resource during research and development (ie the identification and isolation of chemical compounds, synthesis of compounds in the laboratory, pharmaceutical applications of the compound, the manufacturing process for market, etc.).

Even within the pharmaceutical industry there are widely varying estimates of the economic value of raw natural genetic materials. For example, Dr David Newman of the United States National Cancer Institute considers that: 'The 'value' of a sample, in the absence of any biological assay data, is probably in the range of US$1.00 to US$5.00, irrespective of the cost of collection.'65 While the CSIRO places the value 'typically in the order of A$10 to A$100 per sample'.66 In many cases, once the molecular structures of active compounds from a particular species have been determined, these can be replicated synthetically, thereby alleviating the need to have continued access to the raw resource.

In its submission, the CSIRO cautions that:

> In considering the issues surrounding access to biological resources, it is necessary to distinguish between the physical biological resource itself (ie the living organisms, specimens, or accessions) and the associated knowledge about the resource itself (including embodied intellectual property), or further knowledge gained from the use thereof.67

Overall, there will be a need for an accurate appraisal of the potential economic benefits to Indigenous communities arising from the biotechnology industry as a whole, taking into account its different sectors (ie pharmaceuticals, natural therapies, agriculture, personal care products, food and beverages, etc.). For example, whereas bioprospectors working for pharmaceutical companies may require only a one-off collection of a small amount of a particular biological resource/species, the bushfood industry may require a regular supply of a particular plant as a special food ingredient which may ultimately give rise to the need for commercial production of that species. Such a situation may create the need to establish an Indigenous community- based industry with considerable value-adding potential.

64. For example, Sub.41: Recommedation 1.
65. Sub.39: pp.1-2
66. Sub.65:p.10
67. Sub.65

Geographic range

Another factor which will have a major bearing on benefit-sharing arrangements is the geographic range of the biological resource for which access is being sought.

Wide-ranging species

In the case of a species with a wide geographic range and which is found on the lands of a number of different traditional owner groups, this can be very complex.

In these cases the nature of traditional rights may vary from one group to another in accordance with the customary laws of each group. A particular species may have more 'status' in the cultural, economic, and religious life of one traditional owner group than in that of another, or its role may vary in the secret/sacred life across communities, eg with regard to 'men's business' and 'women's business'. This obviously increases the number of Indigenous stakeholders, and the nature of their interests in a particular wide-ranging species may vary considerably.

This also raises issues of prior informed consent: while one traditional owner group may grant prior informed consent, another may withhold it thus creating a situation which affords opportunities for traditional owner groups to play-off (and be played off against) each other -- a matter further complicated if there is no nationally consistent approach. A particular State's access regime may act to the detriment of a traditional owner group in another State or Commonwealth area while giving advantage to the traditional owner group in the granting State.

It is circumstances like these that would be best addressed by creation of an Indigenous Biodiversity Trust which could mediate arrangements between Indigenous stakeholders to arrive at fair terms for benefit-sharing.

Narrow-ranging species

With regard to a species with a narrow range, in comparatively rare circumstances, some species will be endemic to the lands of a particular traditional owner group, in which case that group might feel they would be entitled to exclusive rights and benefits arising from access to such a genetic resource.

Research v commercial purposes

A number of submissions noted the need to distinguish between access biological resources for 'pure research' (or 'academic research') purposes as distinct from research which has a commercial purpose in mind.68 This distinction is made, for example, in the access application process under the Philippines Executive Order No 247. In reality, however, the boundaries between the two are often blurred.

Research requiring access to biological resources generally falls into five categories, as identified by the Biodiversity and Ethics Working Group of Pew Conservation Fellows.69 These categories have been adapted, below, to apply more appropriately for conditions with regard to Indigenous communities in Australia:

68. For example, Australian Research Council, Sub.40:p.4.
69. Churcher 1997 :2-3

- **Non-Extractive Non-Commercial Research**

  Researchers might undertake research which involves studies of the ecology of an area and there is a need to examine the frequency of the occurrence of individuals of a number of species, or the need to 'track' individuals in order to find out more about their habits, etc, monitoring, risk assessments, etc -- primarily for conservation purposes. In such cases access fees may be waived in return for other benefit-sharing arrangements (eg capacity-building).70

- **Extractive but with Primarily Non-Commercial Research**

  This might involve collection of samples of organisms for taxonomic purposes, or for analysis of the interrelationship between species.

- **Non-Extractive Research with Possible Commercial Potential**

  Ethnobiologists may study plants and animals without collecting samples. These studies may involve documentation of local innovations, traditional knowledge and practices, development of databases of such knowledge, publication of books, films, or other forms of dissemination of local knowledge, for instance electronic communications, CDs, etc. This local knowledge may be documented to preserve or share within the community or beyond it.

- **Extractive Research intended for Commercial Development**

  Extraction could be in small quantity, such as for biotechnological laboratories, or in large quantities, for natural product development. Such research, done by students, academic researchers, corporate researchers or local communities, may be intended to develop new products based on biodiversity traditionally used by local communities or elaborated by individual innovators. It may also involve screening and analysing biodiversity, without making any reference to local uses.

- **Conservation Research Intended for Protection of Biodiversity**

  Academic researchers, non government organisations, government organisations, corporate researchers, or local communities may use all the methods mentioned above to create effective resource management plans and biodiversity education programs.

The kind of research involving access to biological resources will necessarily have a bearing on the kind of benefits that could be shared with traditional owner groups.

70. See Northern, Central and Kimberley Land Councils, Sub. 52 in relation to Dhimarru Land Management Corporation study

Value of traditional knowledge in research and development

To determine appropriate levels of benefits in an access and benefit-sharing arrangement, it is necessary to consider the role and value of biological resources and of associated traditional knowledge in research and development. In the CSIRO's experience:

> ... the value of the associated knowledge of a particular resource is ... limited in most cases; Indigenous knowledge is extremely valuable in conservation and in identifying plants with medicinal properties, but not much used in current bioprospecting activities, which are characterised by mass sampling and mass screening for bioactive molecules.71

However, Professor Noel Dunn, Cooperative Research Centre for Food Industry Innovation, points out that:

> Little work has been done on assessing Indigenous edible plants as sources of food ingredients. Potential ingredients include colours, antioxidants, antimicrobials, phytoestrogens (potential neutriceuticals) which may also offer health benefits and find application in the health care and other industry sectors.72

It should also be pointed out that traditional knowledge of acacias has been particularly important in identifying edible species of wattle seed, and, in some cases, the processes necessary for their preparation for human consumption in order to eliminate toxins. In work carried out by the CSIRO, Aboriginal knowledge was instrumental in identifying 44 of the 49 species of acacias traditionally used by central Australian Aboriginal communities, as potential food species for planting overseas. As Jeannie Devitt concluded: 'With respect to food potential, what is currently known about the food value of acacias has been largely the result of tapping into Aboriginal knowledge.'73

A number of submissions support the Australian Institute of Marine Science conclusion that, 'Biodiversity research is a high cost, high risk, and long-term process. The chances of identifying a lead that is then developed into a vendible product have been likened to those of winning a lottery.'74 The odds of finding a new drug from botanical samples in this lottery have been variously put at: as 'One new drug ... in every 1000 species of plants' by Bio- Gene Bioprospecting Pty Ltd in Western Australia;75 in excess of 1:10000;76 and 'from 1 in 80,000 to 1 in 250,000 plant samples'.77 As Newman, points out:

> What is becoming evident ... is that Nature is probably not going to produce the next 'blockbuster drug' directly, but that the chemical structures that Mother Nature provides, are the structural leads that chemists will then modify to produce 'improved molecules' that no chemist in his or her right mind would have considered making de novo.78

71. Sub.65:p.11.
72. Sub.36.
73. House AP and Harwood CE (eds), 1992:51
74. Sub.50:p.10
75. McIlwraith J, 1999: p.26
76. Newman, United States National Cancer Institue, Sub.39
77. Colunbia University/Biodiversity Action Network, 1999:p87
78. Sub.39.

It is also noted that the biotechnology industry in general is subject to a fair amount of media hype designed to extract funds from investors for much needed venture capital.79

The research and development process itself is outlined by the CSIRO:

> In bioprospecting, biological resources are sampled for input into various screening programs in order to identify biologically active molecules. A separate company, often an overseas entity, may perform these screenings and subsequent product developments. The biological resource is valued, and a collector may be paid for the collection process typically in the order of $10 to $100 per sample. Unsuccessful samples are quickly discarded and [are] therefore valueless. The relatively few successful leads may then pass through further screens, are perhaps enhanced chemically, then pass through formulation and safety trials prior to scale-up and marketing a final product. This always involves a significant research and development component. In many instances, once an active molecule has been found it is then cheaper to manufacture this synthetically rather than continue extracting the compound from biological sources.
>
> The entire product development process is typically a mass process with high throughput and very little knowledge being applied about properties of particular samples. ... There are significant intellectual property and commercial interests at play at the manufacturing end, and any commercial returns would have to offset the significant value-adding processes during the development phase.
>
> It then follows that the commercial returns that may accrue from the exploitation of biological resources through bioprospecting may be quite limited. There is often a commercial separation between the collector and the product developer with the latter taking the commercial risk and therefore entitled to a greater 'fair' share of the potential rewards.
>
> Hence the emphasis of permit schemes should be on strategic use of the associated knowledge, not just on the physical samples.'80

With regard to drug development within the pharmaceuticals industry, Dr David Newman, provides a short description of the drug development system 'used almost universally'.81 The systems used generally fall into the following pattern:

1. Discovery of a lead structure (from nature or chemical synthesis or a combination of both). Takes up to three years and requires collaboration between biologists and chemists. May require the screening of over 50,000 chemicals/extracts/ fermentation broths.
2. Proof that the lead from #1 is a specific agent (only affects the disease that you want to work on); provision of adequate supplies for further work.

79 For example, Monihan R, 1999: pp.25-32.
80 Sub,65:p.10-11.
81. Sub.39.

Identification of actual lead and optimization of similar structures. Can be two or more years. A patent is usually applied for at this stage ... What a patent does is to establish a protection for the inventor and if an access agreement is written correctly, establishes the rights of the Source Country if the lead becomes a drug.

3. Toxicology and pharmacology in animals of the lead structure and usually some back-up compound. At least three years as a two-year toxicology study in two animal species is required by the US FDA (and similarly in some other countries) for any compound that is not an anti-cancer or anti- AIDS candidate.

4. Clinical trials. At least three phases (Phase I, safety; Phase II, efficacy; Phase III superiority to existing treatments). Except in the case of Cancer, all Phase I studies are in normal volunteers. Can take years and many trials at all levels to find a new drug.

Newman concludes that:

> The overall odds of any one extract or compound becoming a drug 10-15 years later can only be calculated after the drug is commercialized, but are well in excess of 1:10000 for any one screen.
>
> What this means in practice is that the larger the number of screens a compound or extract can be put into, the better the odds of finding something effective to commercialize. As far as the Source Country is concerned, the more exposure that its biological resources can be given, the better the odds that there will be a commercial success.

Determining the nature of the benefits

The nature of the benefits which could be anticipated from accessing biological resources are broadly of two kinds: monetary and non-monetary. In any access and benefit-sharing arrangement, as both the CSIRO and Australian Institute of Marine Science submissions have emphasised, there is a need to think strategically rather than monetarily about benefit-sharing arrangements and/or agreements, in other words, about 'a total benefits package'.

Monetary benefits

Monetary benefits to Indigenous stakeholders are likely to occur as access fees for entering onto Indigenous lands; collection fees; informant fees; copyright fees; licensing fees; milestone payments; and/or royalty payments. All are discussed below.

1) ACCESS FEE FOR ENTERING ONTO INDIGENOUS LANDS

For entry onto many Indigenous community-held lands, irrespective of purpose, a permit is required which may also require payment of a standard access fee. Such a permit may detail a set of conditions governing conduct while on their lands, eg routes to be followed, places to be avoided (sacred sites, etc.).

With regard to requests for access to biological resources, in some cases this fee may be all that Indigenous land-holders might legitimately expect if the biological resources to be accessed involve, for example, microbial species (eg soil bacteria) about which there is no traditional knowledge or use.

Such access fees may be dedicated to landcare/biodiversity conservation.

The Australian Research Council, in referring to the 1994 Workshop Report 'Access to Australia's Genetic Resources', considered the issue of fees for access and suggested that a national royalty and fee system be established to protect Australia's interests in the event that functional genetic resources are identified. The Council argues for:

> ... recognition of two categories of sites under a national system and hence developing two categories of access:
>
> a. Sites on freehold or native title tenure land for which some up-front access fees would be reasonable; and
>
> b. Sites with other tenure, eg crown land no fees, but an obligation enforced through grant conditions (here and abroad) to pay a royalty fee in the event of the information or materials being commercialised.82

The royalty fees identified in b) would, ipso facto, apply to materials and information derived from sites identified in category a). In addition, any access and fee regime would need to distinguish between access for basic research purposes, and access likely to generate commercial returns in a fairly short period of time and structure fees accordingly.

It should be noted that native title considerations would still apply for land under claim and access applications would fall under the Native Title Act's future act regime.

2) COLLECTION FEES

Collection fees will vary according to the circumstances.

Members of traditional owner groups may be contracted to provide quantities of particular biological resources found on their lands. A range of situations might occur, for example, a request might specify samples of a particular species for bioassaying in which case only a small amount may be necessary; others may require a regular supply of quite large amounts (particularly for natural product development).

Samples may also be collected by the researchers, in which case a fee per sample arrangement might apply. It also might be carried out as a collaborative exercise, especially where further samples may be needed. When regular supplies of large amounts are required in a situation akin to the harvesting of a biological resource

82. Sub.40:p.4.

(within the limits of sustainability) such fees could be quite lucrative.

3) INFORMANT FEES

An informant fee is a payment for use of traditional knowledge and/or intellectual property especially for identifying useful species, their traditional uses, methods of preparation, etc.[83]

The Australian Institute of Aboriginal and Torres Strait Islander Studies maintains a schedule of fees to be paid by researchers who wish to engage Indigenous people to provide information and such fees are normally factored into the research grant. However, when Indigenous people are providing information, conditions regarding its use, confidentiality, review prior to release, publication (including the possibility of co-authorship), entitlements to royalties in situations in which the information leads to development of commercially useful product, access by others, etc., should be negotiated.

4) COPYRIGHT FEES

Where Indigenous people have provided useful information and the information is included in a publication (scientific paper, book) they should be entitled to a share of any copyright fees the publication attracts. Such payments are not likely to amount to more than pocket money, but the legal protection afforded by copyright may prove important where the information occurring in published form is used by a third party in, for example, a patent application.

5) LICENSING FEES

Posey and Dutfield define a licence as:

> A type of contract between an intellectual property owner and another allowing the latter to use, manufacture, or market the invention in exchange for a royalty, a fee, or an immediate payment. The subject of the licence might be patented information, a trade secret, a copyright protected work, etc.

At least two situations can arise concerning licensing fees.

1. Indigenous traditional biodiversity-related knowledge has played a role in developing a product, and the intellectual property is licensed to another party for commercial application. A proportion of the license fee (ie a royalty) could be paid to the holder or owner of that knowledge. Allowances for such an arrangement should be cemented in the original access and benefit-sharing agreement/contract.

4. A traditional owner group may develop its own product, for example, a new variety of plant derived from a traditionally-used species, which has commercial potential for a particular industry, and for which it has successfully applied for a plant breeder's rights certificate. In this case the traditional owner group can (for a fee) license others to enter into commercial production of the plant variety.

83 Posey and Dutfield 1996:p231.

6) MILESTONE PAYMENTS

These are payments that might be received at various stages of a research and development process, particularly in relation to developing a new pharmaceutical. Again, possible milestones, and the kind of payments to be made, should be mapped out in the access and benefit-sharing agreement/contract, eg after a lead has been discovered, at the conclusion of different phases of clinical trials, etc.84

7) ROYALTY PAYMENTS

Several submissions highlighted the fact that the chances of developing a commercially viable product, based on a particular genetic resource, are exceedingly slim. In the event that a biodiscovery results in a successful commercial application, what might be expected in the way of royalty payments is outlined in the paper, 'Using Genetic Resources after the CBD Implementing Article 15'. Referring to the INBio/Merck Agreement:

> Typical royalties for samples of unknown clinical activity for synthetic chemicals range from 1-5% ... this range developed for new synthetic chemicals will also apply to natural products. Factors such as the enormous effort required to develop a successful commercial product from raw wild genetic resources, the low probability of any particular species being of commercial value ... mean that the holders of unimproved material are unlikely to be able to increase these types of percentages significantly. ...
>
> Furthermore, due to the economics of biotechnology, any attempt to obtain any advance on the royalty is unlikely to result in substantial revenues. Consider an institution that supplies 1000 extracts to a pharmaceutical company in return for a 5% royalty on the net sales of any commercial product. Given a 1 in 10,000 chance of a useful lead being discovered, a 1 in 4 chance of that being developed into a commercial product, a 5% discount rate, 10 years before a product is marketed and 7 years of effective patent protection during the period of marketing and, assuming that the drug generates $10m net annual profit, the present value of the extract is estimated to be only $50,000. Alternatively, if the custodian decides to forego advances on royalty payments, it will be more than a decade after the screening process commences before any royalties can be expected.85

This is not to argue that the possibility of royalty payments eventuating out of an access and benefit-sharing agreement does not exist, and therefore should not form part of such an agreement.

The potential for such payments may vary from industry to industry and should be considered. For example, Professor Noel Dunn,86 has been working with the Aboriginal community to set up a mechanism whereby food ingredients can be

84 Sub.39.
85 'Using Genetic Resources after the CBD Implementing Article 15' pp.15-16.
86 Sub.36.

sourced from Indigenous plants. A proposal has been prepared and ATSIC has given in principle support provided appropriate mechanisms and agreements are set in place. To this end, the Aboriginal community is establishing a company to work with the Cooperative Research Centre company. The Aboriginal company will be responsible for sourcing information nationally right down to the community level. Agreements are being drawn up such that royalties or licenses generated will be shared equally between the Aboriginal company and the Cooperative Research Centre company (Food Technology Innovations Pty Ltd).

Non-monetary benefits

It is clear from the evidence presented that monetary benefits, particularly in the form of royalties, may prove very illusive and that therefore, as the Australian Institute of Marine Science suggests, access and benefit sharing arrangements should focus on 'a total benefits package'.87 For traditional owner groups these benefits may take the general form of capacity building, ie increasing the ability or capacity of such groups to conserve and sustainably use their natural resources, through benefits provided in the form of, for example, information, technology and training. As the CSIRO points out in general terms:

> ... the most valuable benefit arising out of bioprospecting would be capacity building and technology development to foster new, local industries within Australia that in turn provides economic growth.88

While the CSIRO considers that:

> This is achieved most effectively by smart use of any intellectual property leverage to structure agreements between companies and research organisations that retain control within Australia of downstream use of extracts, collected material and associated data.

such a strategy may not be readily available to traditional owner groups.In its submission, ATSIC argues that:

> Indigenous management and control over rights in biological resources and traditional knowledge, innovations and practices is best achieved by the development of capacity building. Such capacity building could provide the basis for a regionally based Indigenous organisation to protect collective rights and interests, and manage the equitable sharing and distribution of benefits at the community level.89

Accordingly, ATSIC recommends:

> Recommendation 3: That consideration is given to implementation, through the Regulations, appropriate forms of capacity building or Indigenous institutional support. The Indigenous Biodiversity Trust model outlined in Section 14 of this submission provides an example.90

87Sub.50:p.4.
88 Sub.65:p.11.
89 Sub.56:p.24.
90 Sub.56:p.5.

The suggestion for a regionally-based organisation, in the form of an Indigenous Biodiversity Trust, is dealt with in 'An Indigenous biodiversity trust' below.

In dealing with access seekers, traditional owner groups will need to keep in mind the respective abilities of such seekers to deliver 'a total benefits package'. Institutional collectors/researchers may be better positioned to provide certain capacity-building benefits (eg technology transfer, training, and repatriation of information concerning traditional knowledge of species held in institutional collections and recorded long ago -- and as referred to in article 17.2 of the Convention on Biological Diversity) than, say, private operators under contract to large multinational corporations, unless of course, such corporations are prepared to deliver. These matters should be addressed during the prior informed consent procedure.

In this regard it should also be pointed out that national institutions like the CSIRO, the Australian Institute of Marine Science, the Australian Research Council, the Australian Institute of Aboriginal and Torres Strait Islander Studies and the university-based cooperative research centres and key centres (particularly those concerned with natural resource use and management) are also bound to follow through with the Commonwealth's obligations to the various international environmental agreements which it has signed, such as those covered by the EPBC Act.

COP5, in decision V/16 paragraph 11, has urged Parties and governments, and organisations representing Indigenous and local communities, among others, to:

> facilitate the full and effective participation of Indigenous and local communities in the implementation of the Convention and to this end:
>
> a. Provide opportunities for Indigenous and local communities to identify their capacity needs, with the assistance of Governments and others if they so require;
>
> b. Provide for sufficient capacity in national institutions to respond to the needs of Indigenous and local communities related to Article 8(j) and related provisions.

Some of the examples of capacity building revealed in the submissions include the training of local Indigenous people in taxonomy.91 The Australian Research Council points out that:

> Other countries are taking a less traditional approach using minimally trained local parataxonomists, which also allows for ready access to knowledge of Indigenous people. This approach (known as parataxonomy) involves collaboration between professionally trained taxonomists and parataxonomists to the mutual benefit of both parties. Researchers are able to draw upon the expertise of local people and local people are able to learn valuable skills.

91 Sub.40:p.4 and Sub.68 re:shortage of trained taxonomists.

> Adoption of such an approach would also contribute to the increased involvement of Indigenous communities, and widen the range of benefits those communities might derive from the access system adopted.92

Bioprospecting activities may also provide information which can be shared with traditional owners for conservation and management purposes, for example, discovery of populations of threatened species (which, in the case of plant species, can provide the genetic material that can be used to propagate the species), identification of rarity, conservation status of a population of a particular species, threats to a species because of alien species encroachment, or identification of alien species infestations.93

A meeting of the Convention on Biological Diversity's Panel of Experts on Access and Benefit Sharing has compiled a list of possible monetary and non- monetary benefits which national governments, research institutions and bioprospecting companies might consider. While not specifically tailored to the needs of Indigenous and local community providers of biological resources, nevertheless many of the listed benefits could be negotiated with such communities. The list is provided in Attachment 6.

Other benefits, more specific to the needs of traditional owner groups in Australia, include:

- repatriation of traditional biodiversity-related knowledge (mentioned above);
- assistance for language revival and maintenance programs;
- recovery and recording of traditional biodiversity-related knowledge;
- sponsorships of traditional owner group member attendance at seminars, workshops and conferences (including meetings under the Convention on Biological Diversity and other relevant fora);
- help to prepare case studies for submission to the Secretariat of the Convention on Biological Diversity in accordance with various invitations under COP decisions;
- help to develop educational packages for local Indigenous community schools; and
- training sponsorships (eg in techniques for breeding new varieties of plants, hydroponic gardening, marketing and management).

There is no doubt there is much our national institutions can do. A virtual state of 'scientific apartheid' exists in Australia as Indigenous research needs and interests in the biological/environmental sciences are widely ignored and Indigenous community representatives are shut out from participating in the nation's important scientific

92 Sub.40:p.4.
93 See example, Professor Ronald Quinn, AstraZeneca research and development, Griffith University, Sub.12; and Australian Institute of Marine Science, Sub.50p5.

institutions, such as the CSIRO, the Australian Institute of Marine Science and the university-based Cooperative Research Centres. For example, in my analysis of Indigenous participation in the Cooperative Research Centre for Ecologically Sustainable Development of the Great Barrier Reef (CRC Reef), I found that:

- there was no Indigenous membership on the Board and its three advisory groups;
- of the more than 115 organisations that CRC Reef was involved with nationally (universities, TAFE colleges, other Cooperative Research Centres, research agencies, state and federal governments and corporations, local government authorities, and private companies and industry groups) none involved an Aboriginal organisation; and
- in the CRC Reef's research output (PhD, Masters and honours theses; research publications; technical reports; and conference and seminar presentations) covering some 400 research topics, only one dealt directly with an Indigenous reef concern or issue.

This has occurred in spite of the fact that Indigenous peoples are major stakeholders and users of the Great Barrier Reef and large areas of the Great Barrier Reef Marine Park are the subject of native title claims. In summing up this situation, I wrote:

> On the evidence presented, one can justifiably conclude that Indigenous reef interests and concerns have been entirely written out of the research agenda of the CRC Reef and that the Centre has comprehensively failed to meet its obligations under the Convention on Biological Diversity and the National Strategy for the Conservation of Australia's Biological Diversity. This situation also exhibits the classic symptoms of institutional racism.94

This situation is to be found, to a greater or lesser extent, in most of Australia's research institutions, although there are positive signs of emerging collaborations, for example, Cooperative Research Centre for Tropical Rainforest Ecology and Management, Northern, Central and Kimberley Land Councils;95 Key Centre for Tropical Wildlife Management, Northern Territory University.96

Stronger collaborative links between the nation's scientific institutions and Indigenous communities, such as that being forged between the Cooperative Research Centre for Food Industry Innovation and an Aboriginal company97 will also significantly advance the cause of reconciliation. The Council for Aboriginal Reconciliation points out that it:

> ... has long recognised the important links between reconciliation and control of access to biological resources. Council strongly supports initiatives which will improve recognition of the intellectual property rights of Aboriginal and Torres Strait Islander peoples and which will increase the sustainable use of the environment while also protecting the heritage and cultures of the first Australians.98

94 Fourmaile HL 1998:p.10
95 Sub.52.
96 Sub.51.
94 Sub.36.
98 Sub.64.

To which can be added the comment from the Tasmanian Conservation Trust:

> Taking the necessary time to build a consensus throughout the Australian community on how best to establish and operate such an equitable benefit-sharing regime has the potential to make a substantial contribution to the process of reconciliation between Aboriginal and other communities in Australia as well as to identify a broad range of other potential beneficiaries from the full implementation of the Convention on Biological Diversity.99

Determining appropriate levels of benefits

A number of submissions noted the tendency of statutory bodies charged with administering permit regimes over government-controlled areas to focus on, or over-emphasise, the value of royalties in an access and benefit-sharing arrangement and to overlook the possibilities of other benefits. For example, the CSIRO notes that:

> ... most permits issued for bioprospecting activities are predominantly focused on royalties arising from the subsequent sale of products derived from biological resources. CSIRO has observed that some such permit schemes appear to be driven by a perception of the need to avoid 'lost opportunities' rather than being clear about what strategic benefits can realistically be expected; the focus seems to be on the biological resource itself rather than the accompanying intellectual property.100

while the Australian Institute of Marine Science points out that:

> ... within agencies there is a focus on the prospect of royalties and other monetary benefits, and an unrealistic over-expectation of their probability, timing and quantum. ... The misunderstanding over potential monetary benefits is impossible to definitively resolve at the point of initial access, because the product leads, their proposed commercial application and potential value are unknown.101

The Institute summarises its approach thus:

> By defining a broad array of benefits that are available for sharing, the AIMS approach formally acknowledges all benefits of biodiscovery research including some that, to date, have been overlooked by many resource stakeholders. When seen in the context of the total benefits package, purely monetary returns such as potential royalties take on minor importance.

While each benefit-sharing agreement would be negotiated on a case-by-case basis, the Institute has developed the following framework within which it would expect these agreements to sit.

> Prior to emergence of a lead, benefits will be non-monetary. They will comprise documentation of biodiversity including lodgement of taxonomic vouchers in relevant museums, description of new species, and provision of data to aid resource management (identification of rarity, threats etc); opportunities for scientists in the jurisdiction of origin to participate in collection expeditions, and other collaborations

99 Sub.54.
100 Sub.65:p.10.
101 Sub.50:p.4.

> which provide opportunity for the development of intellectual property in commercial discoveries (eg taxonomy, chemical ecology, natural products chemistry, biology).
>
> Once a lead has emerged, the research focuses on individual species and the potential commercial target. Thus, the potential commercial benefits are more specific and definable, and include the possibility of monetary returns such as an agreed percentage of monetary benefits received by AIMS (eg milestone payments, license fees, royalties). The actual percentage due to the resource owners will reflect the resource owner' intellectual property and other contributions to the discovery and development of the lead.
>
> More significant benefits at this point relate to opportunities for participation of scientists in the jurisdiction of origin in recollections and the development of intellectual property in options for long-term large-scale supply of active compound and other 'value adding' initiatives. Such involvement can produce the technology base for potential new marine biotechnology industries in the jurisdiction of origin.[102]

The Institute's benefit-sharing agreements are proposed to be broad in scope to capture benefits from all leads that use a sample as a source of innovation, regardless of whether or not lead development involves derivation (synthetic) approaches. They will provide legal certainty over the Institute's right to use the samples for biodiscovery research, including to transfer the samples to third parties. They will define all benefits to be delivered to the Institute, without "triggers' for further negotiations with the 'owner'. However, there should be provisions for review of the operation and success of the agreement as a whole, and procedure for amendments.'[103]

In an analysis of a number of access agreements negotiated under selected access regimes in overseas countries, carried out by Columbia University for the Biodiversity Action Network,[104] it was concluded that:

> The main benefits to be obtained from access agreements will most likely be non-monetary, ie capacity building, technology transfer, joint research, and training. ... Many of the access agreements reviewed here -- those in the Philippines, the SIDR-USP agreement in Fiji, INBio-Merck, the African ICBG, the NCI-University of Yaounde Letter of Collection, and the NCI-UNIP MoU, as well as the BioAndes application -- strongly emphasize the training and capacity-building responsibilities of the foreign parties. Therefore training and capacity-building, as emphasized by these agreements, are likely to be much more important than monetary benefits in the short and long term. They may also address conservation goals in a shorter term.

It was therefore recommended in the study that:

> When establishing agreements, all parties should acknowledge that benefits obtained from access will for the most part be non-monetary, and that monetary benefits may be elusive. Education of resource owners should emphasize that long-term royalty benefits are unlikely.

102 Sub.50:pp.4-5.
103 Sub.50:p.7.
104 Columbia University School of International and Public Affairs 1990:pp.86-7

Biodiversity contracts

Existing intellectual property rights do not protect traditional biodiversity- related knowledge, including that related to uses of plants and other natural resources, against unauthorised commercial exploitation unless the knowledge is recorded in some way.

It is important to note that international intellectual property rights regimes are likely to apply to development and diffusion of technologies which make use of genetic resources (including 'improved' plant varieties), however, they do not require a sharing of benefits with the providers, implemented with the requirements of the Convention on Biological Diversity. For these reasons, more formalised arrangements governing access to genetic resources may provide an important avenue for recognising the contribution of the traditional biodiversity-related knowledge of Indigenous communities, and ensure an equitable sharing of the benefits.

Intellectual property protection for traditional biodiversity-related knowledge may be sought by applying alternative legal forms to those of patents, trade secrets, plant breeder's rights and copyright. Such alternative forms, under the umbrella term 'biodiversity agreements', encompass both legally binding and non-binding agreements and would be based on the prior informed consent of the relevant community, be subject to mutually agreed terms and would include benefit-sharing arrangements. The former include contracts, material and information transfer agreements and licensing agreements, while the latter can involve letters of intent. The United States National Cancer Institute uses such an arrangement with memoranda of understanding and covenants.105

Legally binding contracts, in particular, have become the standard modus operandi of a number of corporations that have been accessing biological resources and their traditional biodiversity-related knowledge within Indigenous territories for a decade or more. Many of these agreements are, however, not required or guided by legislation. They are established on mutual trust arising from a long and close contact between the communities and the researchers/collectors.

Reliance upon such contractual methods to capture benefit for Indigenous communities is widely thought of as the most practical approach to ensure the equitable sharing of benefits referred to in Article 8(j) and to protect a community's intellectual property rights. It is considered attractive because the contractual concept is one with which most societies are familiar and because it is a relatively private bargain involving minimal governmental intervention.

However, the contractual approach can present some severe limitations. Factors such as:

- contracts not being binding on third parties;
- high transaction costs for the parties;

105. Newman, Sub.39

- the unfamiliarity of members of traditional owner groups with the national legal systems (eg relationship between Commonwealth and State/Territory laws, the role of the courts, the common law, and native title rights);

- disparity in bargaining power;

- lack of resources to hire the best legal expertise; and

- problems which arise in dealing with research and development

- institutions and corporations located outside the providing country;

all significantly limit the extent to which Indigenous communities can use the contractual approach to gain protection for, and capture the true value or benefit for, the use of their traditional biodiversity-related knowledge.

In general terms, a biodiversity agreement may involve two or more parties in obligations that are to be fulfilled by all sides. It may have a fixed time limit, or its duration may depend upon completion of obligations or mutual agreement to terminate it. Such agreements may be used to establish and define certain relationships legally, such as those between employer and employee, or between a drug company and a supplier of biological samples.

Know-how and confidentiality agreements, for example, are contracts (or clauses of contracts) made by parties, one of which may be a patent owner, who seek to exploit an invention or inventive process through exchange of information. Agreements are usually in the form of written documents signed by all parties, may require quite limited legal assistance and may be useful mechanisms for Indigenous communities to ensure any transfer of knowledge and resources is fairly compensated.

Biodiversity agreements could provide for the following benefits: up-front payments, training, licences, technology transfer, royalties, establishment of trust funds and other financial and non-monetary forms of benefit sharing. Agreements are considered to be an important means of distributing the costs, benefits and risks. They are a market-oriented means of achieving direct control of the bargaining process of access that allows for a more immediate return of the benefits to those directly interested.

However, bilateral agreements (ie those which do not involve governments) in particular inevitably carry risks. They may be difficult to negotiate, draft and enforce, and may turn out to be expensive. Also, they may include obligations to perform environmentally unsound or anti-competitive practices, and may not necessarily have the public good in mind with regard to benefit-sharing. Professor Conyngham puts forward the view that:

> Access to biological resources (on Commonwealth lands) for the purposes of bioprospecting (searching for specific forms of biological activity or the genes controlling specific traits) should be encouraged and not be subject of any exclusive agreements with any multinational or national organisation (other than an independent national organisation, without self-interest, that is

responsible for supervising use). All access for this purpose (which would include, species improvement, pharmaceutical, agrochemical, neutriceutical, other health and personal care uses) should be governed by an agreement which includes a set of schedules for payment into a common fund where products are commercialised.106

These risks, however, may not necessarily outweigh the positive features of bilateral agreements which seem to be the more immediate and effective way of giving companies and Indigenous stakeholders some certainty and clarity on the legality of their transactions regarding genetic resources and associated traditional biodiversity-related knowledge.

The Cooperative Research Centre for Food Industry Innovation 107 has adopted this approach which has been working with the Aboriginal community to set up a mechanism whereby food ingredients can be sourced from Indigenous plants. A proposal has been prepared and ATSIC has given in principle support provided appropriate mechanisms and agreements are set in place. To this end the Aboriginal community is establishing a company to work with the Cooperative Research Centre company. The Aboriginal company will be responsible for sourcing information nationally right down to the community level. Agreements are being drawn up such that royalties or licenses generated will be shared equally between the Aboriginal company and the Cooperative Research Centre company (Food Technology Innovations Pty Ltd).

In considering the substance of biodiversity agreements, if the claims and aspirations of Indigenous communities, as well as the goals of conservation and sustainable use of genetic resources, are to be dealt with effectively and fairly, certain matters have to be subject to clearly defined deeds and regulations. Two issues in particular need to be addressed:

- who would determine access to resources and on what terms? In this respect, the principle of prior informed consent is of paramount importance; and

- how would fair and equitable compensation be calculated for the contribution of all those who have invested in the discovery, use and continued existence of genetic resources? These would include Indigenous stakeholders, researchers, collectors, producing companies and source countries.

In addition, there are likely to be at least three parties to any biodiversity agreement, namely, the Indigenous community (or communities); the researcher/collector and associated interest/stakeholder groups; and the government (national or state, or both) with an interest in overseeing such agreements to ensure they comply with the law, satisfy taxation requirements, and for statistical and monitoring purposes. Each party will have its own concerns and interests which it will want to have acknowledged and protected within an agreement.

106. Sub.11.
107. Dunn,Sub.36

With regard to Indigenous stakeholder interests, it is necessary to consider:

- what is to be protected?
- what is the nature of the material?
- who owns it?
- who will protect it?
- against whom will protection be enforced?

The answers to these questions will determine the kind of agreement to be negotiated. For example, is the purpose of the agreement to prevent use, stimulate the market, or stimulate innovation? If the means is to achieve the end, it will be important to have these issues clear before formulating the mechanism for protection. If, for example, Indigenous stakeholders want to secure financial reward the mechanism adopted must be one which maximises returns. If, on the other hand, the main objective is to prevent unapproved use, or to impede use altogether of traditional biodiversity-related knowledge, a strict and demanding access regime might be what is needed.

Governments, because of the range of rights and responsibilities affirmed by the Convention on Biological Diversity, are increasingly likely to be involved in some way with any arrangements forged between Indigenous communities and private sector interests, particularly if they are from outside the country. A number of countries have, or are in the process of, formulating standardised biodiversity contracts under their access regimes which are enforced by national legislation (see Attachment 5). These generally include other levels of prior informed consent which might be required (for example, that of a relevant Indigenous or local community) before a responsible national authority authorises 'the deal' to go ahead.

Governments at the appropriate level could also make access to genetic resources conditional on payment of a licence or user fee or compliance with certain provisions (particularly regarding prior informed consent). However, concerns that may arise over such arrangements include:

- the administrative capacity of national authorities to establish mechanisms which can ensure compliance, and
- if the system is overly expensive, benefits will be consumed by its maintenance and will not reach Indigenous communities. This point in particular will need to be taken into consideration if considered when the proposed Indigenous Biodiversity Trust is to be established (see 'An Indigenous biodiversity trust' below).

There is little doubt that some form of agreement between a collector/researcher and an Indigenous community (or communities), is of great potential. However, experience, to date, suggests that to protect Indigenous community collective

traditional biodiversity-related knowledge a number of principles or elements should guide any agreements. Such principles or elements should:

- ensure recognition of the collective nature of the knowledge, both within and among generations of Indigenous communities;

- ensure control of the use of knowledge remains firmly in the hands of the Indigenous communities of origin, even where such information is found within the public domain;

- ensure the exercise of rights by any Indigenous community, or group of communities, does not infringe the rights of other communities to use, dispose of, or otherwise control use of, their resources;

- avoid creating monopolistic rights over knowledge, and prevent the possibility of the acquisition of monopolistic rights over knowledge or the biological resources to which it is associated;

- ensure equitable benefit sharing within and among communities;

- help re-evaluate traditional biodiversity-related knowledge, promote traditional use and minimise adverse impacts on resources and cultures; and

- establish a presumption that use of resources over which there exists knowledge, in particular regarding medicinal plants, implies use of that knowledge.

At all stages, there must be the widest consultations with the relevant traditional owner groups and any developmental, resource use and conservation measures must be compatible with, and build upon, their cultures.[108]

Mutually Agreed Terms

Before any access agreement or contract can be drawn up, all parties must agree upon the terms. Environment Australia points out that:

> Mutually agreed terms presupposes prior informed consent to the access and benefit-sharing arrangements. Mutually agreed terms imply a prior discussion or negotiation between the party providing the biological resource and the potential user. The terms which may be mutually agreed upon include:

- type and quantity of the resource;

- appropriate benefit-sharing arrangements;
- provision of research results;

108 This section summarises information in fourmile-marrie HL 2000.

- ownership of the resource;
- duration of the scheme; and
- rights to transfer to third parties.109

The sticking point in arriving at mutually agreed terms in many cases will most probably be the issue of third party involvement. The Australian Institute of Marine Science advises that:

> In order to utilise facilities and funding opportunities outside AIMS through collaborations and joint ventures, it is typically necessary to transfer samples to third parties. Where the third party is not located within Australia, export permission will be required and applicants should be required or at least encouraged to maximise the opportunity for development of intellectual property within Australia. The need to transfer samples to third parties is inevitable because the full gamut of expertise and facilities to do everything from primary collection, through lead identification, and onto product development, will never occur within the one single organisation. In order to provide certainty to investors in biodiscovery research, it is essential that the terms and conditions of third party transfers are set up-front, at the time permission for primary access to in situ resources.110

Legal and technical support for Indigenous groups

The negotiation of access and benefit-sharing agreements or contracts requires time, money and legal assistance. Indigenous stakeholders generally have few resources at their disposal and therefore must have recourse to independent outside assistance, where necessary. Such assistance should be seen in the context of capacity building.

As recognised by Environment Australia:

> Any access scheme should give appropriate recognition of Indigenous intellectual property rights. Knowledge, innovations and practices should be recognised and benefits based on these should flow back to the relevant traditional owners. The traditional owners of Indigenous people's land (as defined in the Aboriginal Land Rights Act 1976 and the EPBC Act 1999) should have the right to determine who, when and where researchers can access biological resources on Indigenous people's land and a say in the ongoing security arrangements for the data or biological resources collected.
>
> The definition and defence of intellectual property rights may be complex and expensive, however. Design of the access scheme should thus consider providing an appropriate level of independent legal and technical support, and recover the full cost of negotiation of appropriate commercial arrangements by traditional owners. Any scheme should seek to minimise such costs by recognising and incorporating existing sources of legal advice for traditional owners, and facilitate the sharing of such advice.

109. Sub.70:p7.
110. Sub.50:pp.12-13.

> Consideration should also be given to the provision of assistance to those institutions responsible for the collection of data and biological resources that are the custodians of such Indigenous intellectual property. Such assistance could be designed to aid these institutions to effectively disperse information, safeguard it in culturally acceptable ways, and ensure that the collection of such information in the future is in accordance with procedures that meet scientific standards and requirements of Indigenous owners, government, and end users.111

In dealing with these issues generally, ATSIC has recommended:

> That consideration is given to implementing, through the Regulations, appropriate forms of capacity building or Indigenous institutional support. The Indigenous Biodiversity Trust model outlined in Section 14 of this submission provides an example.112

Section 14 in this reference is dealt with in 'An Indigenous biodiversity trust' below.

One of the tasks COP5 identified to help implement the program of work adopted at the meeting, with regard to participatory mechanisms for Indigenous and local communities, is for:

> Parties to take measures to enhance and strengthen the capacity of Indigenous and local communities to be effectively involved in decision-making related to the use of their traditional knowledge, innovations and practices relevant to the conservation and sustainable use of biological diversity subject to their prior informed approval and effective involvement.113

An Indigenous biodiversity trust

The centre piece of ATSIC's submission is 'an Indigenous biodiversity trust, established to hold rights in biological resources and traditional knowledge, and to control and manage these rights and interests in accordance with custom and Indigenous law'.114 ATSIC's model is based on that recommended by Langton M, Epworth D and Sinnamon V (1999). The establishment of such a trust is also supported by the Northern, Central and Kimberley Land Councils115 with secondary endorsement from the Kimberley Aboriginal Law and Cultural Centre.116

Establishing such a trust may be particularly significant for managing benefits associated with species that have a wide geographic range and occur in different ecosystems/bioregions. The traditional knowledge of that species may differ among different traditional owner groups and may reflect factors concerning sustainable use and management within the context of different ecosystems, soil types and climatic conditions.

111 Sub.70:p7
112 Sub.56:p.5.
113 Decision V/16, Annex, Programs of work Element 1, Task 1.
114 ATSIC, Sub.56:p.4.
115 Sub.52.
116 Sub.61.

Establishing some form of body to act on behalf of the Indigenous community is supported in a number of submissions. Dr David Bennett, for example, proposes:

> ... an Indigenous intellectual property foundation operated by Indigenous people to stand in stead of collective owners. ... a legal entity operating on a nationwide basis and capable of having 'ownership' of traditional ecological knowledge intellectual property for all individuals and groups who have a legitimate (under customary and administrative systems and practices) claim to 'the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices'.117

The Australian Research Council points out that it '... may .... prove appropriate that access fees and other benefits be forwarded to authorities charged with the local provision of services, or to an overarching authority such as ATSIC'.118

The Australian GeneEthics Network believes that: 'Some benefits (whether royalties or not) from products that are developed from Australian biota should be put directly into; (ii) a general Indigenous fund that could be accessed for supporting Indigenous concerns'.119

Professor Barry Conyngham argues that: 'Knowledge held by Indigenous people, if in the public domain, should be open to exploration using the biological resources of Commonwealth areas ... with the added proviso that a proportion of any profit arising be attributable to a general fund for the development of all Indigenous people in Australia.'120

The ATSIC proposal is as follows:

> One suggested model is that of an Indigenous Trust. This could be based on a region, such as a bioregion, to be agreed and defined by Indigenous peoples. This could, for example, comprise an area defined on the basis of its specific biodiversity type, such as wet tropics or savannahs, or other types of environmental characteristics (eg a riverine ecosystem) or biological diversity. Or it could be established on the basis of building capacity among a grouping of existing Indigenous organisations such as land councils and other bodies within a region.
>
> The Indigenous Trust would have the following functions, defined on the basis of relevant provisions of the Convention on Biological Diversity and the National Strategy for the Conservation of Australia's Biological Diversity:
>
> - To assert, and to hold Indigenous collective rights in biological diversity and traditional knowledge for and on behalf of native title holders.
> - To make decisions about the control and management, and to advocate legal and other forms of protection and recognition of these rights.
> - To determine the rightful owners, custodians and managers of Indigenous biodiversity related knowledge and intellectual property.

117 Sub.9:pp.7-8
118 Sub.40:p.7.
119 Sub.59:p.15.
120 Sub.11.

- To distribute benefits accrued from the wider uses of biodiversity related knowledge, innovations and practices, in accordance with agreed customary rules and procedures.

- To conduct research, information, education and awareness activities.

> The Indigenous Trust would be established on the basis of agreed principles of customary law. These principles, which could be entrenched in community protocols and guidelines, would underpin all transactions involving benefit sharing and use of traditional knowledge, innovations and practices.
>
> [A Trust of this type] ... which recognises, respects and gives meaning to Aboriginal law is the most appropriate mechanism for the collection and distribution of royalties and other payments.
>
> [It is also] ... best placed to pursue the necessary research, advocacy and litigation on behalf of traditional and native title owners of cultural and intellectual property in biota and traditional ecological knowledge of the use of biota, for ownership, control and management of these natural resources and resource rights.'121

COP5 adopted a program of work to further the implementation of Article 8(j) of the Convention. Of the tasks chosen to help carry out the work program, in accordance with Task 4, Parties are:

> ... to develop, as appropriate, mechanisms for promoting the full and effective participation of Indigenous and local communities with specific provisions for the full, active and effective participation of women in all elements of the programme of work, taking into account the need to:

- build on the basis of their knowledge;
- strengthen their access to biological diversity;
- strengthen their capacity on matters pertaining to the conservation, maintenance and protection of biological diversity;
- promote the exchange of experience and knowledge;
- promote culturally appropriate and gender specific ways in which to document and preserve women's knowledge of biological diversity.

As noted in the *Our Culture: Our Future* report, the National Aboriginal and Torres Strait Islander Rural Strategy proposed establishing an Indigenous-managed Australian Centre for Traditional Medicines at Wujal Wujal. The centre, if established would undertake research, documentation, harvesting and processing functions, and help Indigenous communities negotiate contracts with research companies seeking to

121 Sub.56:p.24-25, see also fn 36.

use their knowledge. It was suggested that such a centre could play a role in setting standards for sharing Indigenous traditional knowledge resources with the biotechnology industry (p.229). Thus many of the functions to be performed by the Centre for Traditional Medicines would be the same as those envisioned for the Indigenous biodiversity trust.

The concept of an Indigenous biodiversity trust and the functions it might perform find some precedent in the National Indigenous Arts Advocacy Association.122

Community and National Registers of traditional knowledge

The ATSIC submission also contains a proposal for community and national registers of traditional biodiversity-related knowledge:

> Provisions may be made for supporting the development of Indigenous community registers or inventories of biological and genetic resources, derivatives and knowledge.
>
> These registers to be owned, controlled and managed by local and/or regional Indigenous community organisations.
>
> The concept of a National Register could also be considered, ensuring that such a register would provide adequate safeguards for secrecy and confidentiality regarding traditional knowledge and cultural matters.123

The idea of such a register is also supported by Alistair Graham, World Wide Fund for Nature (Australia), Humane Society International (Australia) and the Tasmanian Conservation Trust which points out that:

> Establishing beneficiaries is likely to be difficult and protracted and would involve establishing and maintaining a register of holders of (traditional) knowledge about identified components of biological diversity. This is one area where the Indian experience could save much time and heartache.124

This proposal is linked to that of a National Biodiversity Screening Centre proposed by Graham, World Wide Fund for Nature (Australia), Humane Society International (Australia) and the Tasmanian Conservation Trust. The idea is to 'establish registers of in situ custodians of both biological resources and knowledge about them as potential beneficiaries of any benefit-sharing arrangements -- in the context of a proposal for a National Biodiversity Screening Centre'.125

COP5, in paragraph 17 of decision V/16, has requested:

The issue of establishing registers and databases of cultural material and knowledge belonging to Indigenous local communities has been addressed in the *Our Culture: Our Future* report.126 One such database concerning Indigenous visual artists has already been established within the Australian Institute of Aboriginal and Torres Strait Islander Studies. The Our Culture: Our Future report concludes that:

122 Janke T 1998,pp.256-7.
123 ATSIC, Sub .56; see also Attachment 1 below.
124. Sub.54:p.9. Graham, Tasmanian Conservation Trust, lodged this submission on behalf of the world Wide Fund for Nature (Australia), the Humane Society International (Australia) as well as the Tasmanian Conservation Trust.
125. Sub.54:pp.17-18.
126. Janke T 1998, p.231.

After the analysis of feedback received, it appears there is scope for registers or databases to be of use in so far as they relate to material that is already, publicly available in some material form. New material or secret and sacred knowledge would need greater rights protection.

Furthermore, Indigenous people should have control over the content of any databases established, as well as who can access and use the knowledge and related information on the register.

If the register is to act as a clearance system, it must be appropriately designed and operate on the premise of prior authorisation rather than under a blanket authorisation.

The cost of establishing and maintaining a register (or a number of regionally-based registers) of traditional biodiversity-related knowledge is an important consideration. It should, however, also be borne in mind that, in the absence of legislation to provide effective protection to traditional biodiversity-related knowledge, a registry system may help prevent further cultural harm and insult caused through the illicit and unauthorised use of such knowledge. At the same time, the register could ensure that those whose knowledge is the subject of a request for access can be easily located so they can negotiate the terms of access and benefit-sharing arrangements.

Careful thought and planning is essential when designing such a register (or registers) to ensure appropriate access while protecting confidentiality. Decisions about how to store, file and cross-index information need to be made as well as the level of information which can be openly accessed by a wide range of potential users (ie other Indigenous groups, intellectual property officers, researchers, industry, biological resource managers, etc.). Security codes could be built into the register database so confidential information can only be accessed by its owners, thus ensuring access seekers have to consult knowledge holders/owners before further information can be divulged. This will enable the knowledge owners to work through their own prior informed consent procedures and set the terms and conditions (in contractual form if needs be) for the further application of their knowledge.

Recommendation

Consideration should be given to establishing a national register which identifies the owners of Indigenous cultural and intellectual property. Any established register should not be a means of evidencing title. The Register should be used only to provide contact details for subsequent users of Indigenous material to contact the relevant community for prior consent. The register should be designed, managed and controlled by Indigenous people.[127]

127. op.cit.,p.238.

Developing an Indigenous code of ethics

A number of submissions comment on the need for some form of regulation, guidance, model or protocol for executing agreements. The Australian Biotechnology Association notes that:

> Commercialisation agreements could be expedited by new legislation providing guidelines to the expected stakeholders including federal and state governments, traditional landowners and custodians, researchers, financiers and business interests, so that reasonable returns are provided to the community.128

The Australian GeneEthics Network proposes a bioprospecting research agreement model to be monitored by a federal regulator,129 while Professor Conyngham submits that:

> Where Indigenous knowledge is not in the public domain but there is a desire to bring it to the attention of organisations or individuals who might be able to add value to that knowledge this needs to be done through a formal set of protocols. This can open the knowledge to a process where tenders are invited for undertaking development or where an individual or individual organisation is identified as a development partner.130

The Australian Science, Technology and Engineering Council report, *Environmental Research Ethics: National Principles and Guidelines for the Ethical Conduct of Research in Protected and Environmentally Sensitive Areas* (1998), contains a set of 'Principles particularly relevant to Aboriginal and Torres Strait Islander Peoples' Concerns'.131 A number of submissions, including ATSIC,132 referred to this report. Professor Helene Marsh regards the Inquiry as:

> the ideal opportunity to provide regulatory 'teeth' to the management of the issues outlined in the ASTEC Report. ... To date, I am aware of only two Commonwealth agencies that have begun to address these issues: The Great Barrier Reef Marine Park Authority and the Antarctic Division.133

While it appears there are no protocols, guidelines, or codes of ethics developed specifically for bioprospecting in Indigenous territories in Australia (apart from locally specific policies/guidelines adopted by some land councils), there is, nevertheless, no shortage of ethics documents that could serve as models. Foremost amongst these are the funding guidelines developed by the Australian Institute of Aboriginal and Torres Strait Islander Studies, and those of the National Health and Medical Research Council. Others include the Ethics Policy and Research Protocol developed by the Centre for Indigenous Natural and Cultural Resource Management, Northern Territory University; the Australian Anthropological Association Code of Ethics: Consulting Work; the Australian Association of Consulting Archaeologists: Code of Ethics; the Aboriginal Languages Association: Resolutions and the Social Research Association Ethical Guidelines.

128 Sub.37:p.4.
129 Sub.59:pp.14-15.
130 Sub.11.
131 See Attachment 4 below.
132 Sub.56.
133 Sub.33.

The Australian Institute of Aboriginal and Torres Strait Islander Studies guidelines have been described in detail in the *Our Culture: Our Future* report.134 Internationally, many such industry-specific guidelines have been developed (see Attachment 5 below). Amongst the best of these is the Code of Ethics developed by the International Society of Ethnobiology and adopted at its sixth international congress in New Zealand in 1998.

One short-coming of codes of ethics/conduct/practice is their uncertain legal status and/or lack of 'teeth'. Members of some professions (eg doctors, lawyers, chartered accountants) are legally bound by their respective codes. Similarly, breaches of codes maintained by funding institutions, such as the Australian Research Council and the Australian Institute of Aboriginal and Torres Strait Islander Studies, can be dealt with swiftly. Difficulties may arise, however, in relation to non-institutional and private collectors (who may also bioprospect under contract for overseas companies -- the third parties). In this regard, we should heed the findings of a study of 98 of Canada's largest corporations operating abroad (in a range of industries) which has shown that the majority has not adopted codes of conduct dealing with basic human rights, and of those which have such codes, they generally do not have any mechanisms for ensuring their codes are respected.135

Lessons could also be learned from the Australian Broadcasting Authority's cash-for-comment inquiry into commercial radio. The inquiry found 95 separate breaches of either the Broadcasting Services Act or the Commercial Radio Codes of Practice showing that: '2UE's management either ignored its legal obligations or decided that within the construct of self-regulation such breaches did not matter'. The report exposes the Australian Broadcasting Authority to criticism that it has not developed an effective monitoring system for an industry that won the right to self-regulation in 1992. The code of practice breaches carry no sanction other than the Australian Broadcasting Authority's ability to impose conditions on a broadcaster's licence.136

It is therefore recommended that any code of ethics to regulate bioprospecting and/or biodiscovery in Indigenous territories be overseen by an ethics committee. Furthermore, it is recommended that all bioprospectors/biodiscoverers who wish to operate in Indigenous territories register with any body set up by the Commonwealth Government to administer the regulations under s301 of the EPBC Act. Such registration must be conditional upon receipt of a signed commitment to abide by the Code of Ethics for Bioprospecting on Indigenous Territories, and such an undertaking must be binding on third parties in an access and benefit-sharing agreement.

A nationally recognised code of ethics for accessing biological resources on Indigenous lands could be embedded in any access and benefit-sharing agreements between traditional owner groups and any party accessing biological resources and associated knowledge on their lands.

The Indigenous community might therefore wish to develop its own 'regulatory approach' to access to genetic resources on Indigenous territories by setting some

134 pp.250-3.
135 Forcese C 1997: p.15.
136 *The Australian* 2000:p12.

industry standards or 'bottom-line principles' to curtail the problem of access-seekers playing one traditional owner group/community off against another -- referred to by the CSIRO as 'access shopping'137 -- and thereby potentially lowering the bottom line with regard to benefits packages.

Recommendation

A Code of Ethics Governing Access to Biological Resources on Indigenous Territories be developed through consultation between all relevant Indigenous, and public and private sector groups.

Such a code should be formally adopted by the national regulatory body overseeing the regulations under s301 of the EPBC Act, by all relevant research and funding bodies, and by private sector bioprospectors.

An ethics committee be established to hear complaints concerning alleged breaches of the Code and to provide advice on how they should be dealt with. The committee is to include membership from the Indigenous Advisory Committee established by s505A and s505B of the EPBC Act.

Furthermore, it is recommended that all bioprospectors/biodiscoverers who wish to operate in Indigenous territories register with any body set up by the Commonwealth Government to administer the regulations under s301 of EPBC Act and that such registration is conditional on receipt of a signed commitment to abide by the Code of Ethics for Bioprospecting on Indigenous Territories.

Such an undertaking to be also binding on third parties in any access and benefit- sharing agreement.

Commonwealth access regulations as a model for a national approach to access and benefit sharing

Many submissions expressed the need for a nationally consistent approach for access and benefit sharing and raised the hope that the regulations developed and adopted by the Commonwealth might serve as a model for adoption by the States and Territories. For example, the Commonwealth Department of Industry, Science and Resources recommended that:

> ... the Commonwealth review, with the States and Territories, the relevance of a Multi- Purpose Contract System, as previously proposed by the Commonwealth State Working Group, or other agreed system, for access to biological resources in Commonwealth areas, with a view to establishing agreed nationally consistent arrangements which can be used either directly or as a model by the states and Territories.138

137 Sub. 65:p.10.
138 Sub.41:p12.

Maxine Chi raised concerns, from an Indigenous perspective, about:

> ... access issues to Western Australian State managed areas (National Parks, Nature Reserves, Crown Land and Aboriginal Lands Trust reserves) and whether the precedent and regulations established under this Inquiry will be adopted by the States.139

For this reason, many submissions intentionally did not confine their comments to access to biological resources in Commonwealth areas. Expressing an Indigenous perspective, the Northern, Central and Kimberley Land Councils stated that:

> The incidents of Indigenous knowledge and ownership are not restricted to political boundaries. Consequently the process of developing an effective and culturally appropriate scheme for controlling access and determining equitable sharing of benefits will have application to all customary estates.
>
> Cadastral boundaries drawn for historical and political reasons are virtually irrelevant to issues of customary estates and traditional responsibilities. Nor do biological resources respect arbitrary lines drawn on a map.
>
> This dissonance poses profound challenges for developing mechanisms to deal with decision-making concerning access to customary estates. The challenge for this Inquiry is to recognise that issues of cross-border and cross-regional resource ownership are difficult and complex, but not insurmountable.140

The Tasmanian Conservation Trust argued that:

> ... Commonwealth legislation, on its own, will go only part of the way to meeting the Commonwealth's outstanding obligation on ratifying the Convention on Biological Diversity. The Commonwealth has a responsibility in international law to ensure that a regime is established to allow control of biological resources throughout all areas subject to the jurisdiction of all Australian governments -- not just the Commonwealth.
>
> To be most helpful, therefore, we suggest that this Inquiry frame its recommendations with respect to Commonwealth legislation bearing in mind the Commonwealth's responsibility to ensure that all Australian governments must adopt analogous legislation. Indeed, the Commonwealth's legislation should be explicitly developed:
>
> - as model legislation which sets minimum standards for such legislation throughout Australia with respect to not only access issues but also resource and information management issues; and
> - as the legislation which establishes the actual regime for trade and benefit sharing issues.
>
> To do this effectively, the Commonwealth will need to rely on its constitutional powers over both foreign affairs and trading corporations.141

139 Sub.62.
140 Sub.52:pp.1 and 4.
141 Sub.54:p.3.

This position was also supported by the Environmental Defenders Office (Vic) Pty Ltd,142 which recommended that a national scheme for the control of access to Australia's biological resources be implemented, pointing out that the legislative power of the Commonwealth to implement such is clear and certain under the external affairs power in order to implement the Convention on Biological Diversity and address a matter of high international concern.

If the scheme to control access to biological resources in Commonwealth areas is to act as a model for the States and Territories, it is necessary to make doubly sure the regime adopted accords well with the aspirations of the traditional owner groups and adequately addresses their concerns. Most importantly, it needs to provide certainty and legal clarity to traditional owner groups. They need to know they:

- can reasonably control the conditions of access to and use of biological resources on their territories and any associated traditional biodiversity-related knowledge, and

- can be guaranteed to benefit from any access agreements they enter into.

Once the Commonwealth has adopted such a regime in relation to Commonwealth areas, it may serve as a model in the context of any bilateral agreements forged between the Commonwealth and States and Territories under Chapter 3 - Bilateral Agreements of the EPBC Act.

Indigenous communities must remain alert to the possibilities offered under such agreements and be prepared to negotiate with the responsible Federal and State or Territory Ministers.

To this end, the recommendation ATSIC put forward should be supported.

Recommendation

That the design and implementation of the Regulations are carried out only with the full and equitable participation of Aboriginal and Torres Strait Islander people. The Indigenous Advisory Committee established under s505A and s505B of the EPBC Act should be the mechanism through which such participation is achieved.143

A Commonwealth regulatory body to oversee access to biological resources

A number of submissions supported the idea of a single Commonwealth regulatory body to oversee access to biological resources in Commonwealth areas, offering a 'one-stop-shop' approach to processing access applications, seeing that all requirements for prior informed consent are met, and for granting final approval.

142 Sub.55:p.2.
143 Sub.56:p.5.

Need for further consultation with the Indigenous community

In concluding this analysis on access to biological resources and benefit sharing, I note that a number of submissions emphasised the need for further research and consultation with Indigenous stakeholders.

The Northern, Central and Kimberley Land Councils recommended the need for further research and consultation to develop the most appropriate mechanisms for determining access and benefit sharing -- the process to be Indigenous controlled, noting that regional definitions, such as bioregional zones, are a necessary subject for further research and consultation; a wide range of models and options be included in the process; and the trust model, recommended by Langton, et al., be used as a starting point for consultation.144

The Australian GeneEthics Network expressed the view that the 'cultural value of Australian biota to Indigenous peoples must be recognised, with extensive consultation provided to Indigenous communities, especially community Elders, on access to native biota'.145 While the Biological Diversity Advisory Council suggests that 'awareness is raised of intellectual property and 'ownership' in both the public and private sectors, and that this includes Indigenous Australians'.146

Recommendation

That the Indigenous Advisory Committee, established under s505A and s505B of the EPBC Act, conduct a series of regional access and benefit sharing workshops to enable Indigenous traditional owner groups and communities, industry representatives and researchers to examine issues of access and benefit sharing in relation to biological resources and associated knowledge on Indigenous territories.

Any conclusions, findings and/or statements which result from the workshops should be used to help formulate a national Indigenous code of ethics to guide bioprospecting and biodiscovery on Indigenous territories.

Attachments to Appendix 10

Attachment 1: Elements of a Scheme for Regulations under s301 of the EPBC Act147

The following suggests a framework for the Regulations to be introduced under s301 of the EPBC Act. At the heart of this framework is a model for equitable benefit

144 Sub .52.
145 Sub.59:p.3.
146 Sub.3:p.4.
147 ATSIC,Sub.56.

sharing with Indigenous rightful owners, holders and custodians of biological resources and traditional knowledge, innovations and practices.

The Regulations

Terms and definitions

The following terms must be adequately defined.

'Biological resources'

'Genetic resources'

'Traditional knowledge, innovations and practices' means the intangible, intellectual aspects of biological and genetic resources, and any innovations and practices based on that knowledge. Traditional knowledge must be acknowledged as having a spiritual, as well as secular, component.

'Indigenous rights' refers to the collective rights of Indigenous peoples in biological and genetic resources and in traditional knowledge, innovations and practices.

Capacity building

To establish partnership arrangements with Indigenous peoples, to advise and recommend on the introduction of appropriate capacity building structures, such as Indigenous regional trusts. These bodies would hold and assert Indigenous rights in biological resources, traditional knowledge, innovations and practices, and make decisions regarding management and control of biological resources, and traditional knowledge, innovations and practices.

Processes for benefit-sharing agreements

A process must be introduced, in agreement with the relevant Indigenous Trust, for formulating appropriate benefit-sharing arrangements and agreements for access for each case in which biological or genetic resources or their derivatives, and/or traditional knowledge, innovations or practices are sought.

Benefit-sharing arrangements that are introduced should include at least the following elements, to be agreed by the appropriate Indigenous owners, custodians and managers:

- Royalties must be adequate, and reflect realistic market prices.
- Benefits to be determined may include, as appropriate, various combinations of financial payments such as up-front payments, research and development payments, 'milestone' payments, capacity building, infrastructure and community support payments.

- Benefits should include non-financial benefits such as capacity building, community infrastructure and support, such as training and education, full and equitable community participation, language, cultural, heritage and ethnobotanical programs and projects.

Consultation with rightful Indigenous owners and custodians

On the basis of appropriate consultation and agreement with the relevant Indigenous trust, any process for seeking access to biological and genetic resources and their derivatives must be conducted only after having first identified, and sought the consent of the rightful Indigenous owners, holders and custodians.

Prior informed consent

Prior informed consent with the rightful Indigenous owners, custodians and managers must be the basis for any agreements regarding access to, and use of biological resources and traditional knowledge.

Prior informed consent is to be obtained from rightful Indigenous owners, holders and custodians on the basis of community derived principles of rights and ownership of biological resources and traditional knowledge, including intellectual property rights.

Agreements and contracts

Agreements and contracts for access to biological resources and traditional knowledge, innovations and practices should contain:

- Details of the Community/locality/source/region of origin of the biological resources being sought,

- Details of any actual or potential Indigenous traditional knowledge, innovations or practices associated with the resources being sought,

- Details of actual or potential uses of the biological and genetic resources and derivatives being sought,

- Details of the purposes for which the biological and genetic resources are sought,

- Details of the parties seeking access to the biological and genetic resources, and

- Details if known, of the commercial and market potential of the biological and genetic resources and derivatives sought, including any potential intellectual property aspects such as proposals for patenting.

Mutually agreed terms

Contracts and agreements must be based on mutually agreed terms between the seekers of biological resources, and the providers and/or Indigenous rightful owners, holders and custodians.

Protection for Indigenous rights

Access agreements must contain provisions explicitly aimed at preserving customary and traditional uses in accordance with relevant provisions of the Convention on Biological Diversity, the National Strategy for the Conservation of Australia's Biological Diversity, and relevant legal developments (eg *Yanner v Eaton*).

Access agreements must contain provisions ensuring protection of Indigenous rights and interests in biological resources, traditional knowledge, innovations and practices, including protection of secrecy, confidentiality and Indigenous intellectual property rights.

Access agreements will contain provisions to ensure that such agreements do not in any way limit, impose constraints on, or restrict customary use of such resources and knowledge.

Community and national registers

Provisions may be made for supporting the development of Indigenous community registers or inventories of biological and genetic resources, derivatives and knowledge. These registers to be owned, controlled and managed by local or regional Indigenous community organisations.

The concept of a National Register could also be considered, ensuring that such a register would provide adequate safeguards for secrecy and confidentiality regarding traditional knowledge and cultural matters.

Penalties and sanctions

Appropriate penalties and sanctions to be imposed for breaches of Indigenous rights in biological resources and traditional knowledge, innovations and practices.

Attachment 2: Possible elements of sui generis legislation to protect the knowledge, innovations and practices of local and Indigenous communities [148]

- Recognition of ancestral community rights over knowledge, innovations and practices related to genetic resources.

- Recognition that such rights exist even where information may be in the 'public domain'.

148 UNEP/CBD/COP/5/8, annex vi, 2 November 1999.

- Establishment of the principle that such rights may be collective in nature.

- Distinction between rights over genetic resources (where vested in the State) and rights over knowledge associated with such resources (vested in local and Indigenous custodians).

- Presumption that use of genetic resources implies use of associated knowledge, innovations and practices.

- Establishment of administrative and judicial review processes to resolve disputes regarding the granting of access on the basis of potential environmental, economic, cultural or social impacts.

- Creation of benefit-sharing mechanisms/obligations to ensure equitable distribution of benefits amongst custodians, whether parties to access agreements or not.

- Establishment of local and centralised registers of traditional knowledge, innovations and practices of local and Indigenous communities.

- Creation of programmes and processes for the strengthening of traditional knowledge systems.

Attachment 3: Report of the 1994 Australian Research Council Workshop on Access to Biological Resources

'The Workshop recognises the rights of Aboriginal and Torres Strait Islander people stem from their prior occupation of Australia and following the High Court's Native Title ruling, what we now know as Aboriginal lands may increase.

The Workshop agreed that an underlying principle which must contextualise any discussion of Australian Indigenous peoples' rights is that all interactions with Aboriginal and Torres Strait Islanders will involve negotiation as well as consultation.'

Noting that ILO Convention 169, the Convention on Biological Diversity, and the Rio Declaration on Environment and Development all contain important provisions regarding Indigenous peoples' rights to natural resources, '... and with these conventions in mind, and noting that there is also a Declaration on the Rights of Indigenous Peoples already in draft form, the workshop agreed on the following set of principles in relation to Aboriginal and Torres Strait Islander rights which need to be recognised in a national policy on access to genetic resources:

- the close and traditional dependence on many Aboriginal and Torres Strait Islander communities embodying traditional lifestyles on biological resources;

- the notion of self-management of resources by Aboriginal and Torres Strait Islanders;

- the right of Aboriginal and Torres Strait Islanders to participate fully in environmental matters, including sustainable development and measures of protection;

- the need to respect, preserve and maintain knowledge, innovations and practices of Aboriginal and Torres Strait Islanders with their approval and involvement;

- the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices with Aboriginal and Torres Strait Islanders; an

- the need, where appropriate, for the implementation of special measures to restore and protect the Indigenous environment and where damage to the environment has occurred as a result of activities by governments or corporations, the right to fair compensation.

Recommendations

The workshop recommends that the above principles be incorporated in the national policy on access to Australia's genetic resources.

The workshop recommends that both consultation and negotiation should contextualise any discussion regarding the rights of Australia's Indigenous people.

Attachment 4: Australian Science, Technology and Engineering Council Report

Environmental Research Ethics: National Principles and Guidelines for the Ethical Conduct of Research in Protected and Environmentally Sensitive Areas (1998)

1.2 Principles particularly relevant to Aboriginal and Torres Strait Islander Peoples' concerns

Goal
Indigenous Australians, confident that research in protected and environmentally sensitive areas:

- respects their values and customary obligations;

- benefits and empowers traditional owners -- management agencies have a key role in facilitating this;

- respects their need for self determination;

- acknowledges their association with and rights to and in their traditional environments (lands/seas) including the natural and cultural resources therein;

- protects their rights to own and control their knowledge and intellectual property; and
- protects their right to receive the full protection afforded them by relevant international instruments ratified by the Australian Government.

Strategies

Researchers must:

- negotiate all aspects of research with traditional owners of protected areas. (Here, the Management Agency may have information or existing mechanisms set up to assist, and the researcher should explore these opportunities and seek the advice of the Management Agency);

- obtain the informed consent of traditional owners before beginning or continuing any research in protected areas;

- disclose to traditional owners all aspects of the research proposal including the objectives and methodology as well as how the results might be used and who will benefit;

- conduct themselves with respect and utmost good faith, where they have access to Indigenous knowledge;

- acknowledge Aboriginal and Torres Strait Islanders' right to control any use of their knowledge or intellectual property by the researcher; their entitlement to fair remuneration for the use of their knowledge; and their right to exclude from publication and/or keep confidential any of their intellectual property;

- acknowledge Aboriginal and Torres Strait Islander peoples' right to share in any profits derived from the use of their knowledge in the development and subsequent sale of bioproducts or publications;

- make all reasonable endeavours to provide opportunities in education and training for Aboriginal and Torres Strait Islander people, where they use Indigenous knowledge for science and humanity;

- provide Aboriginal and Torres Strait Islander people with the opportunity to participate actively in all phases of research from inception to completion, including management decisions;

- acknowledge the traditional owners of the protected areas in any publication of the research results;

- make available the research results to the relevant communities;

- ensure that their activities have minimum impact on the Indigenous Australian peoples and their local communities;

- assist Aboriginal and Torres Strait Islander peoples to protect and enhance their relationship with the environment in order to maintain cultural values and biological diversity; and

- acknowledge the right of Aboriginal and Torres Strait Islander peoples to compensation for any adverse impacts on them as a result of research - this is a complex matter that needs careful exploration by implementing authorities.

Attachment 5: International developments

International processes, UN Agency Guidelines, etc.

Code of Conduct for Plant Germplasm Collecting and Transfer (FAO)

Principles and Guidelines for the Protection of the Heritage of Indigenous People Elaborated by the Special Rapporteur of the Sub-Commission on Prevention of Discrimination and Protection of Minorities, Mrs. Erica-Irene Daes

Operational Directive 4.20: Indigenous peoples (World Bank)

Strategies and Procedures on Socio-Cultural Issues Related to the Environment (Inter-American Development Bank)

Policy on Indigenous peoples (draft) (Asian Development Bank)

Guidelines for Support to Indigenous peoples (draft) (United Nations Development Programme)

The draft UN Declaration on the Rights of Indigenous Peoples

ILO Convention 169

World Intellectual Property Organisation /UNESCO Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions (1985)

The World Trade Organisation TRIPs Agreement

Agenda 21

The Ramsar Convention on Wetlands

Convention to Combat Desertification

Intergovernmental Forum on Forests

International Union for the Protection of New Varieties of Plants

Other regional and national developments

Andean Pact Decision 391: A Common System on Access to Genetic Resources

Philippines Presidential Executive Order No. 247 of 1995 prescribing guidelines for bioprospecting, etc.

Costa Rica Biodiversity Law

Organisation of African Unity: Draft Legislation on Community Rights and Access to Biological Resources

India's proposed sui generis System for Protection of Plant Variety Rights

Indigenous Peoples' statements on rights

Declaration of Principles of the World Council of Indigenous Peoples

Kari-Oca Declaration and the Indigenous Peoples' Earth Charter (Kari-Oca, Brazil, May 25-30, 1992)

Charter of the Indigenous Tribal Peoples of the Tropical Forests (Penang, Malaysia, February 15, 1992)

The Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples (Whakatane, Aotearoa/New Zealand, June 12-18,1993)

Recommendations from the Conference 'Voices of the Earth: Indigenous Peoples, New Partners and the Right to Self-Determination in Practice' (Amsterdam, Netherlands, November 10-11, 1993)

Statement from the Regional Meeting sponsored by COICA and UNDP on 'Intellectual Property Rights and Biodiversity' (Santa Cruz de a Sierra, Bolivia, September 28-30, 1994)

Statement from the 'Asian Consultation on the Protection and Conservation of Indigenous Knowledge'(TVRC Tambunan, Sabah, Malaysia, February 24-27, 1995)

Final Statement from the 'Consultation on Indigenous Peoples' Knowledge and Intellectual Property Rights' (Pacific Concerns Resource Centre, Suva, Fiji, April, 1995)

The Julayinbul Statement on Indigenous Intellectual Property Rights and Declaration Reaffirming the Self-Determination and Intellectual Property Rights of the Indigenous Nations and Peoples of the Wet Tropics Rainforest Area (Jingarrba/Daintree, Australia, November 25-27, 1993)

Treaty for a Lifeforms Patent-Free Pacific and Related Protocols (Suva, Fiji, April 1995)

Beijing Declaration of Indigenous Women (Huairou, Beijing, Peoples Republic of China, August 30 - September 8, 1995)

Indigenous Peoples' Statement on Access and Intellectual Property Rights (IPBN, Jakarta, Indonesia, November 10, 1995).

Statement of Indigenous Nations, Peoples, and Organizations (New York, December 9,1992)

Ukupseni Kuna Yala Declaration

Oka Declaration on a Sustainable Future for the Environment and Traditional Peoples of the Okinsky Territory (Okinsky Territory, Siberia, September, 1994)

The Chiapas Declaration

Declaration of Indigenous Peoples of the Western Hemisphere Regarding the Human Genome Diversity Project (Phoenix, Arizona, February 19, 1995)

Resolutions of the Women's Commission, First Continental Conference of Indigenous Peoples on 500 Years of Resistance (Quito, Ecuador, July 1990)

Research Principles for Community-Controlled Research with the Tapirisat Inuit of Canada

The Jovel Declaration on Indigenous Communities, Indigenous Knowledge and Biodiversity

Leticia Declaration and Proposal for Action with regard to the Management, Conservation and Sustainable Development of All Types of Forests (Leticia, Colombia, 13 December, 1996)

Inuit Resource Conservation Strategy

The 'Heart of the Peoples' Declaration (North American Indigenous Peoples Summit on Biological Diversity and Biological Ethics, Fort Belknap Reservation, Montana, USA, August 7, 1997)

Declarations, statements, guidelines, models, etc., by Non Government Organizations and Fora

The Manila Declaration

The Declaration of Belem

A Rights Regime for the Protection of Indigenous Rights and Biodiversity Third World Network, Penang, Malaysia)

Rural Advancement Foundation International (RAFI)

The Crucible Group

The Covenant of Intellectual, Cultural and Scientific Resources Indigenous Peoples and Conservation: WWF Statement of Principles

Guidelines for Equitable Partnerships in New Natural Products Development:

Recommendations for a Code of Practice, National Cancer Institute: Conclusions of the Workshop on Drug Development, Biological Diversity and Economic Growth

Williamsburg Declaration by the American Society of Pharmacognosy

Bukittinggi Declaration (West Sumatra, Indonesia, 1992)

Statement of the Fifth Global Biodiversity Forum to the Third Meeting of the Conference of the Parties to the Convention on Biological Diversity (Buenos Aires, 3 November, 1996)

Conclusions and Recommendations of the Panama City Conference on Sustainable Harvest and Marketing of Rain Forest Products, 20-21 June 1991

Guidelines for Equitable Partnerships in New Natural Products Development: Recommendations for a Code of Practice

Chiang Mai Declaration for Conservation of Medicinal Plants

Attachment 6: Benefit sharing options and mechanisms identified by the Convention on Biological Diversity's Panel of Experts on Access and Benefit Sharing[149]

B. Benefit sharing options and mechanisms

74. Benefits arising from the utilization of genetic resources can be either monetary or non-monetary.

75. Examples of monetary benefits include:

a. 'Up-front' payments;

b. Milestone payments;

c. Royalties;

d. Research funding:

e. Licence fees; and

f. Salaries.

76. Examples of non-monetary benefits include:

77. Some other important non-monetary benefits are often overlooked in benefit sharing discussions. These include:

a. Biological inventories and taxonomic studies, integral components of many bioprospecting activities, can provide important benefits for conservation and sustainable use of biological diversity;

b. Contributions to the local economy through 'value-added' activities such as the cultivation of a species that is needed in large quantities for natural-products research, development and production as a commercial commodity;

149 UNE/CBD/COP/5/8, 2 November 1999, pp.15-16.

c. Public (Indigenous community) health benefits for source countries (communities), in cases where access and benefit-sharing agreements

d. encompass a commitment by a firm seeking genetic resources to invest in or support research on locally important diseases for which there is relatively little private-sector investment;

e. The institutional and personal relationships that can arise from an access and benefit-sharing agreements and subsequent collaborative activities under it -- between a local university and an international research centre, for example -- are in themselves an extremely important non-monetary benefit. Often these relationships lead to important follow-on scientific collaboration and increased access to international funding sources; and

f. Human and material resources to strengthen the capacities of personnel responsible for the administration and enforcement of access regulations.

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Appendix 11: What the Inquiry is about and what it means for Indigenous communities

Purpose of the Inquiry

The purpose of the Inquiry is to find a way to:

- ensure that Indigenous communities (and Australia) share in any benefits from the search for new medicines and products that come from discovering the uses of native plants and animals on Commonwealth lands; and

- ensure that this search does no harm to the land or to its people.

To help the Federal Government choose the best way to control access to biological resources, the Environment Minister, Robert Hill, has established this Inquiry. Section 301 of the new Commonwealth *Environment Protection and Biodiversity Conservation Act 1999* allows for regulations to be made to control access. The Inquiry is to advise the Minister on what should be in this law. The Minister has asked for the Inquiry to advise him by 30 June 2000.

The Inquiry covers Commonwealth lands and waters. This includes, for example, land owned by the Department of Defence or other Commonwealth government departments around Australia. Commonwealth lands also includes Aboriginal land leased to the Commonwealth, such as at Kakadu. The Inquiry does not cover State or Territory land and marine waters. Each State and Territory will have to design its own laws.

The Importance of Biological Resources

Biological resources (often called genetic resources) provide us with many medicines and industrial products. For example, aspirin is based on a chemical from willow trees. Quinine, used for 300 years to treat the sickness of malaria, is made from the bark of the yellow cinchona plant. For many years the search for plant products useful for medicine or for industry has not been controlled. Owners of the plants or owners of the knowledge about their use have not shared in the financial benefits made from discoveries. This is not fair.

Australia has many biological resources that might be used in scientific and technological research. Some of these might also be developed into commercial products. Only about one-fifth of Australia's plant species have been investigated, so useful products and drugs may still be found. Many companies are already exploring Australia's land and marine areas and taking very small samples of plants and animals for further studies.

This process, known as bioprospecting, or biodiscovery is expensive and takes a long time. From the many thousands of tiny samples taken, perhaps only one or two may prove to be useful. It may take ten or twelve years before any product is manufactured for sale.

The need to recognise Indigenous knowledge

Indigenous peoples of the world have a vast knowledge about the properties of plants and animals they have used for tens of thousands of years. However, there have been cases where companies have used this knowledge for their own gain, with very little being returned to the Indigenous people.

The Inquiry is looking at ways to ensure Indigenous people maintain control over their knowledge and their land. The decision to share their knowledge is one for them to make. They may choose to say 'yes' or may choose to say 'no'. The Inquiry thinks the new law should protect this right to choose. The Inquiry recognises the importance of respecting culture and is looking at ways to ensure the law does this.

The need to recognise Indigenous knowledge is also in an international agreement. This is known as the Convention on Biological Diversity. The Convention encourages the fair sharing of the benefits from the use of traditional knowledge, innovations and practices. Australia agrees to be bound by this Convention. The Inquiry supports this Convention.

Recognising the special knowledge about Australia's biodiversity held by Indigenous people, the Inquiry will work to ensure the fair sharing of benefits from the use of Indigenous knowledge and practices. The Inquiry must also report on ways for ensuring that the collection of biological resources does not damage any species of plant or animal.

Fairness to others

Access to biological and genetic resources for environmentally sound uses is important to developing industry in Australia. The inquiry will look at ways for making a fair and simple system that protects the environment and is also fair to industry and makes their effort and investment worthwhile.

Who is running the Inquiry?

South Australian lawyer, Mr John Voumard is the Chairman of the Inquiry. He is independent. He is not part of government. He is supported by a group of experts. They have special knowledge in the environment, law, business, Indigenous issues and science. Environment Australia provides support for the Inquiry.

Consultation

The Inquiry is an important opportunity for everyone with an interest in these issues to contribute to a system which will ensure the Australian community gets maximum benefit from the commercial and scientific potential of our diverse biological resources.

The Inquiry has considered public submissions from governments, business, environment organisations and universities. Submissions have also been made by Indigenous representative bodies such ATSIC and the Land Councils. The Inquiry has

conducted hearings and meetings around Australia. The Chairman has visited Commonwealth areas where Indigenous people have an interest, such as national parks at Uluru, Booderee and Kakadu. He has wanted to talk to the owners of the land and to listen to them.

What are Commonwealth areas?

Commonwealth areas include:

Uluru-Kata Tjuta National Park,
Kakadu National Park,
Booderee National Park,
Christmas Island National Park,
Norfolk Island National Park,
Pulu Keeling National Park,
Great Barrier Reef Marine Park,
marine reserves managed by the Commonwealth,
marine waters in the exclusive economic zone, and
land owned or leased to the Commonwealth.

Although the inquiry is not addressing access to biological resources under the control of the States and Territories, the Inquiry's advice will help the States and the Commonwealth to work towards a common approach to access to biological resources by all governments.

What issues are being considered?

There is a range of issues about which the Inquiry would like to receive the views of traditional owners. They include:

- Do owners want to allow access to plants and animals in their areas?

- How would owners like to control access to plants and animals in their areas? For example, through the Board of Management of the Park or by dealing direct with the assistance of the Land Council?

- What type of benefits should the owners receive for material sourced from their areas? For example, money up front, employment, training, facilities for the community or some combination of both.

- Who should receive benefits? For example, the local community, individuals or could it go to a trust fund for distribution to a wider group of Indigenous people who also have the same plant growing in their country?

- If community traditional knowledge is used to help discovery or commercial use of a plant or animals should any benefits flowing from that go to the community or should it be shared with other Indigenous communities who also have that same knowledg
- Would owners prefer a one-off payment, some part-ownership of a company or a share of any profits?

- If communities want to share benefits outside their community, what is the best way to do this? For example, would they wish to put some of the money into a trust fund to benefit other Indigenous communities?

- Would owners like to see some of any benefits used to protect the environment on their land?

- How would owners like to see benefits (money) used?

Other Questions and Answers

What does bioprospecting or biodiscovery involve?

Bioprospecting does not involve disturbing the ground with machines. Scientists are particularly interested in examining plants and small organisms, many of which are invisible to the naked eye without a microscope. They generally do not collect large animals such as kangaroos, possums or birds. The search usually involves a few people, often on foot, looking at the plants and organisms in an area for a limited time. To understand the nature of each plant they need only take a sample of its bark, leaf, flower and seeds. This may involve no more than a handful of material. The sample is later studied in a laboratory.

Is there much money to be made from allowing access for bioprospecting?

This is usually not an activity which generates much money. A relatively small fee per sample is usually negotiated, and a larger fee is payable if anything significant is found. Fees per sample paid in Australia are often less than $10 each and sometimes less than $5 each. The only prospect of significant money arises when a substance is found which is able to be turned into a new product, such as a medicine. This takes a long time to develop, often more than 10 years. If a product is found, however, any agreement with the owners should ensure that a royalty is paid to them.

What other benefits may be payable if communities do not want to focus on money?

Some communities find money causes disputes and prefer to takes benefits in ways such as training, and employment of community members or building a community facility.

What are the chances of making a discovery in a sample?

Generally the chances are very low and are about the same as winning a lottery: maybe one in a 100,000 samples or one in several 100,000 samples. It is important not to expect to make money every time.

Is successful bioprospecting like mineral prospecting?

No. With minerals the value can be determined at the beginning, with bioprospecting this will not be known for many years and may come to nothing.

Does bioprospecting take away anything from our land?

No. Apart from the very small samples, the land is untouched.

Is the Inquiry likely to recommend taking anything away from us?

No. The Inquiry has taken the view that Indigenous landowners and holders of traditional knowledge in Commonwealth areas have rights which must be respected. These include the right to grant or refuse entry to their land to bioprospect. The right to decide the conditions under which any bioprospecting may take place and to agree on the level of benefits to be paid by the bioprospector to the community.

The Inquiry is considering that this may be achieved by empowering the community to negotiate a benefit-sharing agreement with a bioprospector if they wish. In addition, a bioprospector would be obliged to apply to the Minister for a permit. This would only be granted if the Minister was satisfied that the agreement with the community was fair and the environment would not be harmed and that the community also agreed.

Does bioprospecting affect the way we use our land?

No matter what is found, the community continues to use its land as it wishes. The Inquiry considers there should be no doubt about this point and is likely to recommend that this be made clear in the new law.

Can communities supervise the access and sampling?

Yes. The Inquiry considers that any agreement made by the community should determine who can be involved, when they may come, where they may go and how the community should be advised of the results of the work. These are matters to be under the control of the owners.

Some communities may require that the bioprospector must be accompanied by a member of the community at all times. The Inquiry believes that the landowner has the right to make these conditions.

Could we expect to receive more money for the use of our traditional knowledge?

Yes, the Inquiry believes that, if a community chooses to make it easier for a company to find particular plants or chooses to tell it of the uses of particular plants or animals, the company benefits and should pay more.

Could a community expect to be paid more for samples where there is traditional knowledge about the sample which they did not share with the bioprospector?

No. The Inquiry believes it would only be fair to pay a community extra for use of traditional knowledge if the community chooses to share that knowledge.

How could our traditional knowledge be protected?

The Inquiry has in mind that special conditions be included in any agreement between a company and the community to ensure that knowledge used is valued, respected and properly recognised according to the wishes of the community. Further use of that knowledge by another party would require the community's approval.

Would there be any obligation to provide our traditional knowledge?

No. The Inquiry believes the traditional knowledge of a community belongs to the community and no-one can take it away. Only the holders of the knowledge can decide when it should be shared.

How would we know that any agreement we reached was fair?

The Inquiry is considering recommending that Indigenous communities receive independent legal advice and that the basis of any agreement must be a contract that everyone agrees is fair and protects the interests of all parties to the agreement. A community will always retain the right to say 'no' if they don't like an agreement.

In addition, the Inquiry is likely to recommend that a permit for access only be granted if the Minister is satisfied that a fair agreement has been reached and neither the land nor its people would be harmed in any way.

How would we know if a company is straight with us?

The Inquiry has considered this problem. The Inquiry believes it is important the community approached be given all the information it needs to make a fully informed decision. This is principle is sometimes referred to as 'informed prior consent'.

It is likely that the Inquiry will recommend the new law will make it a permit approval condition that the applicant has provided the community with all the information it may need to make a fully informed decision. If a company fails to be straight with the community, it would not be granted a permit.

This would be in addition to the community having access to independent legal advice and agreements being based on agreed fair contracts.

What would happen if a company breaks its agreement with us?

The Inquiry has in mind that if the agreement is broken the Minister would take away the permit. The community could then require the company to leave and may choose to take legal action.

What could we do if the Minister would not issue a permit after we have reached an agreement with a bioprospector?

The Inquiry has formed the view that in this situation the community or the company could ask the Minister to reconsider the decision. If the Minister still did not issue the permit the matter could be taken to the Administrative Appeals Tribunal for a ruling.

Further Questions

The community may have more questions. If so please do not hesitate to contact the Secretariat of the Inquiry for answers or explanations. We are happy to talk to owners or their representatives at any time.

For further information about the inquiry contact:

The Director
Access Taskforce
Environment Australia
GPO Box 787
CANBERRA ACT 2601

Phone 02 6274 2528
Fax: 02 6274 2723
Email: geoff.burton@ea.gov.au

Geoff Burton: Inquiry Executive Officer
June 2000

Appendix 12: Legal and Constitutional Framework of Australia's Marine Areas

This appendix is from Environment Australia 1998, Australia's Oceans Policy, Environment Australia, Canberra; Appendix 2. Electronic copies are available at http://www.environment.gov.au/net/oceanspo.html.

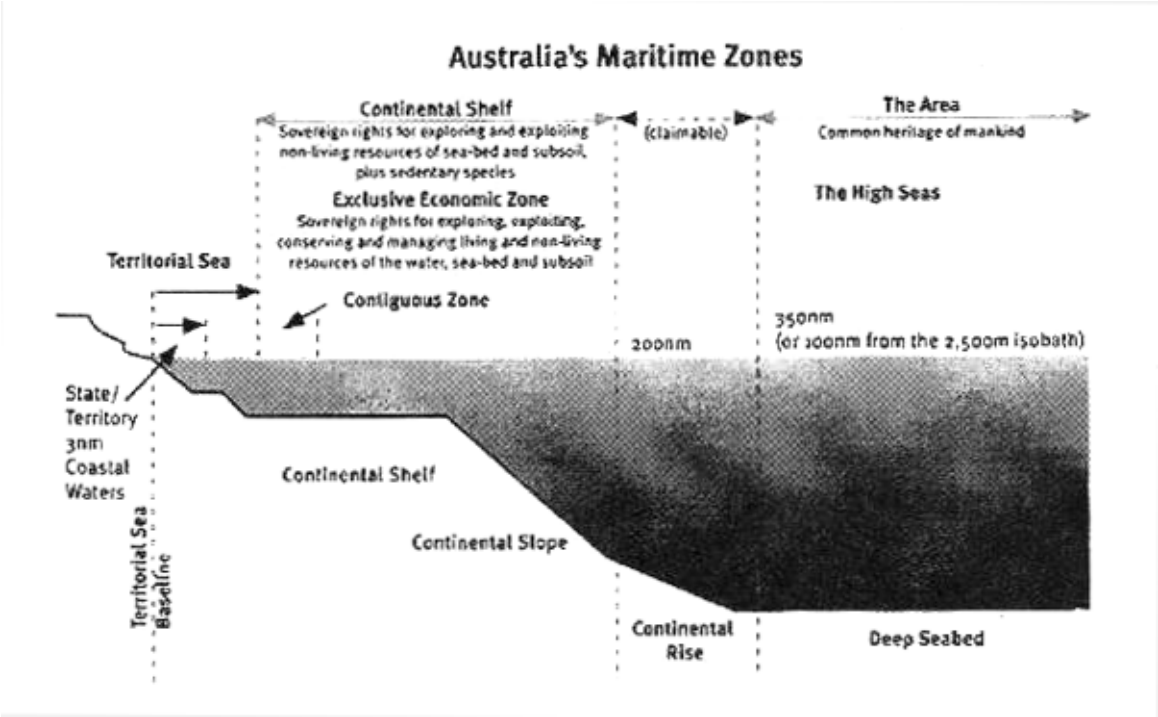
Maritime zones

Consistent with the provisions of international law, Australia has declared a range of maritime zones under the Seas and Submerged Lands Act 1973. The outer limits of all of these zones are measured from the territorial sea baseline, located for the most part at the low-water line along the coast. However, it also consists of bay and river closing lines and some straight baselines between the mainland and adjacent islands and across parts of the coast that are deeply indented.

The zones, which are measured both from mainland Australia and from islands forming part of Australia, including the external Territories, are as follows:

> **The territorial sea** -The outer limit of the territorial sea is 12 nautical miles (nm) seaward of the baseline. Australia has sovereignty over the territorial waters. It may therefore impose comprehensive controls in this area, with the one major exception that it must respect the right of innocent passage of foreign vessels.
>
> **The contiguous zone** -This is the area between 12 nautical miles and 24 nautical miles seaward of the baseline. In the contiguous zone, Australia can take limited enforcement measures in relation to customs, fiscal, sanitary and immigration matters.
>
> **The Exclusive Economic Zone** -This is the area between the lines 12 nautical miles and 200 nautical miles seaward of the territorial sea baselines. In this area Australia has the right to explore and exploit living and non-living resources, and the concomitant obligation to protect and conserve the marine environment.
>
> **The continental shelf -** The area between 12 nautical miles and 200 nautical miles seaward of the territorial sea baseline (that is, it covers much of the same area as the Exclusive Economic Zone) and any areas of physical continental shelf beyond 200 nautical miles. Australia has the right to explore and exploit the living and non-living resources of the shelf. A diagram of our maritime zones is [below].

An Australian Fishing Zone (AFZ) was declared in 1979 and is now under the Fisheries Management Act 1991. The zone is the area of waters between three nautical miles and 200 nautical miles seaward of the baselines. Waters off the Australian Antarctic Territory were excepted from the AFZ in 1979 for foreign and national vessels. These waters are regulated in accordance with the Convention on the Conservation of Antarctic Marine Living Resources (CCAMLR).



The Offshore Constitutional Settlement

In the early 1970s the States challenged the Commonwealth's assertion of sovereignty under the Seas and Submerged Lands Act 1973 over the then three nautical mile territorial sea.The High Court upheld the Commonwealth's assertion of sovereignty in the Seas and Submerged Lands Case.The Commonwealth and the States subsequently came to a series of arrangements collectively known as the Offshore Constitutional Settlement (the OCS).The purpose of the OCS was to give the States a greater legal and administrative role in offshore areas.The principle legislation implementing the OCS (Coastal Water States,Power and Title Act 1982)entered into force in February 1983.

There are two fundamental elements underpinning the OCS arrangements.First,the States and the Northern Territory were given title to an area called 'coastal waters' consisting of all waters landward of the three nautical mile limit but not including internal waters that are within the constitutional limits of a State;for example,Sydney Harbour.Second,the States and the Northern Territory were given concurrent legislative power over coastal waters;that is,they were given the same power to legislate over coastal waters as they would have over their land territory.The legislation implementing the OCS made it clear that should the territorial sea subsequently be extended from three nautical miles to 12 nautical miles the OCS arrangements would continue to apply only to the three nautical miles limit.In 1990 the territorial sea was extended to the 12 nautical miles limit,but the relevant limit for the purposes of the OCS remains at the three nautical miles.

In effect,through the OCS,the Commonwealth agreed to give the States primary responsibility over coastal waters (out to three nautical miles).Beyond that the Commonwealth retains primary responsibility.The OCS also included a number of cooperative arrangements for the management of resources offshore,such as fisheries and petroleum.These cooperative arrangements are reflected in the relevant Commonwealth,State and Northern Territory legislation.

Examples of such arrangements are those entered into under the Fisheries Management Act 1991 to enable a fishery both within and outside State coastal waters to be managed by one authority (State or Commonwealth) under one law (State or Commonwealth).

Constitutional power

A range of constitutional powers enable the Commonwealth Parliament to pass laws relating to the oceans and their management. These include: Commonwealth powers over trade and commerce, external affairs, corporations, defence, fisheries, territories and quarantine. A number of aspects of the external affairs power are relevant, but principally that aspect that allows the Commonwealth to legislate with respect to matters physically external to Australia, that is, beyond low water mark. The Commonwealth can also legislate under the external affairs power to give effect to treaties, matters of international concern and matters affecting Australia's relations with other countries.

As noted, the States and the Northern Territory were given power to legislate over coastal waters as part of the OCS. After implementation of the OCS in 1983, however, the High Court held that the general power of each State to make laws for the 'peace, order and good government' of the State enables each State to legislate in relation to its adjacent maritime area, provided there exists a reasonable connection between the State and the activity covered by the legislation.

This means that the extension of State legislative powers to coastal waters as part of the OCS is now largely redundant.

The OCS does not prevent either the Commonwealth or the States from exercising their full legislative powers in the offshore area. However, the practice largely has been to exercise those powers in a manner consistent with the OCS. Nevertheless, if there is a conflict between State and Commonwealth laws applying to the maritime area then, in accordance with section 109 of the Constitution, the Commonwealth law would prevail. The State law would be invalid to the extent of the inconsistency.

Appendix 13: Scientific Transactions

Wildlife Trade

Advice on Australian wildlife trade controls under the *Wildlife Protection (Regulation of Exports and Imports) Act 1982*

Information Sheet No 5
Revised January 2000

SCIENTIFIC TRANSACTIONS

About Wildlife Import and Export Controls

The *Wildlife Protection (Regulation of Exports and Imports) Act 1982* (the Act) is the legislative basis for conservation-orientated controls on the export and import of wildlife and wildlife products. Controls under this Act apply to transactions undertaken by museums, zoos, scientific organisations, commercial organisations, tourists, migrants and the general public.

The Act controls the export of most Australian native animals and plants and fulfils Australia's legislative requirements as a signatory to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

The Act regulates the importation of most live animals and plants. These controls are in addition to those exercised under the *Quarantine Act 1908*.

Scientific Transactions

The import or export of specimens for scientific purposes may be approved if:

- specimens are being exchanged between two organisations entered on the 'register of scientific organisations' (Facilitated Scientific Exchange System); or

- the specimens are for use by an organisation which has been declared a 'prescribed scientific organisation' for the specific research project they intend to undertake.

Facilitated Scientific Exchange System

The Facilitated Scientific Exchange System (FSES) enables the non-commercial loan, donation or exchange of herbarium specimens, other preserved, dried or embedded museum specimens, and live plant material between organisations where both parties have been entered by Environment Australia on the 'register of scientific organisations' as defined by Regulation 10 of the Act (see page 4 for copy of Regulation 10). **Live animals cannot be exchanged** under the FSES.

Australian organisations, such as museums or herbaria, wishing to participate in this system must apply for registration with Environment Australia (form R4). The organisation will also need to apply for an authority to export or import wildlife specimens.

Overseas organisations wishing to receive preserved specimens and/or live plants of Australian native species not listed on Schedules 1, 2 or 3 of the Wildlife Protection Act must also register with Environment Australia (form R4). If they wish to receive or send preserved specimens or live plants listed on Schedule 1, 2 or 3 of the Wildlife Protection Act they will also need to be registered with the CITES Management authority in their own country.

Exports under the FSES

Environment Australia will supply the holder of an authority with labels which are held by a nominated officer in the organisation. These labels are in effect a permit and must be attached to each package containing the specimens. There are two types of labels issued for facilitated exchange:

- MC labels are to be used where the specimens are of species from Australia or overseas listed on Schedules 1, 2 or 3 of the Act.

- MN labels are to be used only for Australian native specimens not listed on Schedules 1, 2 or 3 of the Act.

A record of all labels used must be kept by the organisation and be made available for review by Environment Australia when requested.

Imports under the FSES

An authority issued by Environment Australia is required by the Australian organisation importing CITES specimens from an overseas organisation registered with the CITES Management authority in their own country. In these cases, the overseas organisation is responsible for supplying the details of the specimens on their own certificates/labels. As for exports, details of such imports must also be recorded by the Australian organisation and made available for review by Environment Australia.

Please note: Overseas registered scientific organisations which have been included in the Environment Australia Register and whose code number end in 'A' are not permitted under the Act to be involved in exchange of specimens listed on the Schedules 1, 2 or 3 of the Act. Schedule 3 lists all cetaceans. Schedules 1 and 2 comprised the following categories:

Schedule 1: Appendix 1 to CITES - except cetaceans;

- elephants and elephant products;

- species listed on the Schedules to the Endangered Species Protection Act 1992; and
- birds listed in the Agreement between the Government of Australia and the Government of Japan for the protection of Migratory Birds and Birds in Danger of Extinction and the Environment.

Schedule 2: Appendix II to CITES - except cetaceans and elephants.

Prescribed Scientific Research System

The Wildlife Protection Act provides for permits to be issued for the import or export of specimens for the purpose of specific scientific research by an organisation which is defined in the Act as a 'prescribed scientific organisation'. The criteria for defining a 'prescribed scientific organisation' are specified in Regulation 3 of the Wildlife Protection Act (see page 5 for copy of Regulation 3).

Organisations must apply to become prescribed scientific organisations using form R3. The head of the organisation should endorse the form and proposed research (a précis of the proposed research should be attached).

Once an organisation has been approved for the specific research, the organisation is eligible to apply for permits to export or import specimens. Where the same organisation wishes to carry out different research for protected wildlife, it will need to be approved for that particular research. For example, although an organisation has been previously approved to carry out research on Australian mammals, the same organisation will need to be approved to undertake research on Australian birds.

In addition to satisfying the requirements of Regulation 3, the recipient of live vertebrate species must be able to show that the facilities and personnel in the organisation can care for, and confine the species. Photographs and plans of the facilities which are intended to hold the animals should be provided, together with details of their care. Organisations wishing to hold live vertebrates, CITES-listed invertebrates or non-native invertebrates in Australia, need to apply to become approved institutions (form R1).

In the cases of the export of native specimens, an export permit cannot be issued until it has been established that the specimens were obtained legally and that the relevant Australian State and Territory laws have been complied with before the export is approved. Therefore, it may be easier if an Australian organisation applies for the permit on behalf of the overseas organisation.

Permit Applications

An Australian permit must be issued prior to the consignment of the specimens. Application forms are available from Environment Australia.

Please note: failure to obtain an Australian permit prior to consignment of the specimens may result in confiscation. Severe penalties exist for persons or companies breaching the Environment Australia Act.

Fees

Fees can be paid by credit card, cheque or money order and should be made payable to the 'Collector of Public Monies'. Please note: overseas organisations must pay in Australian dollars.

- fee for a permit - $30
- fee for approval as an approved institutions (ie for keeping live animals) - $150
- fee for an authority - $150
- there are currently no fees for applications to be placed on the register of scientific organisations or to become a prescribed scientific organisations

Other Approvals

The import and export of wildlife and wildlife products may also be subject to controls administered under the Quarantine Act 1908. Information about quarantine matters may be obtained by contacting the Australian Quarantine and Inspection Service (AQIS), GPO Box 858, Canberra ACT 2601, phone 02 6272 3933 or visit their web site at:www.aqis.gov.au.

The information above is subject to change in order to reflect changes to the Wildlife Protection (Regulation of Exports and Imports) Act 1982 and to meet Australia's commitment to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

Which system should I use?

The following examples have been selected to highlight some of the cases in which the Facilitated Scientific Exchange System (FSES) or the prescribed scientific research can be used. Where there is any doubt about the controls under the Wildlife Protection Act, the organisation should contact Environment Australia before the proposed export or import takes place.

Case 1: An Australian ornithologist wants to send study skins of several species of parrots to an overseas museum who will return the skins after six months.

Comments: This transaction could take place under the Facilitated Scientific Exchange System, provided the Australian organisation is registered with Environment Australia and the overseas organisation is registered with its CITES Management Authority. As parrots are listed under CITES, the package will need to have the Wildlife Protection Act MC Labels attached. On return of the skins from overseas, the package will need to have that country's CITES labels attached.

Case 2: A researcher at an Australian museum wants to import live frogs for research purposes.

Comments: As this import involved live animals, it cannot take place under the Facilitated Scientific Exchange System. Before an import permit can be issued, the place where the animals will be held will need to be gazetted as an approved organisation to hold and care for that species. The organisation will be also need to be approved as a prescribed scientific organisation for the research. An import permit must also be obtained for each consignment.

Case 3: A researcher from Germany wants to export blood samples taken from platypus for research purposes.

Comments: This export can only occur as prescribed scientific research. The receiving (overseas) organisation needs to apply, using the R3 form, to become approved as a prescribed scientific organisation for that particular research. An export permit must also be obtained for each consignment of blood.

Case 4: An overseas zoological and botanical garden wants to collect and export live Australian insects to augment an Australian flora and fauna public display.

Comments: This export can occur as prescribed scientific research, as the definition of prescribed scientific research includes public education programs. The receiving (overseas) organisation needs to apply, using the R3 form, to become approved as a prescribed scientific organisation for that particular education program. A State or Territory collection permit will also need to be obtained. An export permit must be obtained for each consignment.

For Further Information Please Contact

The Director
Wildlife Protection
Environment Australia
GPO BOX 787
CANBERRA ACT 2601

Telephone: 02 6274 2291 Facsimile 02 6274 1921
email: wps@ea.gov.au

ACRONYMS

AFZ	Australian Fishing Zone
ANZECC	Australian and New Zealand Environment and Conservation Council
AQIS	Australian Quarantine Inspection Service
ARA	Acacemic Research Agreement
ATSIC	Aboriginals and Torres Strait Islanders Commission
CCAMLR	Convention on the Conservation of Antarctic Marine Living Resources
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
COP	Conference of the Parties
CRA	Commercial Research Agreement
CSIRO	Commonwealth Scientific and Industrial Research Organisation
EEZ	Exclusive Economic Zone
EPBC Act	Environment Protection and Biodiversity Conservation Act 1999
FSES	Facilitated Scientific Exchange System
GBRMPA	Great Barrier Reef Marine Park Authority
ILO	International Labour Organization
MOU	Memorandum of Understanding
MTA	Material Transfer Agreement
OCS	Offshore Constitutional Settlement
PU	Penalty Unit
SSL Act	Seas and Submerged Lands Act
TRIPS	Trade Related Aspects of Intellectual Property
UPOV	International Union for the Protection of New Varieties of Plants
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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