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Statutory Review of the *Biodiscovery Act 2004* (Queensland)

The Hon Andrew Fraser MP
Treasurer and Minister for Employment and Economic Development

The Hon Kate Jones MP
Minister for Climate Change and Sustainability

19 October 2009

Dear Ministers

Review of the *Biodiscovery Act 2004* (Qld)

DLA Phillips Fox is pleased to submit its report on the review of the *Biodiscovery Act 2004* (Qld) (**the Act**) to you.

In summary, the submissions and roundtable discussions revealed that, whilst the Act is achieving its purpose, it would operate more efficiently if:

- some provisions of the Act are amended and relevant codes reviewed; and
- additional education was provided in respect of the Act and its operation.

The recommended changes arising from the review will improve the operation of the Act whilst ensuring that it continues to achieve its purpose. The recommendations are listed at pages 12 to 17 of this document.

We thank all those who took part in the review process, either by providing submissions or other information to us or by taking part in the public forums.

We recommend the report to you and your Ministerial colleagues.

Yours sincerely

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1 List of acronyms and abbreviations

Act	*Biodiscovery Act 2004* (Qld)
Andean Community	An intergovernmental agreement currently comprising of the South American countries of Bolivia, Columbia, Ecuador and Peru.
Bonn Guidelines	*Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilisation*
BSA	Benefit Sharing Agreement
CBD	Convention on Biological Diversity
Code of Ethics	*Queensland Biotechnology Code of Ethics*
Commonwealth Regulations	Chapter 8A *Environment Protection and Biodiversity Conservation Regulations 2000* (Cth)
Compliance Code	Compliance code for taking native biological material under a collection authority (Qld)
DEEDI	Department of Employment, Economic Development and Innovation
DERM	Department of Environment and Resource Management
ILUA	Indigenous Land Use Agreement
National Forum	National Forum on Biodiversity, Biodiscovery and Traditional Knowledge at the Shine Dome in Canberra on 14 September 2009
Nationally Consistent Approach	*Nationally Consistent Approach for Access to and Utilisation of Australia's Native Genetic and Biochemical Resources* (endorsed by 14 Commonwealth, State and Territory Ministers on 11 October 2002)
NT Act	*Biological Resources Act 2006* (NT)
Review	*Biodiscovery Act 2004* (Qld) Review Panel - DLA Phillips Fox
State	The State of Queensland
Working Group	United Nations Ad Hoc Open-ended Working Group on Access and Benefit Sharing

2 Executive Summary

Background

The *Biodiscovery Act 2004* (Qld) (**the Act**) commenced on 12 November 2004.

The Act provides for streamlined and sustainable access to the State's native biological resources for the purposes of biodiscovery whilst returning a fair and equitable benefit to the State, for the benefit of all Queenslanders.

The objectives are achieved through the provision of:

- a regulatory framework for taking and using native biological resources;
- a contractual framework for benefit sharing;
- a compliance code and collection protocols; and
- monitoring and enforcement provisions.

Section 121 of the Act required a review to be undertaken within five years of the commencement of section 121. The purpose of the review is to decide whether the provisions of the Act remain appropriate.

The Act requires the Minister to table a joint report about the outcome of the review in the Legislative Assembly as soon as practicable after finishing the review.

Conduct of the Review

The Review prepared an Issues List based on both the key issues raised in the submissions received in response to the Terms of Reference and from consideration of national and international developments in biodiscovery.

Public and stakeholder consultation was then carried out by way of roundtable discussions in Brisbane and Cairns as well as individual teleconferences and meetings with interested parties who were unable to attend the forums. The purpose of the roundtable discussions was to provide a forum for interested parties to raise issues and give their input on the operation and effect of the Act.

In undertaking the review and making the recommendations that follow, the Review considered the submissions received, the issues raised during the roundtable discussions, the practical operation of the Act to date, the operation of Acts in other jurisdictions, emerging trends and international developments in biodiscovery (and related areas of law such as native title) and a range of research reports and related literature.

Purpose of the Act

The Review found the policy objectives of the Act, as set out in sections 3 and 4, remain valid and the scope of the Act should be maintained. It found that most parties did not raise any concerns about the overall policy objectives and scope of the Act however noted that there

appears to be some confusion about the purpose of the Act which, consequently, has coloured some of the comments and issues raised in relation to the Act.

Private Land

In considering whether or not the Act should extend to private land, the Review received submissions which suggested that the Act be amended to include private land in accordance with the Nationally Consistent Approach. The Commonwealth Regulations and the NT Act currently extend to private land. The Review considered the rationale adopted by each jurisdiction, in particular, the need for legal certainty.

However, the Review noted that, under the NT Act, the government is not involved in negotiating BSAs over private land. The Review also considers that biodiscovery entities in Queensland have entered into their own BSAs with private landowners and concluded that the Act should not be amended to include private land. However, the Review recommends that the State provide some publicly available guidelines to assist parties to negotiate BSAs with private landowners.

Native Title

The Review noted that there have not been any native title developments which would require an amendment to the definition of State Land under the Act. The Review considered that the Act should continue to exclude land in respect of which there has been a determination of exclusive possession.

Since the commencement of the Act, ILUAs have been negotiated in respect of land in Queensland which is high in biodiversity. The Review determined that these ILUAs did not necessitate any amendment to the definition of State Land under the Act. This is because the land covered by the ILUAs do not per se amount to a determination of exclusive possession. However, some ILUAs also cover land in respect of which a determination of exclusive possession has been made. With the exception of land which is the subject of a determination of exclusive possession (and also covered by an ILUA), other land covered by an ILUA will fall within the scope of the Act.

The Review concluded that should access be required in respect of land which is the subject of determination of exclusive possession the interested party may consider entering into an ILUA which would provide access to the relevant land (the subject of the ILUA). The Review has recommended an education process in respect of ILUAs and notification process be specifically included in the Compliance Code in respect of land which is known to be occupied by indigenous people.

Genetic Resources

The issue of ownership of genetic resources attracted little comment during the consultation phase of the Review. However, the Review considered approaches taken in other jurisdictions (in particular, international developments).

Overall, the Review concluded that the Act should not be amended in respect of the treatment of genetic resources.

Traditional Knowledge

In considering the issue of traditional knowledge, the Review noted the Nationally Consistent Approach and acknowledged that both the Commonwealth Regulations and the NT Act have legislated in respect of the indigenous and traditional knowledge.

However, comments made during the roundtable discussions suggested that adopting these approaches may create more confusion than certainty especially when more than one indigenous group may claim ownership of the traditional knowledge.

The Review considered this issue in detail. In doing so, the Review considered national frameworks to protect traditional knowledge. The Review concluded that the regime adopted for addressing the issue of traditional or indigenous knowledge in other jurisdictions does not seem sufficiently certain to justify the amendment of the Act in this way. Additionally, the Review considers this matter is adequately addressed in the Code of Ethics but recommends that the DERM consider including a similar provision in the Compliance Code.

International Developments

The Review noted that the United Nations has established a Working Group with a review to implementing an international regime on access and benefit sharing agreements. This is unlikely to be finalised for some time. However, progress should be monitored.

Definitions

It became apparent to the Review through the submissions and roundtable discussions that the definitions of *biodiscovery*, *biodiscovery research* and *commercialisation* in the Act are not sufficiently clear. The Review received suggestions in relation to the apparent inconsistency in Act between the relatively narrow definition of *biodiscovery research* and the intent of the broader definition of *commercialisation* as it relates to *biodiscovery*. Overall, the Review recommends adopting a new definition of *biodiscovery research* which removes the reference to *commercialisation.* The Review considered this would enhance the certainty of the Act.

With respect to the definition of *commercialisation*, research institutions and universities consistently raised the concern of determining the point at which *biodiscovery research* becomes *commercialisation*. This issue was discussed in the context of the background of section 54(3) of the Act which exempts educational institutions from entering into BSAs it relation to activities which are not commercial. The Review noted that many educational institutions receive benefits by way of milestone payments or research funding. The Review recommended the Act be amended to clarify what is meant by a 'gain' - the definition should refer to the actual receipt of monies, including but not limited to, licence fees, royalties or milestones. However, it must exclude private research grants.

Act achieving its Purpose

The Review considers the purpose of the Act is being achieved and the regulatory framework of the Act is appropriate, and therefore should not be amended. In making this recommendation, the Review considered all the Terms of Reference and made an assessment based on the conclusions and recommendations set out in the report.

Some parties, who did not carry on biodiscovery activities under the Act, questioned whether the Act was achieving its purpose or whether it was simply a 'feel good' piece of legislation. The Review considers that some parties' confusion about the purpose of the Act has coloured comments about whether or not the Act is achieving its purpose.

It should be noted that the Review received positive comments about the operation of the Act from those stakeholders who regularly undertake biodiscovery in accordance with the Act. In particular, they informed the Review that they had received positive feedback from international pharmaceutical companies which indicated that arrangements undertaken under the auspices of the Act provided certainty and a sound basis for the investment of funds into continuing research.

Operation of the Act

Collection Authorities

The Review received a number of submissions and comments during the round table discussions in respect of collection authorities. It was clear that clarification was required as to whether a party acquiring samples from another party (that has collected them pursuant to a collection authority) is required to obtain a collection authority (in addition to a BSA). It was determined that this clarification could be achieved through the use of Material Transfer Agreements which would document the transfer of samples of native biological material collected pursuant to a collection authority. This will also assist in evidencing a clear chain of title to the samples.

The Review heard that it would beneficial if information in relation to collection authorities was provided in a publicly accessible online format. This would allow parties to ensure that the appropriate collection authority is obtained and the permitting system under the Act is being followed. To promote transparency and pursuant to the powers under the Act, the Review recommends that the publicly available part of the collection authority register be converted into a publicly available online format.

It was submitted to the Review that the Queensland Museum would prefer to obtain collection authorities under the Act (as they are required to do under the Commonwealth Regulations) to assist it in marketing its collection of samples which may be acquired by other organisations. The Review recommends that the Queensland Museum be able to apply for and hold a collection authority. Furthermore, for consistency, the Review this approach may also be adopted in relation to the Queensland Herbarium. As a matter of policy, these organisations may not be required to enter into BSAs as they represent the State.

Labelling and Samples

The Review was informed that there is an ongoing issue of initial labelling of biological material used for biodiscovery and subsequent relabelling of downstream products. As such, identification of end products can become more difficult and eventually impossible when derivatives are developed.

It was also suggested that further guidance is needed in relation to storing samples. The Review concluded that the issues in respect of labelling and storage of samples be considered as part of the review of the Compliance Code.

The Review was also informed that the terms used in the Act in respect of storage for microorganisms or microbes are vague or silent and that no repository for microorganisms exists in the State.

This means the State is potentially compromising any benefits which may be received from development of those microorganisms or microbes in the biodiscovery industry. The Review recommends that the State should consider establishing a microorganism and microbe repository.

Benefit Sharing Agreements

The Review received a number of submissions and comments during the roundtable discussions in relation to BSAs. In particular, some comments made were contrary to the requirement of paying royalties to the State.

The model BSA was also criticised during the roundtable discussions. In particular, it was noted that it was one sided and not suited to all situations. The Review considers the model BSA is intended to represent the starting point of discussions with the State. Furthermore, the Review has determined that in light of the ever changing landscape of the biodiscovery industry, it is appropriate for the State to negotiate the BSAs on a case by case basis with each biodiscovery entity.

Educational and training institutions (including universities)

Comments were also made during the roundtable discussions in relation to when researchers should be required to enter into a BSA.

The Review was informed that the issue of whether and when educational and training institutions (including universities) are required to enter into a BSA is not clearly stated in the Act. Therefore, the Review considers that the exclusion of educational and training institutions from the requirement to enter into a BSA circumstances set out in section 54(3) could be more clearly restated earlier in the Act.

Additionally, the Review concluded that a positive obligation should be placed on educational and training institutions to enter into BSAs when the institution becomes aware that the relevant native biological material is being used for *commercialisation.* Furthermore, the Review was informed it would not be practical for each researcher to enter into an individual BSA with the State and therefore recommends that each institution enter into a head BSA with the State.

Concerns have also been expressed to the Review in relation to research where the initial investigation was purely scientific in nature (and a collection authority was not required) but subsequently turned commercial. In these circumstances, a BSA will be required and a collection authority may also be required to keep any of the relevant native biological material. The Review recommends that this be incorporated into a new section within the Act.

Enforcement

The Review considered the Terms of Reference as a whole and the few comments that were made during the roundtable discussions in respect of enforcement of compliance with the Act. Overall, the Review concluded that the provisions in the Act dealing with enforcement of compliance are appropriate and should not be amended.

Regulatory Burden

Costs compared to Benefits

The Review did not receive many submissions or comments during the roundtable discussions. On the other hand, the Review received information that some groups felt the Act has an unnecessary red-tape burden and on the other hand there were those which considered that the costs are appropriate in the context of the levels of certainty and commercial advantage provided by the compliance with the Act.

Overall, the Review considers the intention of the administrative and compliance system is directed towards achieving the purposes of the Act set out in section 3 and is therefore justified in its information requirements.

However, some organisations have also indicated that it the navigation of the collection authority regime under the Act (in the context of other permitting regimes) is quite difficult. Therefore, to reduce the administrative and compliance costs, the Review considers that biodiscovery entities would benefit from further education and clarification in relation to dealing with collection authorities and sample requirements under the Act.

Application Process and Regulatory Requirements

The Review found that the system of approvals and the application of regulatory requirements are appropriate to the level of risk and does not recommend that they be amended. However, the Review did receive some comments, during the roundtable discussions, from stakeholders who did not understand the permitting regime and that the requirement to enter BSA were too onerous. Therefore, the Review recommends that the State ensure that extra information in relation to the regime be publicly available. The Review considered that the State could accommodate the differing nature of biodiscovery entities through the BSA negotiations.

Interface with Other Systems

Commonwealth Regulations

The Review found that there is no regulatory overlap between the Act and the Commonwealth Regulations as they concern separate jurisdictions. However, in conducting a comparison, the Review noted that the Commonwealth Regulations apply to private land, consider traditional knowledge and provide a permitting process to regulate non-commercial research.

A comprehensive comparison of the relevant provisions of the Act and the Commonwealth Regulations appears at **Table 1**.

NT Act

Again, the Review found that this is no regulatory overlap between the Act and the NT Act as they concern separate jurisdictions. However, the Review compared the Act to the NT Act and noted that, like the Commonwealth Regulations, the NT Act applies to private land and includes a regime dealing with indigenous knowledge.

A comprehensive comparison of the relevant provisions of the Act and the NT Act appears at **Table 2**.

The Review does not recommend any harmonisation between the Act and any other acts or schemes at this stage (pending the review of and continued monitoring of the international regime and the legislation in other states of Australia).

Changing Circumstances

Consideration of Emerging Trends

Other than already addressed in the recommendations in this Report (specifically the proposed amendment to the definition of *biodiscovery research* described in Recommendation 3.8), the submissions and information received by the Review did not reveal any concerns that the Act would be inflexible in the face of emerging technologies.

In particular, it was submitted that the Act may not have fully considered the emergence of screening libraries, the increased trend for developing natural products, and the potential to use the native biological material in relation to:

- the use of raw materials and extracts in food;
- nutraceutical formulations;
- cosmetic ingredients;
- other consumer products; and even
- industrial applications.

It was generally accepted that any peculiarities in the nature of use of the native biological material (to the extent it impacts the benefit sharing regime) would be able to be addressed through the negotiation of an appropriate BSA between the relevant biodiscovery entity and the State.

With respect to the international context, the Review considered the developments in certain countries including the Andean Community, Canada, Costa Rica and South Africa. The Review found that Queensland and Australia are well advanced in their consideration of issues relating to access and benefit sharing. Furthermore, the Review did not consider that any of the international regimes necessitated any amendments to the Act.

However, the Review considered it appropriate that a further review date be set for the Act to ensure it continues to address international, national and industry developments.

3 List of Recommendations

Chapter 3: Purpose of the Act (Term of Reference 1)

Review the purposes of the Act to determine whether the policy objectives remain valid and consider other issues that may be included in the scope of the Act including:

(a) consideration of whether the ambit of the legislation should extend to private land and if so, options on how this would be achieved

(b) examination of how recent developments in native title determination granting rights of exclusive possession since the commencement of the Act impact on its application

(c) consideration of ownership of genetic resources

(d) consideration of developments internationally and re-examination of how traditional knowledge and ownership of genetic resources are considered

(e) the definitions in the Act, and the need for the definition of other terms.

Recommendation 3.1

The Review recommends that the policy objectives remain valid and the scope of the Act should be maintained.

Recommendation 3.2

The Review recommends that publicly available information (for example online) be provided which clearly states that the Act does not apply to private landowners and provides some guidelines of matters to be considered in negotiating access agreements with private landowners.

Recommendation 3.3

The Review recommends that publicly available information (for example online) be provided which provides direction as to the location and source of information in respect of negotiating access arrangements (ILUAs) in respect of land which is subject to a native title determination of exclusive possession.

Recommendation 3.4

The Review recommends an update to the Compliance Code so that notification is required to be provided to indigenous occupiers of land to advise when the land will be accessed pursuant to a collection authority issued in relation to that land (but only where contact details of the indigenous occupiers of the land are available).

Recommendation 3.5

The Review recommends that the State monitor the movement towards the development of a legal framework implemented to protect traditional and indigenous knowledge in Australia to determine whether any consequential amendments to the Act are required at that time.

Recommendation 3.6

The Review recommends that the DERM undertake a review of the 'Compliance code for taking native biological material under a collection authority' to consider including a provision addressing traditional knowledge to reflect the provision in the Queensland Biotechnology Code of Ethics.

Recommendation 3.7

The Review recommends that the movement towards the development of an international regime be closely monitored.

Recommendation 3.8

The Review recommends that the definition of biodiscovery research be amended to reflect the following revised definition.

'Biodiscovery Research means the:

- *identification, assessment, evaluation, research, testing or use of;*
- *research into*

native biological material associated with the commercialisation or intended commercialisation of the material. Biodiscovery research methods may include, but are not restricted to, analysis of molecular, biochemical or genetic information about native biological material'.

Recommendation 3.9

The Review recommends that paragraph (1) of the definition of 'commercialisation' be amended to clarify that that the reference to 'gain' in that definition is a reference to the actual receipt of monies including but not limited to licence fees, royalties or milestones.

Recommendation 3.10

The Review recommends that paragraph (2) of the definition of 'commercialisation' be amended to also exclude private research grants. The Review further recommends that consideration be given to ensuring this exclusion applies to grants received for genuine research purposes.

Chapter 4: Act achieving purposes (Term of Reference 2)

Investigate whether the purposes of the Act are being achieved and whether the regulatory framework stipulated in the Act is still appropriate.

Recommendation 4.1

The Review concluded that the object of the Act is being achieved and the principles of the regulatory framework stipulated in the Act should be maintained.

Chapter 5: Operation of the Act (Terms of Reference 3, 4 & 5)

1 Examine the structure and effectiveness of the permitting regime stipulated in Parts 3 and 4 of the Act.

2 Examine the structure and effectiveness of the contractual framework for benefit sharing agreements stipulated in Part 5 of the Act.

3 Determine whether the powers of the Act allow enforcement of compliance which is effective and appropriate to the circumstances.

Recommendation 5.1

The Review recommends that information be provided in relation to the use of Material Transfer Agreements. Material Transfer Agreements may be used in relation to the transfer of samples of native biological material (collected pursuant to a collection authority under the Act) to another party which intends to use those samples for biodiscovery (pursuant to the Act). The review recommends a copy of the signed Material Transfer Agreements be lodged with DEEDI once executed.

Recommendation 5.2

The Review recommends that the publicly available part of the collection authority register be converted into a publicly available online format.

Recommendation 5.3

The Review recommends the Queensland Museum and Queensland Herbarium be able to apply for and hold collection authorities under the Act.

Recommendation 5.4

The Review recommended that issues of labelling and storage of samples of material be considered as part of the review of the Compliance Code.

Recommendation 5.5

The Review recommends the State develop a policy position in relation to the samples required to be provided pursuant to Section 30 of the Act. If the improvement in scientific method or technologies necessitates a change in the way or nature of the information provided, the Review recommends the State consider implementing regulations to address this issue.

Recommendation 5.6

The Review recommends the State gives consideration and develops a policy position in relation to the length of time receiving parties under section 30 are required to retain samples provided under that section.

Recommendation 5.7

The Review recommends that the State investigate options for the storage of microorganisms and microbes. This may take the form of an independent repository.

Recommendation 5.8

The Review recommends section 54(3) of the Act in relation to educational and training institutions be deleted and restated as an exclusion to section 17 of the Act.

Recommendation 5.9

The Review recommends section 54(3) of the Act be redrafted to reflect the exclusion in section 17 of the Act (as per Recommendation 5.8).

Recommendation 5.10

The Review recommends a positive obligation be included in section 17 requiring educational and training institutions to enter a benefit sharing agreement within a reasonable time of becoming aware that they are engaging in commercialisation in relation to the relevant native biological material.

Recommendation 5.11

The Review recommends that the State adopt a policy pursuant to which educational and training institutions (including universities) enter into head benefit sharing agreements with the State. Subsequently researchers who are engaging in commercialisation of native biological material will enter addendums to the head benefit sharing agreement (setting out specific details including benefits, royalties etc) which incorporates the terms of the head benefit sharing agreement.

Recommendation 5.12

The Review recommends that a new section be included in the Act requiring biodiscovery entities to enter into benefit sharing agreements with the State in circumstances where native biological material has been collected under licences or permits in other acts but which, in light of commercialisation of the relevant material, should have been subject to the regulatory regime and framework set out in the Act.

Recommendation 5.13

The Review recommends section 54(2) of the Act (in relation to biodiscovery entities which engage other parties for fee for service work) be deleted and restated as an exclusion to section 17 of the Act.

Recommendation 5.14

The Review recommends section 54(2) of the Act be redrafted to reflect the exclusion in section 17 of the Act (as per Recommendation 5.12).

Recommendation 5.15

The Review does not recommend that the enforcement or compliance provisions of the Act be amended.

Chapter 6: Regulatory Burden (Terms of Reference 6 & 7)

4	Examine whether compliance and administrative costs, including information requirements, for biodiscovery entities are reasonable and justified compared to benefits achieved and possible alternatives to legislation.
5	Review the system of approvals and the application of regulatory requirements commensurate to the level of risk.

Recommendation 6.1

The Review recommends that additional information be publicly available online to simplify and provide directions in relation to collection authorities and the interaction between collection authorities under the Act and licences and authorities available under other legislation and regimes.

Recommendation 6.2

The Review recommends that the Compliance Code be reviewed to incorporate additional information about the samples to be deposited pursuant to section 30 of the Act and the impact on the deposit of those samples on the minimal quantity available for biodiscovery.

Recommendation 6.3

The Review does not recommend any amendments to the compliance and administrative costs under the Act.

Recommendation 6.4

The Review does not recommend any change to the regulatory requirements in the Act.

Chapter 7: Interface with other Systems (Term of Reference 8)

6	Examine the interface between the Act and other Acts and schemes (either Australian Government or State and Territory) that regulate biodiscovery. Identify any discrepancies including regulatory gaps and areas needing consistency and harmonisation of provisions.

Recommendation 7.1

The Review does not recommend any harmonisation between the Act and any other acts or schemes at this stage (pending the review of and continued monitoring of the movement towards an international regime and legislation in other states of Australia).

Chapter 8: Changing Circumstances (Terms of Reference 9 & 10)

7	Examine emerging trends and international developments in biodiscovery and its regulation and whether the regulatory system stipulated by the Act is flexible enough to accommodate changing circumstances.
8	Recommend amendments to the Act, or alternatives to legislation, which improve the effectiveness, fairness, timeliness and accessibility of the regulatory system.

Recommendation 8.1

The Review recommends that the Act be reviewed again, within five years, to accommodate emerging trends and international developments.

4 Chapter 1: Introduction and Terms of Reference

In July 2009, the Queensland Government issued the following Terms of Reference for the review:

The *Biodiscovery Act 2004* (Qld) (the Act) commenced by proclamation on 12 November 2004. The legislation provides streamlined, sustainable access to the State's native biological resources for the purposes of biodiscovery whilst returning a fair and equitable benefit to the State, for the benefit of all Queenslanders. These objectives are achieved through a regulatory framework for taking and using native biological resources, a contractual framework for benefit sharing, a compliance code and collection protocols, and monitoring and enforcement provisions. The Act fulfils Queensland's commitment to Article 15 of the international *Convention on Biological Diversity*, agreed to by Australia in 1993.

Section 121 of the Act stipulates that the Ministers responsible for administering the Act must review it within five years of the commencement of section 121 to decide whether its provisions remain appropriate. The Act requires the Ministers to table a joint report about the outcome of the review in the Legislative Assembly as soon as practicable after finishing the review.

The review of the *Biodiscovery Act 2004* (Qld) (the Act) must be completed by 12 November 2009.

Having particular regard to the experience of the first five years of the operation of the Act, and noting the object and regulatory framework set out in the Act, the following terms of reference for the review of the Act have been established:

Terms of Reference

Purpose of Act

1 Review the purposes of the Act to determine whether the policy objectives remain valid and consider other issues that may be included in the scope of the Act including:

(a) consideration of whether the ambit of the legislation should extend to private land and if so, options on how this would be achieved

(b) examination of how recent developments in native title determination granting rights of exclusive possession since the commencement of the Act impact on its application

(c) consideration of ownership of genetic resources

(d) consideration of developments internationally and re-examination of how traditional knowledge and ownership of genetic resources are considered

(e) the definitions in the Act, and the need for the definition of other terms.

Act achieving purposes

2 Investigate whether the purposes of the Act are being achieved and whether the regulatory framework stipulated in the Act is still appropriate.

Operation of the Act

3 Examine the structure and effectiveness of the permitting regime stipulated in Parts 3 and 4 of the Act.

4 Examine the structure and effectiveness of the contractual framework for benefit sharing agreements stipulated in Part 5 of the Act.

5 Determine whether the powers of the Act allow enforcement of compliance which is effective and appropriate to the circumstances.

Regulatory burden

6 Examine whether compliance and administrative costs, including information requirements, for biodiscovery entities are reasonable and justified compared to benefits achieved and possible alternatives to legislation.

7 Review the system of approvals and the application of regulatory requirements commensurate to the level of risk.

Interface with other systems

8 Examine the interface between the Act and other Acts and schemes (either Australian Government or State and Territory) that regulate biodiscovery. Identify any discrepancies including regulatory gaps and areas needing consistency and harmonisation of provisions.

Changing circumstances

9 Examine emerging trends and international developments in biodiscovery and its regulation and whether the regulatory system stipulated by the Act is flexible enough to accommodate changing circumstances.

Changes to the legislation

10 Recommend amendments to the Act, or alternatives to legislation, which improve the effectiveness, fairness, timeliness and accessibility of the regulatory system.

The reviewer will be required to consult with key interest groups and affected parties, receive submissions and take into account overseas experience.

Process

Call for Submissions

The Queensland Government released the Terms of Reference for the review and some background information on biodiscovery in Queensland when it made a call for submissions in August 2009.

The call for submissions was made using the following forums:

- www.industry.qld.gov.au;
- www.getinvolved.qld.gov.au;
- Email to a targeted list of stakeholders;
- The Courier Mail;
- The Australian;
- The Cairns Post;
- The Toowoomba Chronicle;
- The Townsville Bulletin; and
- The Rockhampton Morning Bulletin.

A total of seven written submissions were received. **Appendix 1** to this report provides details of the organisations and individuals who made written submissions.

Issues List

The Review analysed the submissions and identified a number of key issues that were raised in relation to the Act and the operation of biodiscovery in Queensland. The following Issues List was developed and was provided to each organisation and individual invited to attend a roundtable discussion:

Issues List for roundtable discussion

In addition to the issues raised in the Terms of Reference we have set out the following issues for your consideration before the roundtable discussions.

These issues will be used to generate discussion. There may also be other issues which you would like to discuss on the day.

As you are aware, the review of the Act is not designed to revisit issues which have previously been considered at a policy level before the legislation was passed. However, if there have been developments since 2004 when the Act was passed (including the way other legislation has addressed certain issues) that would improve the operation of this Act then we would welcome your comments in respect of those issues.

1	Do you think that the definition of '*biodiscovery*' is sufficiently clear? Do you think it requires further clarity including by providing specific examples?
2	Should the definition of 'biodiscovery research' cover the collection of a sample which is not subject to 'analysis of molecular, biochemical or genetic information about native biological material for the purpose of commercialising the material'?
3	Do you think these are issues which are covered in Commonwealth and Northern Territory legislation dealing with Biodiscovery which may improve the operation of the Act?
4	Are there any concerns or issues in relation to the collection authority regime under the Act? Specifically:
4.1	Does the process seem too onerous, regulated or restrictive?
4.2	Is the process unclear or confusing?
5	How will emerging scientific or commercial research trends be affected by the Act?
6	Will the Act encourage or restrict the research and develop of biodiscovery products in the future?
7	Are there any developments in the biodiscovery (within Australia or internationally) which should be reflected in the operation of the Act?

Roundtable Discussions

The Terms of Reference and the Issues List served as the basis for the roundtable discussions which took place in Brisbane and Cairns in September 2009.

Members of the public who provided written submissions and relevant stakeholders (identified as a result of their involvement in biodiscovery and biotechnology related activities) were invited to attend. In addition, those who were unable to attend a roundtable discussion, in either Brisbane or Cairns, were invited to participate in an individual discussion to give the opportunity for all relevant parties to be consulted.

A total of 14 stakeholders attended the roundtable discussions. **Appendix 2** to this report provides details of the individuals and organisations that participated in the roundtable discussions.

A total of 9 stakeholders participated in private consultations either in person or by way of a teleconference. **Appendix 3** to this report provides details of the individuals and organisations that participated in an individual discussion.

The Review also attended the National Forum on Biodiversity, Biodiscovery and Traditional Knowledge at the Shine Dome in Canberra on 14 September 2009 (**National Forum**). The purpose of attending the National Forum was to enable the Review to consider emerging trends in biodiversity, biodiscovery and traditional knowledge both nationally and internationally.

Matters Considered by the Review

The Review was satisfied that the public and stakeholder consultation undertaken prior to enacting the Act ensured that all relevant policy considerations were taken into account. Therefore, the Review only focused on issues which have emerged or charged since the passing of the Act as well as matters which have developed from the practical operation of the Act.

As such, the Review considered the following in reaching its recommendations:

- submissions in relation to the Terms of Reference;
- issues raised during roundtable and private discussions;
- the experience of the operation of the Act to date;
- the experience and operation of similar legislation enacted in other jurisdictions;
- practical operational issues that have arisen to date;
- changes in business practices in biodiscovery and biotechnology business since 2004 (including practical implications of the current economic condition) and emerging trends in biodiscovery;
- international developments in biodiscovery and its regulation; and
- reports and related literature.

Form of Recommendations

The Review has made specific recommendations in circumstances where the Review determined that changes were warranted and necessary. Issues have been addressed through recommendations only some of which require amendments to the Act.

Acknowledgements

The Review acknowledges the time, effort and assistance of those who made submissions and participated in the roundtable and private discussions.

The Review acknowledges the work undertaken and assistance provided by the Office of Biotechnology and Therapeutic Medicines and Devices, Department of Employment, Economic Development and Innovation.

5 Chapter 2: Background on Biodiscovery

What is Biodiscovery?

Biodiscovery involves the study of samples which have been taken from animals, plants or microbial life for the purpose of considering their genetic and biochemical make-up. Biodiscovery activities in Queensland are regulated by the Act.

The Schedule to the Act provides the following definitions of *biodiscovery*:

> ***biodiscovery*** means—
>
> (a) biodiscovery research; or
>
> (b) the commercialisation of native biological material or a product of biodiscovery research.
>
> ***biodiscovery research*** means the analysis of molecular, biochemical or genetic information about native biological material for the purpose of commercialising the material.

The definition of *biodiscovery* in the Act is discussed in detail in Chapter 3 of this document.

***Biodiscovery Act 2004* (Qld)**

The Act commenced on 12 November 2004.

The Act provides for streamlined and sustainable access to the State's native biological resources for the purposes of biodiscovery, whilst returning a fair and equitable benefit to the State for the benefit of all Queenslanders.

The objectives are achieved through the provision of:

- a regulatory framework for taking and using native biological resources;
- a contractual framework for benefit sharing;
- a compliance code and collection protocols; and
- monitoring and enforcement provisions.

The Act helps fulfil Queensland's commitment to Article 15 of the International Convention on Biological Diversity (**CBD**), ratified by Australia in June 1993.

The Act is Queensland's response to complying with the *Nationally Consistent Approach for Access to and Utilisation of Australia's Native Genetic and Biochemical Resources* (endorsed by 14 Commonwealth, State and Territory Ministers on 11 October 2002) (**Nationally Consistent Approach**).

The mechanisms above seek to provide legal certainty for both individuals and organisations undertaking biodiscovery while promoting benefit sharing in favour of the State. It was hoped

that the Act would encourage research and commercialisation using Queensland's rich biodiversity.

Coinciding with the commencement of the Act, the State developed a 'Compliance Code for Taking Native Biological Material under a Collection Authority' (**Compliance Code**) and a series of information sheets and guidelines which are aimed at assisting users of the Act with navigating the permitting regime established by the Act.

The Act provides that a biodiscovery plan (setting out proposed biodiscovery activities) must be submitted by applicants for a collection authority (as defined in the Act).

The use of material under the Act is governed by a Benefit Sharing Agreement (**BSA**) which is negotiated with the State. The BSAs are based on the world's best practice guidelines, the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilisation* (**Bonn Guidelines**).

The *Queensland Biotechnology Code of Ethics* (**Code of Ethics**) also sets out requirements for the ethical development of the biotechnology in Queensland. The Code of Ethics addresses the approach to dealing with traditional knowledge. Parties who have signed a BSA or received a government grant in respect of related activities are contractually bound to comply with the Code of Ethics.

The Department of Environment and Resource Management (**DERM**) also works with the Department of Employment, Economic Development and Innovation (**DEEDI**) to administer the Act. The DERM administers the issuing and regulation of collection authorities. This includes reviewing applications for collection authorities and implementing the Compliance Code.

Section 121 of the Act required a review to be undertaken within five years of the commencement of section 121. The purpose of the review is to decide whether the provisions of the Act remain appropriate.

The Act requires the Minister to table a joint report about the outcome of the review in the Legislative Assembly as soon as practicable after finishing the review.

6 Chapter 3: Scope of the Act

Term of Reference 1:

Review the purposes of the Act to determine whether the policy objectives remain valid and consider other issues that may be included in the scope of the Act including:

(a) consideration of whether the ambit of the legislation should extend to private land and if so, options on how this would be achieved

(b) examination of how recent developments in native title determination granting rights of exclusive possession since the commencement of the Act impact on its application

(c) consideration of ownership of genetic resources

(d) consideration of developments internationally and re-examination of how traditional knowledge and ownership of genetic resources are considered

(e) the definitions in the Act, and the need for the definition of other terms.

Purpose of the Act

The purposes of the Act are set out in section 3, which provides that:

(1) The main purposes of this Act are—

(a) to facilitate access by biodiscovery entities to minimal quantities of native biological resources on or in State land or Queensland waters (State native biological resources) for biodiscovery; and

(b) to encourage the development, in the State, of value added biodiscovery; and

(c) to ensure the State, for the benefit of all persons in the State, obtains a fair and equitable share in the benefits of biodiscovery; and

(d) to ensure biodiscovery enhances knowledge of the State's biological diversity, promoting conservation and sustainable use of native biological resources.

(2) The purposes are achieved mainly by providing for—

(a) the following streamlined frameworks—

(i) a regulatory framework for taking and using State native biological resources, in a sustainable way, for biodiscovery;

(ii) a contractual framework for benefit sharing agreements to be entered into with biodiscovery entities for the use, for biodiscovery, of State native biological resources; and

(b) a compliance code and collection protocols for taking native biological material; and

(c) the monitoring and enforcement of compliance with this Act.

The reasons why the Act was enacted are set out in section 4, which provides that:

> (1) The Commonwealth has ratified the 'Convention on Biological Diversity', the objects of which are—
>
> (a) the conservation of biological diversity; and
>
> (b) the sustainable use of its components; and
>
> (c) the fair and equitable sharing of benefits arising from the use of genetic resources.
>
> (2) The convention requires countries to develop and implement strategies for the conservation of biological diversity and the sustainable use of its components.
>
> (3) Article 15 of the convention recognises the sovereign rights of the States over their natural resources and the States' authority to decide access to genetic resources, including the fair and equitable sharing of benefits gained from the access.
>
> (4) This Act enacts, as part of Queensland's law, provisions to give effect to Article 15 of the convention to the extent it concerns native biological resources in Queensland.

Subject to comments set out below, the roundtable and private discussions, and the majority of the submissions, did not raise any issues about the overall purposes of the Act and whether or not the policy objectives remain valid.

However, a submission was received which raised concerns that neither ecological sustainability nor biodiversity conservation were expressed to be a central purpose of the Act.

It was argued that it was important to include these objectives within the purpose of the Act because they are the objectives of the CBD which was ratified by the Commonwealth of Australia. Furthermore, whilst acknowledging that the objectives of the CBD are stated in section 4 of the Act, it was argued that the failure to include these objectives in the purposes of the Act meant that the Act did not develop and implement strategies for the conservation of biological diversity and the sustainable use of its components.

The Review considers the purposes of the Act and the Compliance Code adequately address the issues of conservation and sustainability. The Review notes that there are there are other specific acts which are designed to address these particular issues (for example the *Nature Conservation Act 1992* (Qld)). The Review concludes that the intention of the Act was to ensure the activities permitted under the framework of the Act were not contrary to conservation and sustainability. Subject to the comments below, the Review considers this has been achieved through the *minimal quantity* regime which is a requirement of the Act and administered by the DERM through the Compliance Code.

The Review also notes that there appears to be some confusion about the purpose of the Act which has coloured some of the comments and issues raised in relation to the Act. An example of this misunderstanding is the comment in relation to *minimal quantities* described below.

The roundtable and private discussions and some submissions, raised the issue of facilitating access to *minimal quantities* of native biological resources. In particular, it was argued that

there may be a difference between *minimal quantities* and those which are ecologically sustainable.

On the other hand, it was argued that the Act did not allow for sufficient quantities of material to be collected in order to develop some products. Furthermore, it was argued that the Act is too prescriptive in that it does not allow for large quantities of material to be collected even when large quantities are available and collection will not have any detrimental impact on biodiversity.

The Review also considered the importance of the Nationally Consistent Approach and noted that this was generally consistent with the overall objectives of this Act.

The Review considered whether there was any basis for concluding that the purposes of the Act were not being met, and that the policy objectives were invalid.

On balance, the Review concluded that the purposes of the Act should not be amended as the objectives of the CBD are included within section 4, and have therefore been considered throughout the sections which regulate biodiscovery and set out in the Act.

The Review also determined that in light of the administration of the Compliance Code and the recommendations later in this review in relation to education, the consideration of *minimal quantities* in the context of ecological sustainability is appropriate for the scope of the Act.

> ***Recommendation 3.1: The Review recommends that the policy objectives remain valid and the scope of the Act should be maintained.***

Consideration of whether the Act should extend to private land

This issue was raised during the submission and discussion process.

In particular, it was submitted that the Review should consider the possible extension of the Act's application to private land. It was noted that the Commonwealth Regulations extend to private land, including land owned by indigenous people. Furthermore, it was submitted that the extension of the Act to private land would ensure a consistent regulatory approach across different tenures which in turn provides researchers with legal certainty and may also reduce transaction costs by standardising access requirements.

The Review evaluated the approach taken by the NT Act and discussed the practical effects of the NT Act during the public consultation process. The NT Act regulates access to both State and private land. The practical implications for freehold land is that the party seeking access is required to negotiate directly with the land owner who may provide access under the NT Act. The parties then notify the Northern Territory Government that an agreement has been reached. The Department administering the NT Act is not involved in the negotiations of private BSAs under the legislation but confirms that informed consent of the private land owner has been given to the terms of a BSA. Furthermore, private land owners may approach the Government for direction in respect of the BSAs.

The rationale for including private land under the NT Act was to provide certainty to all parties. The Review was advised that the Northern Territory Government has not received any negative feedback in relation to its regulation of access to private land.

In considering the issue of access to private land being regulated by the Act, the Review examined the Commonwealth's *Prime Minister's Science Engineering and Innovation Council 'Biodiscovery' Paper (2 December 2005)* which highlighted the need to achieve legal certainty in order to assist in achieving commercialisation of biodiscovery.

As described above, the NT Act has sought to achieve legal certainty by providing a framework for regulating access to private land. The Act did not take this approach. The Review was requested to consider whether the scope of the Act should be extended to include private land. This would also necessarily require an amendment to Section 3 of the Act.

In considering whether the Act should be extended to private land, the Review also noted that some companies have entered into their own BSAs with private landowners. For example, one biodiscovery entity has negotiated BSAs with private landowners to provide certainty of access and regulate the sharing of benefits derived from samples obtained from that private land.

The Review notes that clearing permits issued by the DERM in relation to 'protected plants' under the *Nature Conservation Act 1992* (Qld) requires the approval of the landowner. Although the permit may apply to private land, a condition of the permit is that the approval of the landowner has been obtained. The Review considered whether this sort of regime could be adopted in the Act - for example, extending collection authorities issued under the Act to private landowners but only with the approval of the landowner. The Review considered this would be cumbersome and would not provide any additional certainty to the collection authority regime. Rather, it is likely to cause more confusion with the need to obtain approvals from landowners before any such permits could be issued.

The requirement for certainty in relation to access to land for the purposes of biodiscovery does not need to be achieved through extending the application of the Act to private land. The Review determined that sufficient certainty could be achieved through the implementation of an education process and the availability of information to interested parties as to what steps can be taken to secure access to private land.

The conclusion drawn by the Review was that the Act should not be amended to encompass private land. In light of the recommendation below, the Review found no compelling case for extension. In making this recommendation the Review notes that the policy decision made at the time of passing the Act (which determined that private land should not be covered by the Act) remains valid.

> ***Recommendation 3.2: The Review recommends that publicly available information (for example online) be provided which clearly states that the Act does not apply to private landowners and provides some guidelines of matters to be considered in negotiating access agreements with private landowners.***

Impact of recent developments in Native Title law

The *Native Title Act 1993* (Cth) was amended in 2007 by the *Native Title Amendment Act 2007* (Cth) and the *Native Title Amendment (Technical Amendments) Act 2007* (Cth) (**2007 Acts**).

In 2009, the *Native Title Act 1993* (Cth) was further amended in 2009 by the *Native Title Amendment Act* 2009 (Cth) (**2009 Act**) which was given Royal Assent on 17 September 2009 and commenced on 18 September 2009.

The Review has considered the amendments enacted by the 2007 Acts and the 2009 Act. The amendments in these amending acts do not impact the Act nor the administrative or regulatory regime under it.

The Review concluded that no consequential amendments to the Act are required as a result of 2007 Acts and the 2009 Act.

The Review also considered the *Cape York Peninsula Heritage Act 2007* (Qld) and *Aboriginal Land Act 1991* (Qld).

Research conducted by the Review in relation to the *Aboriginal Land Act 1991* (Qld) did not reveal any change in the legal position since the time the Act was passed.

The research conducted by the Review in relation to the *Cape York Peninsula Heritage Act 2007* (Qld) confirms the creation of the 'national park (Cape York Peninsula Aboriginal land)' is consistent with the *Aboriginal Land Act 1991* (Qld).

The Review concluded that no change was required to the Act in light of the *Aboriginal Land Act 1991*(Qld) and the *Cape York Peninsula Heritage Act 2007* (Qld).The Review notes that the definition of *State Land* in the Act excludes *'land subject to a native title determination of exclusive possession'*.

The Review was not informed by stakeholders as to the interaction between the Act and the native title regime established by the *Native Title Act 1993* (Cth). The Review did not receive any submissions requesting amendments to the definition of *State Land* in the Act. Consequently, the Review concluded the public view was that the existing definition of *State Land* in the Act remained valid and appropriate for the Act.

The Review has determined not to propose any amendment to the definition of *State Land* in the Act to the extent it relates to native title.

On 5 October 2007, the Eastern Kuku Yalanji people, the State of Queensland & Wet Tropics Management Authority entered into an ILUA. The area of the ILUA falls within the jurisdiction of the Cook Shire Council and the Douglas Shire Council, on the Cape York Peninsula. The grant of this ILUA does not necessitate any amendment to the Act.

The Review is informed that some of the areas covered by this ILUA also included land over which a native title determination of exclusive possession has been made. According to the definition of State Land in the Act, these areas are excluded from the scope of the Act. However, any land covered by the ILUA which are not subject to a determination of exclusive possession would still fall within the scope of the Act.

The Review notes that should biodiscovery entities wish to access land which is subject to a native title determination of exclusive possession (and therefore outside the scope of the Act), then they will be required to negotiate an ILUA with the relevant native title group.

The Review considers that an understanding of this process would be facilitated by providing links or directions to access information in respect of this process online. The Review recommends that this information should be provided as part of any explanatory material in relation to the Act (together with the information in relation to negotiating access agreements with private landowners as described above).

> ***Recommendation 3.3: The Review recommends that publicly available information (for example online) be provided which provides direction as to the location and source of information in respect of negotiating access arrangements (ILUAs) in respect of land which is subject to a native title determination of exclusive possession.***

Submissions were made to the Review proposing a notification process whereby biodiscovery entities or individuals which hold collection authorities are required to notify indigenous groups that they are entering on land occupied by that group pursuant to the terms of a collection authority. This proposal would, of course, only apply to *State Land* as defined by the Act.

The Review is informed that biodiscovery entities currently adopt this process when they notify the land manager (for example the manager of the relevant land the subject of the collection authority) that they will be entering the land to collect native biological material pursuant to a collection authority. This notification is provided pursuant to section 4.2 of the Compliance Code.

To promote respect for the indigenous occupiers of the land (which is subject to the Act), the Review considers it appropriate that an obligation be included in the collection authority regime to notify indigenous occupiers of land (where those contact details are available) to advise when the land will be accessed pursuant to a collection authority issued in relation to that land.

Due to the procedural nature of this requirement, the review considers this requirement should be included (or clarified) in the Compliance Code. The Review notes that the appropriate responsible department for the provision of this information in relation to occupiers of indigenous land will need to be identified.

> ***Recommendation 3.4: The Review recommends an update to the Compliance Code so that notification is required to be provided to indigenous occupiers of land to advise when the land will be accessed pursuant to a collection authority issued in relation to that land (but only where contact details of the indigenous occupiers of the land are available).***

Consideration of ownership of Genetic Resources, Traditional Knowledge and International Developments

Genetic Resources

The issue of ownership of genetic resources attracted little comment during the consultation phase of the Review.

In conducting its research, the Review found that many international jurisdictions do not clarify the legal status of genetic resources. Article 15.1 of the CBD recognises the sovereign rights of States over their natural resources, and their ability to determine access to genetic resources.

In particular, there is some international concern that many jurisdictions lack a clear distinction between biological resources and genetic resources.

The Act does not distinguish between genetic resources and biological resources. The definition of *biodiversity* in the Act seems to incorporate both genetic and biological resources.

This can be distinguished from the position in the NT Act which includes a specific definition for *genetic resources* and is incorporated into the definition of *biological resources*. Although the NT Act provides a specific definition of *genetic resources* (which is not the position in the Act), the Review did not consider that any such change was justified in the Act. The definition of *native biological resource* in the Act remains sufficiently broad to encompass genetic resources and therefore an amendment to the Act is not warranted.

In the international sphere, many countries have different approaches to the ownership of genetic resources and benefit sharing methods which range from minimal or no State interference to very detailed rules of access including private contracts. In particular, the Andean Community and South Africa have established a checkpoint to ensure that BSAs are in place by requiring certain information such as origin of material and evidence of a BSA to be disclosed when applying for intellectual property rights.

In the Andean Community, the State owns all biological and genetic resources therefore checkpoints are likely to be in place to ensure that royalties are received by the State. In contrast, in South Africa BSAs are negotiated directly with local communities. Therefore, State regulation ensures that community rights are not infringed.

The Review did not receive and its investigations did not reveal sufficient evidence to support an amendment to the Act in respect of the treatment of genetic resources.

Traditional Knowledge

The Review received a submission inviting it to consider strengthening the Act in respect of the use of traditional knowledge. This submission was based on the importance of the Nationally Consistent Approach. It was submitted, that the use of traditional knowledge within the Act would be strengthened by including a mechanism to ensure compliance with the undertaking currently made under the Code of Ethics which provides that '*where in the course of biodiscovery and research we obtain and use traditional knowledge from indigenous persons or communities, we will negotiate reasonable benefit sharing arrangements with these persons and communities*'.

The Review also took into account the NT Act's approach to traditional knowledge. Pursuant to the Northern Territory Legislation, a party entering into a BSA must make a statement regarding:

- any use of indigenous people's knowledge (section 29(1)(h)); and
- benefits to be provided or any agreed commitments given in return for the use of the indigenous people's knowledge.

While this approach appears to include a broad treatment of traditional knowledge, the NT Act goes on to narrow the meaning of indigenous knowledge by limiting it to knowledge obtained from an indigenous person and not obtained from scientific or other documents or otherwise in

the public domain (section 29(2)). The application of this section relating to indigenous knowledge is therefore significantly limited in its scope.

The consideration of this issue during the roundtable discussions revealed a concern (although the attendees at the roundtable discussions had no personal experience with the NT Act) that this approach may create more confusion than certainty especially when more than one indigenous group may claim ownership of the traditional knowledge. There is also the concern of having to determine the extent of the disclosure of the indigenous knowledge in the public domain.

In addition to the matters raised below, after a detailed consideration by the Review, the regime adopted under the NT to address the issue of traditional or indigenous knowledge does not seem sufficiently certain to justify the amendment of the Act in this way.

Since the passing of the Act, there has been an increase in the frequency and intensity of the debate seeking a solution to how traditional knowledge will be treated and whether it should receive its own sui generis system of protection. The direction this will take remains unclear.

The Review notes that in June 2009 Australia participated in the Meeting of the Technical and Legal Experts on Traditional Knowledge associated with Genetic Resources in the context of the International Regime on Access and Benefit-Sharing. The meeting considered the issues surrounding the treatment of traditional knowledge in the international regime including prior informed consent of indigenous owners for traditional knowledge, whether traditional knowledge which is in the public domain is publicly available for use by others and common characteristics of traditional knowledge.

These developments should be monitored to determine whether the Act requires amendment in response. In light of these international developments the Review considered (in addition to its other concerns in relation to traditional knowledge) whether to amend the Act in view of the fact that the Act is likely to require amendment once the new international regime is finalised. This will also depend on whether the new regime is legally binding. It is important to note that any amendment at this stage will only be in relation to the compliance aspects as the Commonwealth is likely to legislate in relation to traditional knowledge (as described below).

The Review also noted that any legislation dealing with traditional knowledge is likely to fall within the scope of the Commonwealth's right to legislation in respect of traditional knowledge.

Section 51(xviii) of the Constitution of the Commonwealth of Australia provides that the Commonwealth can make laws for the peace, order and good government of the Commonwealth with respect to, 'copyrights, patents of inventions and designs, and trade marks'. On a literal review, this does not seem to extend to traditional or indigenous knowledge.

Cases such as *Grain Pool of Western Australia v Commonwealth* (2000) 202 CLR 479 at 492 have extended the operation of this seemingly narrow power to such intellectual property regimes as plant breeder's rights. It is therefore reasonable to expect that this constitutional power will also be extended to cover legislation in respect of traditional or indigenous knowledge. However, this is not certain.

Consistent with the policy decision at the time of the passing of the Act, the Review did not consider the Queensland Government had the necessary authority to legislate in respect of traditional or indigenous knowledge. This would only serve to create uncertainty in the Act.

In view of the ambiguity in relation to the legal treatment of traditional or indigenous knowledge in Australia, the Review is satisfied that the obligations in the Code of Ethics in relation to traditional knowledge are adequate. As noted earlier in this report, signatories to BSAs under the Act (and recipients of grants relating to the subject matter of the Code of Ethics) are contractually bound to comply with the Code of Ethics.

The Code of Ethics is scheduled to be reviewed in 2011.

The Review noted that only parties to BSA's under the Act are bound to comply with the Code of Ethics. However, there are some situations (section 54 of the Act) in respect of which BSAs are not required. In those circumstances a holder of a collection authority under the Act would not be bound to comply with the treatment of traditional knowledge under the Code of Ethics.

The Review considers that this issue could be addressed by included a similar section dealing with traditional knowledge (as in the Code of Ethics) in the Compliance Code (which applies to collection authorities issued under the Act).

> ***Recommendation 3.5: The Review recommends that the State monitor the movement towards the development of a legal framework implemented to protect traditional and indigenous knowledge in Australia to determine whether any consequential amendments to the Act are required at that time.***
>
> ***Recommendation 3.6: The Review recommends that DERM undertake a review of the 'Compliance code for taking native biological material under a collection authority' to consider including a provision addressing traditional knowledge to reflect the provision in the Queensland Biotechnology Code of Ethics.***

The Review also considered the *Cape York Peninsula Heritage Act 2007* (Qld) (on 25 October 2007) and determined that its operation does not necessitate any amendment to the Act. This is because it does not address matters which are the concern of the Act. However, the Review noted that the Compliance Code did address some of the issued covered by the *Cape York Peninsula Heritage Act 2007* in the context of the administration of the collection permit regime.

During the private consultation stage of the review, a concern was raised as to the operation of the Act in conjunction with the *Aboriginal Cultural Heritage Act 2003* (Qld). In that regard, the Review notes that the *Aboriginal Cultural Heritage Act 2003* (Qld) requires all persons to take all reasonable and practicable measures to ensure their activities do not harm Aboriginal cultural heritage. Failure to do so may attract a penalty of up to 1000 penalty units for an individual and 10,000 penalty units for a corporation.

The Review considers that clauses 2.8 and 2.9 of the Compliance Code sufficiently address the *Aboriginal Cultural Heritage Act 2003* (Qld). Therefore, the Review does not recommend that the Act be amended to incorporate further provisions about indigenous cultural heritage resources.

International Developments

In addition to considering developments in respect of genetic resources and traditional knowledge, the Review considered the movement towards an international regime for regulating biodiscovery.

At the World Summit for Sustainable Development in 2002 in South Africa, governments which had ratified the CBD called for the negotiation of an international regime to promote the fair and equitable sharing of benefits arising out of the utilisation of genetic resources.

In 2003, the Ad Hoc Open-ended Working Group on Access and Benefit Sharing (**Working Group**) was established to elaborate and negotiate an international regime on access to genetic resources and benefit sharing. The aim of the Working Group is to adopt an instrument to effectively implement the provisions of the CBD in respect of access to genetic resources and traditional knowledge.

The co-chairs of the Working Group, Mr Tim Hodges and Mr Fernando Casas, presented at the National Forum in respect of the developments.

It is noted that negotiations are still underway and it is unlikely an international regime will be finalised for some time. However, the Review noted that there is concern in the biotechnology industry as to whether the commencement of any international regime will be retrospective in its operation. This is a very real concern for the biodiscovery industry which relies on the legal certainty of the regime established by the Act in its commercialisation.

A retrospective international regime would also be contrary to the *Prime Minister's Science Engineering and Innovation Council 'Biodiscovery' Paper* (2 December 2005) which promotes certainty in benefit sharing and access arrangements in order to increase the potential for investment in the industry and enhance the possibility of commercialisation.

A recent update provided to the Review indicates that the final text of the international regime is likely to be a legally binding protocol to the CBD. The Review is informed Australia will only support a legally binding instrument if it was compatible with domestic access and benefit sharing arrangements. Australian Government representatives have also noted that Australia is unlikely to support a burdensome regime which requires costly compliance.

As such, the Review recommends that the progress of the international regime be closely monitored to determine the impact on the Act and so any submissions can be made if appropriate.

In the context of discussing international developments, the Review had the benefit of discussing a proposal to deal with the integration of compliance with the Act (specifically the benefit sharing regime) as part of the patent application process. At present, patent applicants are not required to disclose whether they have a BSA in place in relation to the patented invention. The Review considered whether a requirement should be included in the *Patents Act 1990* (Cth) so that a confirmation (that a BSA is in place in respect of the source of the patentable subject matter) must be provided at the time of filing a provisional patent. This would therefore give further certainty in patenting process. A similar system has been adopted in South Africa in circumstances where a patent applicant lodges a statement that acknowledges that the invention is based on or derived from an indigenous biological resource, genetic resource or traditional knowledge or use.

However, this would increase the administrative burden on the Patents Office of IP Australia in its verification of the benefit sharing agreements. The Review has not received any feedback as to whether such a process would be acceptable to the Patents Office. In any event, such change is not within the scope of this review.

> ***Recommendation 3.7: The Review recommends that the movement towards the development of an international regime be closely monitored.***

Definitions in the Act

Definition of biodiscovery

The Schedule to the Act provides the following definitions of *biodiscovery*:

> ***biodiscovery*** means—
>
> (a) biodiscovery research; or
>
> (b) the commercialisation of native biological material or a product of biodiscovery research.
>
> ***biodiscovery research*** means the analysis of molecular, biochemical or genetic information about native biological material for the purpose of commercialising the material.

The Review noted that there has been some confusion as to the definition of *biodiscovery* in the Act.

Arising out of issues raised at the roundtable discussions, the Review considered whether the reference to *or* in the definition of *biodiscovery* should be amended to *and*.

The conclusion drawn by the Review was that the definition of *biodiscovery* should remain unchanged and that the use of the *or* in the definition was appropriate. The Review determined that a change in the definition to the use of *and* would have a limiting impact on other sections of the Act.

For example, a collection authority and a BSA would only be required under the Act (sections 17 and 33) if the biodiscovery entity was undertaking *biodiscovery research* **and** the '*commercialisation of native biological material or a product of biodiscovery research*'. This is contrary to the intention of the Act.

The Review was informed that some parties considered that *biodiscovery* included using the native biological material and extracting something from it which could be commercially valuable. With the movement towards natural products and the use of compounds for other commercial uses including uses in target screening libraries etc, the Review recognised a need to give renewed consideration to a number of definitions in the Act.

The second reading of the Biodiscovery Bill on 18 May 2004 referred to *biodiscovery* as follows:

> *Biodiscovery is the search for active compounds in plants, animals and micro-organisms that*

can be developed into commercial products. Biodiscovery involves collection of only small samples with minimal ecological impact. With its world-class research infrastructure coupled with its unique environment, Queensland is well placed to become a leading international centre for biodiscovery.

While the statement as to the nature of biodiscovery in the second reading speech is quite narrow in its operation, the growth and development of the biodiscovery industry since that time has meant that *biodiscovery* must be given broader consideration.

It became apparent to the Review, through the submissions and roundtable discussions, that the definition of *biodiscovery research* in the Act was not sufficiently clear.

There was some confusion as to whether using a sample of material (in the absence of any other processes - for example crushing samples for oil extraction) obtained pursuant to a collection authority under the Act would fall within the scope of '*analysis of molecular, biochemical or genetic information*' (the current wording used in the definition of *biodiscovery research*).

While this type of activity may not fall within the definition of *biodiscovery research*, it may fall within the second limb of the definition of *biodiscovery* if it is sold for commercial gain. The second limb only requires the *'commercialisation of native biological material'* and does not require any '*analysis of molecular, biochemical or genetic information*'.

The NT Act has defined *biodiscovery* in section 4(1):

***"biodiscovery"** means research on samples of biological resources, or extracts from those samples, to discover and exploit genetic or biochemical resources of actual or potential value for humanity.*

This definition appears to be broader in its application than the current definition of *biodiscovery research* in the Act.

The Review received suggestions in relation to the apparent inconsistency in the Act between the relatively narrow definition of *biodiscovery research* and the intent of the broader definition of *commercialisation* as it relates to *biodiscovery*.

It was submitted that the reference to '*analysis of molecular, biochemical or genetic information*' in the definition of *biodiscovery research* is more descriptive of research methodology rather than the objective or purpose of the research.

As recommended to the Review, *biodiscovery research*, by its current definition, appears to be very strongly focussed on discovery of pharmaceuticals, agrochemicals and related products, while *commercialisation* appears to try to capture a much wider range of other potential new commercial applications of Queensland's biota possibly including use of raw materials and extracts in food, nutraceutical formulations, cosmetic ingredients, other consumer products, and even industrial applications (e.g. microbes for breaking down hydrocarbon wastes etc).

It was submitted that in order to capture the broader scope of *commercialising*, the definition of *biodiscovery research* should be amended.

The Review also considered deleting the reference to *commercialisation* in the definition of *biodiscovery research.*

The Review considers an amendment to the definition of biodiscovery research will enhance the certainty of the Act and would therefore promote the use of the permitting and benefit sharing framework established by the Act.

The concepts of *biodiscovery research* and *commercialisation* under the Act would therefore be more closely aligned and consistent with the purpose of the Act set out in Section 3(1)(b) *'to encourage the development, in the State, of value added biodiscovery*'.

> ***Recommendation 3.8: The Review recommends that the definition of biodiscovery research be amended to reflect the following revised definition.***
>
> ***'Biodiscovery Research means the:***
>
> - ***identification, assessment, evaluation, research, testing or use of;***
> - ***research into***
>
> ***native biological material associated with the commercialisation or intended commercialisation of the material. Biodiscovery research methods may include, but are not restricted to, analysis of molecular, biochemical or genetic information about native biological material'.***

Definition of commercialisation

The Schedule to the Act provides the following definition of commercialisation:

> ***commercialisation***, of native biological material—
>
> 1 *Commercialisation*, of native biological material, means using the material in any way for gain.
>
> 2 The term does not include using the material to obtain financial assistance from a State or the Commonwealth, including, for example, a government grant.

During the roundtable discussions it was submitted that the definition of *commercialisation* is not clear. This is a particular concern when it is necessary to determine the point at which *biodiscovery research* becomes *commercialisation*. This was a concern consistently raised during the review period by research institutions as well as universities. In that regard, it was argued that all research is different and that whilst aiming for commercial development, it may not always be achieved.

This issue was discussed with the background of section 54(3) of the Act which excludes from the offence sections of the Act, the use by an educational institution or a person at that institution from the need to enter into a BSA in relation to activities which do not involve commercialisation of the material.

The Review has made specific recommendations in relation to these exclusions later in this report.

The proposals put to the Review in relation to this issue were varied. These ranged from educational institutions not providing benefits back to the State pursuant to the benefit sharing framework as it was submitted these benefits were already being provided by the institutions in the form of training and research, to institutions only providing benefits when actual monies are received.

It was submitted that most of the time researchers will licence material to companies who will then develop it. Benefits may then be received for example by way of milestone payments or research funding.

In order to provide greater clarity to universities and research institutions, the Review noted that the definition of *commercialisation* should be amended. The amendment should be directed at clarifying the reference to 'gain'.

In was also submitted that the definition of *commercialisation* should exempt private research funding in addition to government grants. It was suggested that to overcome this issue, the Act should define what a gain is and what a gain is not. Recommendation 3.9 below seeks to address this issue.

Submissions were also received in relation to research funding. Universities indicated that *'research funding'* should be excluded from the definition of *commercialisation*. The Review has responded to this concern as described in Recommendation 3.10 whereby the Review recommends that private *'research grants'* be excluded from *commercialisation* (in addition to government grants).

> ***Recommendation 3.9: The Review recommends that paragraph (1) of the definition of 'commercialisation' be amended to clarify that that the reference to 'gain' in that definition is a reference to the actual receipt of monies including but not limited to licence fees, royalties or milestones.***
>
> ***Recommendation 3.10: The Review recommends that paragraph (2) of the definition of 'commercialisation' be amended to also exclude private research grants. The Review further recommends that consideration be given to ensuring this exclusion applies to grants received for genuine research purposes.***

7 Chapter 4: Act achieving purposes

Terms of Reference 2

Investigate whether the purposes of the Act are being achieved and whether the regulatory framework stipulated in the Act is still appropriate.

Investigation of whether the purposes of the Act are being achieved

In determining whether the purposes of the Act are being achieved and whether the regulatory framework stipulated in the Act is still appropriate, the Review considered all the Terms of Reference and made an assessment based on the conclusions and recommendations in relation to each.

The Review has recommended that certain amendments and other processes be adopted to improve the operation and public understanding of the Act. These recommendations respond to comments which indicate there may be some confusion as to the scope of the Act.

The Review did not receive many submissions or comments during the roundtable discussions as to whether or not the Act was achieving its purposes.

Some parties, who did not carry on biodiscovery activities under the Act, questioned whether the Act was achieving its purposes or whether it was simply a 'feel good' piece of legislation.

On the other hand, the Review received positive comments about the operation of the Act from those stakeholders who regularly undertake biodiscovery in accordance with the Act. These stakeholders identified that they had received positive feedback from international pharmaceutical companies which indicated that arrangements undertaken under the auspices of the Act provided certainty and a sound basis for the investment of funds into continuing research.

The Review considered whether there was any basis for concluding that the purposes of the Act were not being achieved.

The Review considers that some parties' confusion about the purposes of the Act, described in Chapter 3, may have coloured comments about whether or not the Act is achieving its purposes.

On balance, the Review concluded that the purposes of the Act are being achieved and should not be amended.

Investigation of whether the regulatory framework is still appropriate

The Review did not receive many submissions in relation to the regulatory framework imposed by the Act.

The submissions which addressed this issue promoted the adoption of the regulatory framework (permitting and BSA regime) implemented in other regimes (for example under the Commonwealth Regulations). On balance, and after the review of those different permitting

regimes, the Review did not consider any amendment to the current regime under the Act was justified.

Similarly, limited comments were made when this issue was raised during the roundtable discussions. The Review considers that the lack of submissions indicates that those who undertake biodiscovery under the Act consider that the regulatory framework is appropriate.

Subject to the Review's recommendations to amend other aspects of the Act, the Review considers that the purposes of the Act are being achieved and the regulatory framework stipulated in the Act should be maintained.

> ***Recommendation 4.1: The object of the Act is being achieved and the principles of the regulatory framework stipulated in the Act should be maintained.***

8 Chapter 5: Operation of the Act

Terms of Reference 3, 4 and 5:

3 Examine the structure and effectiveness of the permitting regime stipulated in Parts 3 and 4 of the Act.

4 Examine the structure and effectiveness of the contractual framework for benefit sharing agreements stipulated in Part 5 of the Act.

5 Determine whether the powers of the Act allow enforcement of compliance which is effective and appropriate to the circumstances.

Examination of the structure and effectiveness of Collection Authorities

Collection Authorities

The Act provides the following in relation to collection authorities:

> **Section 10 What a collection authority authorises**
>
> Subject to section 17, a collection authority authorises its holder to take minimal quantities of stated native biological material from, on or in, State land or Queensland waters, and keep the material, for biodiscovery.
>
> **Section 17 Conditions of collection authority**
>
> 1 It is a condition of a collection authority that the holder, or a person acting for the holder, must not take native biological material under the authority unless a benefit sharing agreement concerning the material is in force.
>
> 2 To the extent the provisions of the compliance code or a collection protocol are applicable to the activities carried out under a collection authority, the provisions are conditions of the authority.
>
> 3 The conditions imposed by the chief executive under section 14(1)(a) (the ***section 14 conditions***) are conditions of the authority.
>
> 4 If there is an inconsistency between a condition mentioned in subsection (2) and a section 14 condition, the section 14 condition prevails to the extent of the inconsistency.

There were many submissions and comments made during the roundtable discussions in respect of collection authorities.

It was suggested that the Review should clarify whether collection authorities are required for merely storing or using biodiversity material as no physical collection has taken place. Researchers advised the Review that they often receive biodiversity material from collectors of

samples. Therefore, researchers need to be aware that the collector's collection authority is and was valid at the relevant time of collection of the material.

It was clear that clarification was required in respect of whether a party acquiring samples from another party (that has collected them pursuant to a collection authority) is required to obtain a collection authority (in addition to a BSA).

The Review concluded that this clarification may be achieved through the use of Material Transfer Agreements. Parties acquiring samples from another party (that has collected the samples pursuant to a collection authority) may enter a Material Transfer Agreement in relation to the transfer of those samples of native biological material. The ability to enter a Material Transfer Agreement in relation to samples should be a condition of the relevant collection authority.

The use of Material Transfer Agreements will assist in providing certainty to parties acquiring samples so they have a clear chain of title to the samples. The Review recommends the Material Transfer Agreement contain a warranty that the relevant samples were collected under a valid collection authority issued pursuant to the Act.

Information in relation to the use of Material Transfer Agreements and sample agreements may be provided on-line in connection with other information relating to compliance with the Act.

Further, the Review recommends a copy of the signed Material Transfer Agreements be lodged with DEEDI so the transfer of samples between parties can be tracked.

The Review did not consider the proposal of Material Transfer Agreements necessitated an amendment to the Act.

> ***Recommendation 5.1: The Review recommends that information be provided in relation to the use of Material Transfer Agreements. Material Transfer Agreements may be used in relation to the transfer of samples of native biological material (collected pursuant to a collection authority under the Act) to another party which intends to use those samples for biodiscovery (pursuant to the Act). The review recommends a copy of the signed Material Transfer Agreements be lodged with DEEDI once executed.***

The Review heard that it would beneficial if this information in relation to collection authorities were provided in a publicly accessible online format.

Researchers and other interested parties will then be able to ensure that the appropriate collection authority is obtained and the permitting system under the Act is being followed.

The Review noted that section 28(1) of the Act currently allows a person to inspect (free of charge) the details contained in the publicly available part of the collection authority register. Section 28(3) of the Act allows for the publication of the details in the register at the times and in the way decided by the chief executive.

To promote transparency and pursuant to the power of the chief executive under section 28(2) of the Act, the Review recommends that the publicly available part of the collection authority register be converted into a publicly available online format.

Recommendation 5.2: The Review recommends that the publicly available part of the collection authority register be converted into a publicly available online format.

The issue of collection authorities also raised the concern as to whether entities (which are associated with the State) should be treated as independent entities under the Act and required to obtain collection authorities in accordance with the Act.

The Review was advised that under the Commonwealth Regulations, the Queensland Museum (established by the *Queensland Museum Act 1970* (Qld)) is required to obtain a collection permit. However, this is not the case under the Act.

It was submitted to the Review that the preferred approach would be for the Queensland Museum to obtain collection authorities under the Act. This would assist the Queensland Museum in marketing its collection of samples which may be acquired by other organisations as it would give confidence and certainty about Queensland Museum's compliance with the Act.

The Review considered that the State's endorsement of the Queensland Museum's ability to hold collection authorities would assist in enhancing the development and the growth of the biodiscovery industry in Queensland.

For the purposes of consistency, the Review further considers that this approach may also be adopted in relation to the Queensland Herbarium, currently under the auspices of the DERM. However, the Review did not receive any submissions in respect of the treatment of the Queensland Herbarium during the course of the Review.

As this would be a policy decision by the State, the Queensland Museum and Herbarium may not be required to enter into BSAs as they represent the State.

Recommendation 5.3: The Review recommends the Queensland Museum and Queensland Herbarium be able to apply for and hold collection authorities under the Act.

Labelling and Samples

The Review was informed of an ongoing issue of initial labelling of biological material used for biodiscovery and subsequent relabelling of downstream products. As such, identification of end products can become more difficult and eventually impossible when derivatives are developed. As a result, the State may risk losing the benefits afforded by the Act. It was suggested that this issue be clarified by providing further guidance in respect of labelling downstream products.

It was also suggested that further guidance is needed in relation to storing samples. For example the purpose of depositing the sample and further information as to how the sample will be stored, maintained and dealt with.

The Review concluded that the issues in respect of labelling and storage of samples be considered as part of the review of the Compliance Code.

Recommendation 5.4: The Review recommended that issues of labelling and storage of samples of material be considered as part of the review of the Compliance Code.

The Review was informed that continual improvement and development will necessitate the ongoing consideration of resourcing, ability to comply and scientific methods in respect of storage of samples pursuant to section 30 of the Act.

This submission highlights the concerns that in the future, the storage of samples may not be the most appropriate method of retaining information in relation to the biological material which has been collected.

The Review was also advised that, as general rule, it required the biodiscovery entity to provide a voucher specimen and State sample in relation to native biological material which had been collected. In response to concerns about lack of storage, the Queensland Museum and the Queensland Herbarium could decline to accept samples (to be reflected in the biodiscovery plan). In addition, the State could agree that only voucher specimens were required to be provided by the biodiscovery entity.

These concerns are not consistent with section 30 of the Act which only addresses the delivery of one sample to the State.

In view of the current wording of section 30 of the Act, the Review did not consider it necessary to propose changes to the Act in relation to this issue.

The Review noted that it had not been informed (by any receiving entities) of any concerns in relation to storage of samples under section 30 of the Act.

It was not clear to the Review whether samples provided under section 30 are required to be retained for a particular period of time by the receiving entity. This issue was also brought to the attention of the Review during the consultation period. In the interests of certainty, the Review considers this matter should be considered by the State and an appropriate policy position adopted.

> ***Recommendation 5.5: The Review recommends the State develop a policy position in relation to the samples required to be provided pursuant to Section 30 of the Act. If the improvement in scientific method or technologies necessitates a change in the way or nature of the information provided, the Review recommends the State consider implementing regulations to address this issue.***
>
> ***Recommendation 5.6: The Review recommends the State gives consideration and develops a policy position in relation to the length of time receiving parties under section 30 are required to retain samples provided under that section.***

It was also suggested that the Review should clarify the legitimacy of samples which were collected before the Act came into force.

The Act sets out transitional provisions in relation to material collected under authorities in existence before the commencement of the Act (section 125 of the Act). The Review considers that section 125 of the Act provides sufficient certainty as to the legitimacy of samples of material collected before the commencement of the Act and no amendment of the Act is required in relation to this issue.

Comments were made during the roundtable discussions, that the terms used in the Act in respect of storage for microorganisms or microbes are vague or silent. In particular, the Act does not provide any information in respect of deposits for future use of microorganisms or microbes.

The Review was also informed that no repository for microorganisms exists in the State. It was also noted cultures of microorganisms or microbes must be stored in a particular way in order to be maintained.

The State's failure to provide a repository for microorganisms or microbes means that it is potentially compromising any benefits which may be received from development of those microorganisms or microbes in the biodiscovery industry. There is also the risk that compliance will not be able to be monitored should these organisms be stored by the biodiscovery entities themselves (due to the absence of an independent repository).

The Review considered that the State should give consideration to the establishment of such a repository. The establishment of a microorganism and microbe repository would not require any amendment to section 30 of the Act as section 30(1(c) already provides for an entity other than the Queensland Museum or Queensland Herbarium to receive samples.

> ***Recommendation 5.7: The Review recommends that the State investigate options for the storage of microorganisms and microbes. This may take the form of an independent repository.***

Examination of the structure and effectiveness of Benefit Sharing Agreements

Benefit Sharing Agreements

The Act provides the following in relation to benefit sharing agreements:

Section 33 Power to enter into agreement
(1) The DSDI Minister may, for the State, enter into an agreement (a ***benefit sharing agreement***) with a biodiscovery entity under which—

> (a) the State gives the entity the right to use native biological material for biodiscovery; and
>
> (b) the entity agrees to provide benefits of biodiscovery to the State.

(2) The Minister must not enter into a benefit sharing agreement with a biodiscovery entity unless the entity has an approved biodiscovery plan.

(3) The parties to a benefit sharing agreement may, at any time, amend the agreement.

(4) The Minister may delegate the Minister's powers under this section to the DSDI chief executive.

Section 34 Content of agreement
(1) A benefit sharing agreement must be consistent with this Act.

(2) The agreement must state each of the following—

> (a) the date the agreement is entered into;

(b) the agreement's term;

(c) the benefits of biodiscovery to be provided by the biodiscovery entity to the State;

(d) when the benefits are to be provided;

(e) if the benefits include the payment of amounts of money to the State—the amounts, or a way of working out the amounts;

(f) if native biological material, the subject of the agreement, is to be taken under a collection authority—the number, or other identification, of each authority under which the material is to be taken;

(g) what matters are reportable matters for the agreement;

(h) the biodiscovery entity's place of business.

(3) The agreement must also include any conditions, other than the conditions mentioned in section 35(1) and (2), of the agreement.

Section 35 Conditions of agreement

(1) It is a condition of a benefit sharing agreement that the only commercialisation activities the biodiscovery entity, with whom the agreement is made, may carry out are the activities detailed in the entity's current approved biodiscovery plan.

(2) It is also a condition of the agreement that the entity must not allow someone else to use any of the native biological material the subject of the agreement for biodiscovery, unless the other person is—

(a) acting for the entity; or

(b) a person mentioned in section 54(2)(a), (b) or (c) or (3); or

(c) a party to a benefit sharing agreement concerning the material.

(3) Subsections (1) and (2) do not limit any other conditions that may be included in the agreement under section 34(2).

Section 54 Using native biological material for biodiscovery without a benefit sharing agreement

(1) A person must not, unless the person is a party to a benefit sharing agreement, use native biological material for biodiscovery, if the material was taken from—

(a) State land or Queensland waters; or

(b) a State collection, if the material was taken or sourced from State land or Queensland waters.

Maximum penalty—the amount equal to the greater of the following—

(a) 5000 penalty units;

(b) the full commercial value of any commercialisation of the material.

(2) However, subsection (1) does not apply to a person who uses the material for carrying out only 1 or more of the following activities—

(a) classifying the material scientifically;

(b) verifying research results concerning the material;

(c) biodiscovery to which a benefit sharing agreement concerning the material applies, carried out for a person who is a party to the agreement.

(3) Also, subsection (1) does not apply to the use by an educational institution, or a person at the institution, for educational or training activities not involving commercialisation of the material.

(4) In this section— ***educational institution*** means—

(a) a school, college, university or university college; or

(b) a TAFE institute, a statutory TAFE institute or a registered training organisation as defined under the *Vocational Education, Training and Employment Act 2000*.

The Review received many submissions and comments during the roundtable discussions in relation to BSAs. In particular, it was submitted that:

- it is inappropriate to enter into an agreement in respect of royalties when it may take a biotech company 10 to 15 years to fully develop a product and receive a financial return.

- a company should not be required to enter into a BSA until a product can be sold. In that regard, the government would still receive benefits through employment and income tax.

  On balance the Review concluded that no change be made to the BSA regime under the Act. The current BSA framework was adopted in the Act to promote the monitoring of compliance with the Act and also to ensure compliance with the CBD. The Review has addressed the issue of when educational and training institutions are required to enter into a BSA by recommending an amendment to the definition of *commercialisation* (Recommendation 3.9) The Review confirms that the requirement to enter a BSA at the permitting stage is consistent with the NT Act.

- every BSA should contain a clause stipulating that any intellectual property rights which may vest in a biodiscovery entity will become public intellectual property rights at the expiration of 10 years after entering into the BSA.

  The Review noted that adopting this recommendation would be contrary to the purposes of the Act (in particular section 3(1)(b)) and would likely operate as a disincentive for biodiscovery entities to engage in *biodiscovery* pursuant to the Act. This proposal is also contrary to patent rights granted under the *Patents Act 1990* (Cth) which grants exclusive rights in relation to the patented invention.

- agreements in relation to ongoing minimum royalties may adversely affect a university. For example, pharmaceutical prices decrease (as does the university's income) once a patent in respect of a drug expires and genetic versions become available.

  The Review concluded that no amendment to the Act is required as a result of this submission as universities are able to negotiate the terms of their BSAs with the State on a case by case basis.

There were also further comments during the roundtable discussions in relation to when researchers should be required to enter into a BSA and when research develops into a 'commercial' activity. In that regard, a number of comments were made including:

- the Review should consider extending a simplified permitting process to regulate non-commercial research in accordance with the Nationally Consistent Approach. The process should contain conditions on the researchers to enter into a BSA upon research turning commercial.

- annual reporting requirements could be imposed upon researchers that would make it easier for all parties to ascertain when research turns commercial.

- a head BSA could be entered into which would encompass all enterprises carried on by a university. This would mean that individual researchers would not be required to enter into a BSA when their research turns commercial.

The Model BSA also received some criticism during the roundtable discussions. In particular, it was submitted that the model BSA:

- is one-sided and that it is commercially unacceptable and impractical for biotechnology companies. As such, it is likely to impair commercialisation, as the biotechnology companies will struggle to attract investors, and be detrimental to both the industry and government.

- does not distinguish between organisations that collect and sell biodiversity and organisations that research and licence biodiversity.

On balance, the Review considers that while the State has provided a form of Model BSA, this model agreement is intended to represent the starting point of discussions with the State in a move towards arriving at any agreement which meets the purposes set out in section 3 of the Act.

The Review has determined that in view of the ever changing landscape of the biodiscovery industry, it is appropriate for the State to negotiate the BSAs on a case by case basis with each biodiscovery entity. The Review recognises there will be different issues which require consideration for each type of biodiscovery entity.

However, on balance, the Review does not consider that any amendments to the Act are required in relation to the basic BSA framework.

The Review will make recommendations in relation to the application of the Act to educational and training institutions (including universities).

Educational and training institutions (including universities)

The Review was informed that the issue of whether and when educational and training institutions (including universities) are required to enter into a BSA is not clearly stated in the Act.

As noted earlier in the Review, section 54(3) of the Act provides that it is not an offence if an educational or training institution does not have a BSA if the educational or training institution is using the material for activities not involving commercialisation of the material.

The Review considers that the exclusion of educational and training institutions from the requirement to enter into a BSA in the circumstances set out in section 54(3) could be more clearly restated earlier in the Act. For example, this amendment could be made to section 17 of the Act which currently sets out the requirement to enter into a BSA before any native biological material is taken under the relevant collection authority.

The restructuring of the Act in this way would make it easier to identify the circumstances in which a BSA is not required (without having to consider the offence provisions of the Act).

> ***Recommendation 5.8: The Review recommends section 54(3) of the Act in relation to educational and training institutions be deleted and restated as an exclusion to section 17 of the Act.***
>
> ***Recommendation 5.9: The Review recommends section 54(3) of the Act be redrafted to reflect the exclusion in section 17 of the Act (as per Recommendation 5.8).***

To enhance the certainty of the application of the Act in relation to educational and training institutions, the Review concluded that a positive obligation should be placed on educational and training institutions to enter into BSAs when the institution becomes aware that the relevant native biological material is being used for *commercialisation.*

This amendment is intended to provide certainty to educational and training institutions in relation to their obligations to enter into BSAs and also provides a right of enforcement for the State in the event those institutions do not take steps to enter into the BSAs at the relevant time.

> ***Recommendation 5.10: The Review recommends a positive obligation be included in section 17 requiring educational and training institutions to enter a benefit sharing agreement within a reasonable time of becoming aware that they are engaging in commercialisation in relation to the relevant native biological material.***

As to the form those BSAs are likely to take, the Review was informed that it would not be practical for each researcher to enter into an individual BSA with the State.

The Review noted that this approach is likely to be unnecessarily burdensome and cumbersome for researchers. The Review therefore recommends that the State adopt an alternative policy in relation to educational and training institutions in relation to the structure of BSAs.

The proposed structure is that an educational or training institution be required to enter into a head BSA with the State. Each time a researcher or department of the educational or training institution is required to enter into a BSA, it will complete an addendum to the head BSA (setting out specific details including benefits, royalties etc) which incorporates the terms of the head BSA.

The Review considers this will facilitate the management of the BSAs with educational and training institutions by eliminating the need to negotiate a new BSA on each time commercialisation of the native biological material commences.

> ***Recommendation 5.11: The Review recommends that the State adopt a policy pursuant to which educational and training institutions (including universities) enter into head benefit sharing agreements with the State. Subsequently researchers who are engaging in commercialisation of native biological material will enter addendums to the head benefit sharing agreement (setting out specific details including benefits, royalties etc) which incorporates the terms of the head benefit sharing agreement.***

In the context of considering the position of educational and training institutions under the Act, the Review has also considered circumstances in which researchers may have collected the relevant material pursuant to permits other than a collection authority issued under the Act (for example a scientific purposes permit issued under the *Nature Conservation Act 1992* (Qld)).

Section 7 of the Act sets out the relationship of licences and permits under other legislation so that any collection authority issued pursuant to this Act overrides the requirement to obtain a licence or permit under any other legislation.

Concerns have been expressed to the Review that collection under a separate permit or authority may mean that any commercialisation using those materials will not be reflected in benefits of biodiscovery accruing to the State (as required under the Act).

This is a particular concern in relation to researchers where the initial investigation was purely scientific in nature - that is, the research did not fall within the definition of biodiscovery (as it did not amount to biodiscovery research (not being for the purpose of commercialisation)) or commercialisation as described in paragraph (b) of the definition of biodiscovery.

In those circumstances, researchers would not fall within the ambit of section 10 of the Act which sets out the circumstances in which a collection authority is required under the Act.

The Review recommends that a section be included in the Act to address this apparent gap. If commercialisation occurs in relation to native biological material which should have been collected pursuant to this Act, then a BSA should be entered into under the Act. It may also mean that a collection authority may be required to keep any of the relevant native biological material.

The Review considers this would also apply to individuals and organisations other than the researchers in educational and training institutions.

Recommendation 5.12: The Review recommends that a new section be included in the Act requiring biodiscovery entities to enter into benefit sharing agreements with the State in circumstances where native biological material has been collected under licences or permits in other acts but which, in light of commercialisation of the relevant material, should have been subject to the regulatory regime and framework set out in the Act.

Other issues in relation to benefit sharing agreements

The Review considers that the exclusions from the offence provisions relating to BSAs in section 54(2) of the Act should be restated earlier in the Act. Section 54(2) of the Act relates to circumstances in which a biodiscovery entity engages another party to perform fee for service contract work.

As noted above, this would make the regulatory framework of the Act clearer and more certain.

Recommendation 5.13: The Review recommends section 54(2) of the Act (in relation to biodiscovery entities which engage other parties for fee for service work) be deleted and restated as an exclusion to section 17 of the Act.

Recommendation 5.14: The Review recommends section 54(2) of the Act be redrafted to reflect the exclusion in section 17 of the Act (as per Recommendation 5.13).

Examination of enforcement of compliance with the Act

The Review did not receive many submissions or comments during the roundtable discussions about the appropriateness and effectiveness of the enforcement provisions in the Act.

It was suggested that the State could easily ensure that biodiscovery entities are obtaining collection authorities and entering into a BSA by requiring evidence of such agreements when entities are applying for intellectual property rights (see section 6.4 of this Report).

This is considered earlier in this report.

Recommendation 5.15: The Review does not recommend that the enforcement or compliance provisions of the Act be amended.

9 Chapter 6: Regulatory Burden

Terms of Reference 6 and 7:

6 Examine whether compliance and administrative costs, including information requirements, for biodiscovery entities are reasonable and justified compared to benefits achieved and possible alternatives to legislation.

7 Review the system of approvals and the application of regulatory requirements commensurate to the level of risk.

Examination of Costs of the Act compared with Benefits of the Act

For the purposes of this chapter of the report, the Review refers to *administrative burden* - as the time and resources committed to meeting the information and reporting requirements under the Act.

While the Review did not receive many submissions or comments during the roundtable discussions in relation to compliance and administrative costs of the Act compared with the benefits achieved, there was some feedback from some groups that the Act has an unnecessary red-tape burden.

The Review considers that the intention of the administrative and compliance system is directed towards achieving the purposes of the Act set out in section 3 and is therefore justified in its information requirements.

The Review was informed, by an entity which regularly operates within the framework of the Act, that the administrative and compliance costs are appropriate in the context of the levels of certainty and commercial advantage provided by the compliance with the Act. The entity is a private company with limited resources. On the basis that this entity considers the compliance and administrative costs to be appropriate, the Review considers that larger organisations should be able meet the administrative and compliance costs.

However, some organisations have also indicated that the navigation of the collection authority regime under the Act (in the context of other permitting regimes) is quite difficult. This confusion also extends to the nature of the samples to be provided to the State pursuant to section 30 of the Act.

An example provided to the Review was that a minimal quantity of native biological material is collected pursuant to the collection authority and out of that minimal quantity a sample is to be provided pursuant to section 30 of the Act. The entity raised the issue that direction is required to assist the entity in determining what it is required to do if the remaining native biological material is not sufficient in quantity to conduct biodiscovery.

With the intention of reducing the administrative and compliance costs, the Review concludes that biodiscovery entities operating under the Act would benefit from further education and clarification in relation to dealing with collection authorities and sample requirements under the Act.

Recommendation 6.1: The Review recommends that additional information be publicly available online to simplify and provide directions in relation to collection authorities and the interaction between collection authorities under the Act and licences and authorities available under other legislation and regimes.

Recommendation 6.2: The Review recommends that the Compliance Code be reviewed to incorporate additional information about the samples to be deposited pursuant to section 30 of the Act and the impact on the deposit of those samples on the minimal quantity available for biodiscovery.

On balance, the Review considers the current compliance and administrative costs are reasonable and justified compared with the benefits received. Therefore, the Review does not consider it necessary to propose any alternatives to legislation.

Recommendation 6.3: The Review does not recommend any amendments to the compliance and administrative costs under the Act.

Consideration of Application process and Regulatory Requirements

For the purposes of this chapter of the report, the Review refers to *regulatory burden* - as the resources committed to complying with the regulatory framework of collection authorities and benefit sharing agreements as imposed by the Act.

As noted above, the Review was informed that the collection authority regime requires some education and clarification. The Review has made recommendations in relation to this issue in this review. The Review also received information that the requirement to negotiate a BSA is burdensome.

It was also submitted to the Review that while negotiating a BSA and applying for a collection authority requires a commitment of resources, this is consistent with the commitment biodiscovery entities are required to make to successfully commercialise a product in the industry.

As noted previously, the Review has concluded that the differing requirements, structure and level of sophistication of biodiscovery entities can be accommodated by the State during the BSA negotiation process.

The Review was informed that the regulatory requirements of the Act are not out of step with the legislative and regulatory requirements which organisations face in respect of other corporate matters.

Recommendation 6.4: The Review does not recommend any change to the regulatory requirements in the Act.

10 Chapter 7: Interface with other Systems

Term of Reference 8:

8 Examine the interface between the Act and other Acts and schemes (either Australian Government or State and Territory) that regulate biodiscovery. Identify any discrepancies including regulatory gaps and areas needing consistency and harmonisation of provisions.

Interface between the Act and the Commonwealth Regulations

There is no regulatory overlap between the Act and the Regulations as they concern separate jurisdictions.

However, in accordance with the Nationally Consistent Approach, it was submitted that the Act be amended to provide confidence and legal certainty for investors and researchers. The primary differences are that, unlike the Act, the Commonwealth Regulations:

- apply to private land (see page 27 of this Report).
- consider traditional knowledge (see pages 31-33 of the Report).
- provide a permitting process to regulate non-commercial research (see Chapter 5 of this Report in relation to the structure and effectiveness of Collection Authorities under the Act).

Table 1 to this report is a comprehensive comparison of the relevant provisions of the Act and the Commonwealth Regulations.

The first 2 points above have been addressed earlier in this report.

In respect of the 3rd point, the Review does not consider it necessary to propose any amendments to the Act as permits for the purpose of non-commercial research are currently issued pursuant to alternative legislation (for example scientific purposes permit under the *Nature Conservation Act 1992* (Qld)).

The Review has sought to address the issue of commercialisation which arises out of research which initially did not fall within the scope of the Act in Recommendation 5.12.

Interface between the Act and the NT Act

Similarly, there is no regulatory overlap between the Act and the NT Acts they concern separate jurisdictions.

There are some differences between the Act and the Northern Territory legislation which are discussed above. In particular, as with the Commonwealth Regulations, the NT Act applies to private land (see page 27 of this Report) and includes a regime dealing with traditional knowledge (see pages 31-33 of this Report).

Table 2 to this document is a comprehensive comparison of the relevant provisions of the Act and the NT Act.

Where appropriate, these differences have been addressed earlier in this report.

> ***Recommendation 7.1 - The Review does not recommend any harmonisation between the Act and any other acts or schemes at this stage (pending the review of and continued monitoring of the movement towards an international regime and legislation in other states of Australia.***

11 Chapter 8: Changing Circumstances

Terms of Reference 9 and 10:

9 Examine emerging trends and international developments in biodiscovery and its regulation and whether the regulatory system stipulated by the Act is flexible enough to accommodate changing circumstances.

10 Recommend amendments to the Act, or alternatives to legislation, which improve the effectiveness, fairness, timeliness and accessibility of the regulatory system.

Consideration of Emerging Trends

Comments were made during the roundtable discussions about the increased trend for developing natural products in the future.

The Review was also informed of the potential to use the native biological material governed by the Act in respect of the following: the use of raw materials and extracts in food, nutraceutical formulations, cosmetic ingredients, other consumer products, and even industrial applications.

Other than already addressed in the recommendations in this Report (specifically the proposed amendment to the definition of *biodiscovery research* described in Recommendation 3.8), the submissions and information received by the Review did not reveal any concerns that the Act would be inflexible in the face of emerging technologies.

It was generally accepted that any peculiarities in the nature of use of the native biological material (to the extent it impacts the benefit sharing regime) would be able to be addressed through the negotiation of an appropriate benefit sharing regime between the relevant biodiscovery entity and the State.

Other than previously set out in earlier recommendations, the Review did not find any other innovative or appropriate approaches to improve the effectiveness, fairness, timeliness and accessibility of the regulatory system. Any possible improvements have been considered and addressed throughout the consideration of the other issues in this report.

With respect to the international context, the Review considered the developments in certain countries including the following:

- The Andean Community - The general approach of the Andean Community in relation to access, benefit sharing and genetic resources has been addressed elsewhere in this report (see also pages 30 and 31 of this Report);
- Canada - The Review's research has indicated that the Canadian governments are considering the development of policy to address access to genetic resources, the fair and equitable sharing of the benefits known as 'Access and Benefit Sharing' as well as traditional knowledge associated with genetic resources. In 2008, a Federal/Provincial/Territorial Task Group was established to examine the issue of 'Access and Benefit Sharing Policy' in Canada.

- Costa Rica - The Costa Rica Biodiversity Law (Law 7788 of May 1998) establishes general provisions and principles and an ownership regime for biological diversity. The Biodiversity Law concurrently recognises that private land owners, owners of biological resources, the Director of a conservation area and the Indigenous People territories can be granted ownership entitlements over biological resources.

- South Africa - The general approach of South Africa in relation to access, benefit sharing and genetic resources has been addressed elsewhere in this report. The National Environmental Management: Biodiversity Act was promulgated in 2004. Section 80 of that Act provides the purpose of chapter 6 entitled "Bioprospecting, Access and benefit-sharing" is to:

    - regulate bioprospecting involving indigenous biological resources;

    - regulate the export from the Republic of indigenous biological resources for the purposes of bioprospecting of any other kind of research; and

    - provide for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous biological resources.

The Review has previously recommended that international regime and other Australian state legislation be monitored to consider the impact of any developments on the operation and framework adopted by the Act.

The Review did not consider that the developments in the international regimes necessitated any amendments to the Act. The Review found that Queensland and Australia are well advanced in their consideration of issues relating to access and benefit sharing in the context of the international biodiversity community.

However, the Review considered it appropriate that a further review date be set for the Act to ensure it continues to address international, national and industry developments.

> ***Recommendation 8.1: The Review recommends that the Act be reviewed again, within five years, to accommodate emerging trends and international developments.***

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13 Table 1: Comparison of the Act to the Commonwealth Regulations

Part A: Equivalent provisions

Purposes				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
3	**3 Purposes of Act** (1) The main purposes of this Act are— (a) to facilitate access by biodiscovery entities to minimal quantities of native biological resources on or in State land or Queensland waters (**State native biological resources)** for biodiscovery; and (b) to encourage the development, in the State, of value added biodiscovery; and (c) to ensure the State, for the benefit of all persons in the State, obtains a fair and equitable share in the benefits of biodiscovery; and (d) to ensure biodiscovery enhances knowledge of the State's biological diversity, promoting conservation and sustainable use	8A.01	**8A.01 Purpose of Part 8A** For section 301 of the Act, the purpose of this Part is to provide for the control of access to biological resources in Commonwealth areas to which this Part applies by: (a) promoting the conservation of biological resources in those Commonwealth areas, including the ecologically sustainable use of those biological resources; and (b) ensuring the equitable sharing of the benefits arising from the use of biological resources in those Commonwealth areas; and (c) recognising the special knowledge held by Indigenous persons about biological resources; and (d) establishing an access regime designed to	The objectives listed in regulation 8A.01(c) to (f) in the Commonwealth Regulations do not have equivalent provisions in the Act, primarily because the Act excludes from its operation land over which native title granting rights of exclusive possession exists.

Purposes				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
	of native biological resources. (2) The purposes are achieved mainly by providing for— (a) the following streamlined frameworks— (i) a regulatory framework for taking and using State native biological resources, in a sustainable way, for biodiscovery; (ii) a contractual framework for benefit sharing agreements to be entered into with biodiscovery entities for the use, for biodiscovery, of State native biological resources; and (b) a compliance code and collection protocols for taking native biological material; and (c) the monitoring and enforcement of compliance with this Act.		provide certainty, and minimise administrative cost, for people seeking access to biological resources; and (e) seeking to ensure that the social, economic and environmental benefits arising from the use of biological resources in those Commonwealth areas accrue to Australia; and (f) contributing to a nationally consistent approach to access to Australia's biological resources. Note For the meaning of **Commonwealth area**, see the Act, section 525.	

Definitions				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
Schedule	**biodiscovery** means— (a) biodiscovery research; or (b) the commercialisation of native biological material or a product of biodiscovery research. **biodiscovery research** means the analysis of molecular, biochemical or genetic information about native biological material for the purpose of commercialising the material. **native biological material** means— (a) a native biological resource; or (b) a substance sourced, whether naturally or artificially, from a native biological resource; or (c) soil containing a native biological resource. **native biological resource** means— (a) a non-human living organism or virus Indigenous to Australia and sourced from State land or Queensland waters; or	8A.03	**8A.03 Meaning of access to biological resources** (1) In this Part: **access to biological resources** means the taking of biological resources of native species for research and development on any genetic resources, or biochemical compounds, comprising or contained in the biological resources (other than an activity mentioned in subregulation (3)). *Examples* Examples of **access to biological resources** include collecting living material or analysing and sampling stored material, for various purposes including taxonomic research, other research and potential commercial product development. Note For the meaning of **biological resources**, **genetic resources** and **native species**, see the Act, section 528. (2) A person is taken to have access to biological resources if there is a reasonable prospect that	Queensland: The Act is centred around the definition of 'biodiscovery'. Note that the Act utilises the term 'biodiscovery', the definition of which has two limbs. Both limbs embed a 'commercial' element, and a definition of commercialisation is provided (i.e. there is commercialisation where there is 'gain'). Also note that both limbs of the 'biodiscovery' definition are premised upon the presence of 'native biological material', which includes 'native biological resources', but does not explicitly include genetic resources or materials. Commonwealth: The instrumentality of the

Definitions				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
	(b) a living or non-living sample of the organism or virus.		biological resources taken by the person will be subject to research and development on any genetic resources, or biochemical compounds, comprising or contained in the biological resources. (3) The definition, **access to biological resources**, in subregulation (1) does not include the following activities: (a) the taking of biological resources by Indigenous persons: (i) for a purpose other than a purpose mentioned in subregulation (1); or (ii) in the exercise of their native title rights and interests; (b) access to human remains; (c) the taking of biological resources that have been cultivated or tended for a purpose other than a purpose mentioned in subregulation (1);	Commonwealth Regulations is centred around the definition of 'access to biological resources', which does include genetic resources. The Act's definition of 'biodiscovery' is similar to the Commonwealth's definition of 'access to biological resources', but the fundamental difference is that the Commonwealth's definition does not include a 'commercial' element. The example given in the Regulations specifically refers only to 'potential commercial development'.
Schedule	***State land*** means all land in Queensland that is not—	8A.04	**8A.04** Meaning of access provider	In the Act, the State is always the party that grants access to biological resources, as it

Definitions				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
	(a) freehold land owned by a person other than the State or an entity representing the State or owned by the State; or (b) land, including land in a freeholding lease as defined under the *Land Act 1994*, contracted to be granted in fee-simple by the State to a person other than the State or an entity representing the State or owned by the State; or (c) land subject to a native title determination granting rights of exclusive possession.	8A.02	(1) In this Part: access provider, for biological resources in a Commonwealth area to which this Part applies, means the following: (a) if the area is land owned by the Commonwealth — the Commonwealth; (b) if the area is land owned by a Commonwealth agency — the Commonwealth agency; (c) if the area is land held under lease by the Commonwealth or a Commonwealth agency and is Indigenous people's land — the owner of the land; (d) if the area is land held under lease by the Commonwealth and is not Indigenous people's land — the Commonwealth; (e) if the area is land held under lease by a Commonwealth agency and is not Indigenous people's land — the Commonwealth agency; (f) if the area is land in an external Territory (except Norfolk Island) or in the Jervis Bay	operates over only State land. Therefore Indigenous land and private land are excluded. However, in the Commonwealth Regulations, the access provider may be the Commonwealth or another party, depending on who owns or controls access to the land. The Commonwealth Regulations also specifically remove 'the taking of biological resources by Indigenous persons' from the ambit of the definition of 'access to biological resources' if native title rights have been recognised. Note that the definition of 'Access Provider' encompasses Native Title Holders and Indigenous Owners of the land, but not private land owners. There is a provision for multiple Access Providers for the one piece of land.

Definitions				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
			Territory, and is not land to which paragraph (a), (b), (c), (d) or (e) applies — the Commonwealth; (g) if the area is a Commonwealth marine area — the Commonwealth; (h) if the area is any other area of land, sea or seabed that is included in a Commonwealth reserve — the Commonwealth; (i) if native title exists in relation to the area — the native title holders for the area. Note There may be more than one access provider for biological resources. For example, if native title exists in relation to a Commonwealth area, the Commonwealth (or Commonwealth agency) and the native title holders are both access providers. (2) A reference to land in subregulation (1) includes a reference to airspace over the land. Note A Commonwealth marine area includes areas of airspace and seabed relating to the area — see the definition of Commonwealth marine area in section 24 of the Act.	

Definitions				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
			8A.02 Application of Part 8A to Commonwealth areas This Part applies to Commonwealth areas but does not apply to land leased by the Commonwealth or a Commonwealth agency unless the Commonwealth or the Commonwealth agency that holds the lease also holds a usage right in relation to the land that entitles the lessee to control access to the biological resources in and on the land. Note 1 For the meaning of Commonwealth area, see the Act, section 525. Note 2 Access to biological resources in Commonwealth reserves must be in accord with provisions of the Act and these Regulations dealing with Commonwealth reserves. **Section 525 *Environment Protection and Biodiversity Conservation Act 1999* (Cth) Commonwealth areas** *What is a Commonwealth area?*	

Definitions				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
			(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	

Definitions				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
			above those waters; (g) any other area of land, sea or seabed that is included in a Commonwealth reserve. *Territory Land in 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 NT 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*	

Definitions				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
			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).	
Schedule	**benefits of biodiscovery** include— (a) any economic, environmental or social benefits for the State, including the following— (i) investment in any of the following— (A) State-based biotechnology industry; (B) State-based entities; (C) research and development infrastructure in the State; (ii) the transfer of technology to State-based entities; (iii) the creation of employment in the State; (iv) the formation of collaborative agreements		**Nil equivalent**	The 'benefits of biodiscovery' under the Act reflect the types of benefits outlined in Appendix II to the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation.* While the Commonwealth Regulations provide for benefits to be outlined in the benefit-sharing agreement, there are no examples provided of the types of benefits that could be included.

Definitions				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
	with State-based entities; (v) the conduct of biodiscovery research involving field and clinical trials in the State; (vi) the undertaking of commercial production, processing or manufacturing of native biological material in the State; (vii) the creation of alternative crops or industries in the State;			
Schedule	**commercialisation**, of native biological material— 1 Commercialisation, of native biological material, means using the material in any way for gain. 2 The term does not include using the material to obtain financial assistance from a State or the Commonwealth, including, for example, a government grant. **commercialisation activities** means activities carried out for commercialising native biological material.		**Nil equivalent**	The Commonwealth Regulations acknowledge the difference between commercial and non-commercial purposes, but donot elaborate on commercialisation as part of the access to biological resources process.

Permits and Application Procedure				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
10	**10 What collection authority authorises** Subject to section 17, a collection authority authorises its holder to take minimal quantities of stated native biological material from, on or in, State land or Queensland waters, and keep the material, for biodiscovery.	8A.06	**8A.06 Access to biological resources requires permit** (1) A person may have access to biological resources in a Commonwealth area to which this Part applies only in accordance with a permit in force under Part 17. Penalty: 50 penalty units. Note The Minister may issue a permit only if the applicant has given the Minister a copy of each benefit-sharing agreement required in relation to the application — see paragraph 17.03A (6) (a). (2) Subregulation (1) does not apply to a person in relation to biological resources that are in a Commonwealth area for which the person is an access provider.	Queensland: The permit required for biodiscovery in Queensland is termed a 'collection authority'. Commonwealth: The permit required for 'access to biological resources' is termed a 'permit in force under Part 17'.
11	**11 Procedural requirements for application** (1) An application for a collection authority	8A.06	**Regulation 8A.06** points to Part 17 of the Act. See the Note in 8A.06: Note The Minister may issue a permit only if	Queensland: There are four key requirements for an application for a 'Collection Authority':

Permits and Application Procedure				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
	must be— (a) made to the EPA chief executive in the approved form; and (b) supported by sufficient information to enable the chief executive to decide the application; and (c) accompanied by each of the following— (i) the application fee prescribed under a regulation; (ii) the registration fee prescribed under a regulation; (iii) any other document, identified in the approved form, the chief executive reasonably requires for deciding the application. (2) The application must also be accompanied by a copy of the applicant's proposed or approved biodiscovery plan. (3) Subsection (2) does not apply if, before the commencement of the subsection, the		the applicant has given the Minister a copy of each benefit-sharing agreement required in relation to the application — see paragraph 17.03A (6) (a). **Division 8A.4 Assessment of applications** **8A.15 Assessment by Minister** (1) In assessing an application for a permit, the Minister may consult any Commonwealth Department, any Commonwealth agency or any other person that may have information relevant to the application. (2) If the application is for access to biological resources for commercial purposes, the Minister: (a) must take into account the extent to which the requirements of regulation 8A.08 have been met by the benefit-sharing agreement; and (b) must consider whether all the other	• 'Approved Form' [see section 11(1)(a); this points to section 12]. • 'Sufficient Information' [see section 11(1)(b)] • Applicable fees [sections 11(1)(c)(i)-(ii)] • A proposed or approved biodiscovery plan [see section 11(2)]. Note that in Queensland, a Benefit-Sharing Agreement does not need to be in force in order to issue a 'Collection Authority'. However, under section 17 a Collection Authority is not to be used for the carrying out of biodiscovery (notwithstanding it having been issued) unless a benefit-sharing agreement has been entered into. Pursuant to section 16, a Collection

Permits and Application Procedure				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
	applicant entered into an agreement with the State— (a) concerning the activity the subject of the application; and (b) providing for the matters mentioned in sections 33(1) and 34. (4) Information in the application must, if the approved form requires, be verified by a statutory declaration. **12 Content of approved form** (1) The approved form for the application must provide for the inclusion of each of the following— (a) the applicant's name and, if the applicant is not an individual, the applicant's ACN or ABN; (b) the applicant's place of business; (c) an appropriate description of the State		requirements of Division 8A.2 have been met. (3) If the application is for access to biological resources for non-commercial purposes, the Minister must consider whether the requirements of Division 8A.3 have been met. **8A.16 Assessment of environmental impact** (1) This regulation applies to an application for a permit to which paragraph 17.01 (ab) applies if the proposed access is not a controlled action. Note For the meaning of **controlled action**, see the Act, section 67. (2) The application must be assessed by public notice if the Minister believes, on reasonable grounds, that the proposed access to biological resources is likely to have more than negligible environmental impact. (3) After all the documents required to consider an application have been received by the Minister and the application is required to be	Authority lapses if a Benefit-Sharing Agreement has not been entered into within 1 year of the issuing of the Collection Authority. Sections 16 and 17 of the Act have the broad consequence that the Queensland permit (the 'collection authority') operates in broadly the same way as the Commonwealth permit. <u>Commonwealth:</u> In contrast to the Queensland position, a permit is only able to be issued if a benefit-sharing agreement(s) is in place. A distinction is drawn between applications for a permit for 'commercial purposes' [see regulation 8A.15(2)] and applications for a permit for 'non-commercial purposes' [see 8A.15(3)]. The Commonwealth Regulations are less prescriptive than the Act as to the content of an application for a permit, but does include a public notice for

Permits and Application Procedure				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
	land or Queensland waters to which the application relates; Example— the real property description or geographic coordinates of the land or waters (d) a description of the type of material, proposed to be taken under the collection authority, of sufficient detail to enable the material to be identified for deciding the application; (e) the material's scientific classification, to the extent known by the applicant; (f) the period for which the collection authority is sought. (2) The approved form may include requirements for the description mentioned in subsection (1)(d). **13 Chief executive's powers before**		assessed by public notice: (a) the Minister must tell the applicant, within 20 business days after receiving all the required documents, that the application is required to be assessed by public notice; and (b) the applicant must give the Minister a summary of the likely environmental impacts of the proposed access; and (c) within 10 business days after receiving the summary, the Minister must: (i) publish on the Internet a notice inviting any person to comment on the likely environmental impacts of the proposed access within a specified time (which must be at least 10 business days); and (ii) invite each person registered under regulation 8A.17 to give comments to the Minister within a specified time (which must be at least 10 business days); and (iii) publish on the Internet any documents relevant to public consideration of the proposed access and its environmental	assessment for controlled actions where there may be more than 'negligible' environmental impact. There is no requirement for a biodiscovery plan per se, however the elements included in a biodiscovery plan are covered in substance in the Commonwealth Regulations (see below for discussion).

Permits and Application Procedure				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
	deciding application (1) Before deciding the application, the EPA chief executive may, by written notice given to the applicant, ask for any further information or document the chief executive reasonably requires to decide the application. (2) The notice must state a reasonable period of at least 20 business days after it is given (the **stated period**) within which the information or document must be given. (3) The chief executive may require the information or document to be verified by a statutory declaration. (4) The applicant is taken to have withdrawn the application if the applicant does not comply with the requirement within the stated period. (5) A notice under subsection (1) must be given to the applicant within 20 business days after the chief executive receives the application.		impact; and (d) within 5 business days after the end of the period allowed by the invitation for comments, the Minister must give the applicant a copy of any comments received by the Minister. (4) The applicant must give the Minister a copy of any response the applicant wishes to make to any comments received. **8A.17 Register for consultation when assessment by public notice is required** (1) At intervals of not more than 12 months, the Minister must publish a notice inviting applications from persons who want to be registered, for a specified period of at least 12 months, to be told of applications to which subregulation 8A.16 (2) applies. (2) The notice must be published: (a) in the Gazette; and (b) on the Department's website,	

Permits and Application Procedure				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
	14 Deciding application (1) The EPA chief executive must consider the application and decide— (a) to grant the application, with or without conditions decided by the chief executive;3 or (b) to refuse the application. (2) The chief executive may grant the application only if the chief executive is satisfied of each of the following— (a) the proposed taking and use of the native biological material— (i) is for biodiscovery only; and (ii) conforms with the compliance code and any applicable collection protocols, to the extent the code and protocols are consistent with the conditions the chief executive proposes imposing under		www.deh.gov.au; and (c) in a daily newspaper that circulates throughout Australia. (3) The Minister must register any person who applies in writing for registration. (4) Registration has effect for the period specified in the notice.	

Permits and Application Procedure				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
	subsection (1)(a); (b) other matters prescribed under a regulation for achieving the purposes of this Act. (2A) Also, if the application relates to State land that is a State plantation forest under the Forestry Plantations Act 2006, the chief executive may approve the application only if the chief plantation forestry officer has approved the granting of the application. (3) Subsection (2) does not limit the matters to which the chief executive may have regard in deciding the application. (4) The chief executive may refuse the application even if a benefit sharing agreement or approved biodiscovery plan is in force concerning the material the subject of the application. (5) In this section— **chief plantation forestry officer** means the chief plantation forestry officer under the			

Permits and Application Procedure				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
	Forestry Plantations Act 2006. **16 Term of collection authority** (1) A collection authority is given for the term stated in the authority. (2) The term must not be more than 3 years. (3) The authority expires at the end of the term. (4) Despite subsections (1) and (3), the authority lapses 1 year after it is issued if a benefit sharing agreement concerning the native biological material the subject of the authority is not entered into within the 1 year period. **17 Conditions of collection authority** (1) It is a condition of a collection authority that the holder, or a person acting for the holder, must not take native biological			

Permits and Application Procedure				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
	material under the authority unless a benefit sharing agreement concerning the material is in force. (2) To the extent the provisions of the compliance code or a collection protocol are applicable to the activities carried out under a collection authority, the provisions are conditions of the authority. (3) The conditions imposed by the chief executive under section 14(1)(a) (the **section 14 conditions**) are conditions of the authority. (4) If there is an inconsistency between a condition mentioned in subsection (2) and a section 14 condition, the section 14 condition prevails to the extent of the inconsistency. **18 Collection authority** A collection authority must be in the approved form and state each of the following—			

Permits and Application Procedure				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
	(a) its number; (b) its issue date; (c) its expiry date; (d) the section 14 conditions for the authority; (e) the holder's name and, if the holder is not an individual, the holder's ACN or ABN; (f) the holder's place of business; (g) the type of native biological material that may be taken; (h) the material's scientific classification, to the extent known by the applicant; (i) the area from which the material may be taken.			

Benefit-Sharing Agreements				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
Part 5	**Division 1 Entering into agreement** **33 Power to enter into agreement** (1) The DSDI Minister may, for the State, enter into an agreement (a **benefit sharing agreement**) with a biodiscovery entity under which— (a) the State gives the entity the right to use native biological material for biodiscovery; and (b) the entity agrees to provide benefits of biodiscovery to the State. (2) The Minister must not enter into a benefit sharing agreement with a biodiscovery entity unless the entity has an approved biodiscovery plan. (3) The parties to a benefit sharing agreement may, at any time, amend the agreement. (4) The Minister may delegate the Minister's powers under this section to the DSDI chief executive.	Division 8A.2	**Division 8A.2 Access to biological resources for commercial purposes or potential commercial purposes** **8A.07 Benefit-sharing agreement required** (1) An applicant for a permit for access to biological resources for commercial purposes or potential commercial purposes in a Commonwealth area to which this Part applies must enter into a benefit-sharing agreement with each access provider for the resources. Note 1 There may be more than one access provider for biological resources — see subregulation 8A.04 (1). Note 2 Since benefit-sharing agreements under this Division may purport to affect native title rights and interests in relation to land or water, applicants need to be aware of the provisions of the Native Title Act 1993 and the availability of Indigenous land use agreements under Division 3 of Part 2 of that Act as a means to validate actions that may otherwise be construed to be invalid future acts by that Act.	<u>Queensland:</u> There are three key points to note: • Under section 33(2), a BSA cannot be entered into unless a biodiscovery plan has first been approved. • Under section 34(2)(c), a BSA must acknowledge the benefits that the State will receive. • Under section 35(1), the biodiscovery plan becomes the basis of the BSA in so far as the commercial endeavours that an entity can undertake under the agreement are limited to those as stipulated in the biodiscovery plan (as the commercial activities listed in the plan become a condition of the agreement).

Benefit-Sharing Agreements				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
	34 Content of agreement (1) A benefit sharing agreement must be consistent with this Act. (2) The agreement must state each of the following— (a) the date the agreement is entered into; (b) the agreement's term; (c) the benefits of biodiscovery to be provided by the biodiscovery entity to the State; (d) when the benefits are to be provided; (e) if the benefits include the payment of amounts of money to the State—the amounts, or a way of working out the amounts; (f) if native biological material, the subject of the agreement, is to be taken under a collection authority—the number, or other identification, of each authority under which the material is to be		(2) If an access provider is the Commonwealth, the Secretary of the Commonwealth Department with administrative responsibility for the Commonwealth area may, on behalf of the Commonwealth, enter into the benefit-sharing agreement. (3) An agreement may be both a benefit-sharing agreement, if it complies with this Division, and an Indigenous land use agreement within the meaning of the Native Title Act 1993. (4) The Minister may publish in the Gazette a model benefit-sharing agreement as a guide for applicants. **8A.08 Benefit-sharing agreements** A benefit-sharing agreement must provide for reasonable benefit-sharing arrangements, including protection for, recognition of and valuing of any Indigenous people's knowledge to be used, and must include the following: (a) full details of the parties to the agreement; (b) details regarding the time and frequency of	<u>Commonwealth:</u> There are several points to note: • Under regulation 8A.07(1), if commercial purposes exist and are the basis for applying for a permit to obtain biological resources, then an applicant for the permit must sign with the access provider (usually the Commonwealth) a benefit-sharing agreement. • Note that under the Commonwealth Regulations, the commercial limb that underpins the need for a BSA in the context of 'access to biological resources' (i.e. the key definition in the Commonwealth Regulations) arises here under Division 8A.02 and not under the definition of 'access to

Benefit-Sharing Agreements				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
	taken; (g) what matters are reportable matters for the agreement; (h) the biodiscovery entity's place of business. (3) The agreement must also include any conditions, other than the conditions mentioned in section 35(1) and (2), of the agreement. **35 Conditions of agreement** (1) It is a condition of a benefit sharing agreement that the only commercialisation activities the biodiscovery entity, with whom the agreement is made, may carry out are the activities detailed in the entity's current approved biodiscovery plan.5 (2) It is also a condition of the agreement that the entity must not allow someone else to use any of the native biological material the subject of the agreement for biodiscovery, unless the other person is—		entry to the area that has been agreed to be granted; the resources (including the name of the species, or lowest level of taxon, to which the resources belong, if known) to which access has been agreed to be granted and the quantity of the resources that has been agreed can be collected; (d) the quantity of the resources that has been agreed can be removed from the area; (e) the purpose of the access, as disclosed to the access provider; (f) a statement setting out the proposed means of labelling samples; (g) the agreed disposition of ownership in the samples, including details of any proposed transmission of samples to third parties; (h) a statement regarding any use of Indigenous people's knowledge, including details of the source of the knowledge, such as, for example, whether the knowledge was obtained from scientific or other public documents, from the access provider or from another group of	biological resources'. Contrast the position in Queensland where the commercial limb is embedded in the definition of 'biodiscovery' (which equates broadly with the Commonwealth's 'access to biological resources'). • Under regulation 8A.07(3) a benefit-sharing agreement may also serve as an 'Indigenous land use agreement' under the *Native Title Act 1993* (Cth). This is not provided for in Act. • Regulation 8A.07(4) provides for a model benefit-sharing agreement to be published. This is not provided for in Act. • Under 8A.08, numerous references are made to the

Benefit-Sharing Agreements				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
	(a) acting for the entity; or (b) a person mentioned in section 54(2)(a), (b) or (c) or (3); or (c) a party to a benefit sharing agreement concerning the material. (3) Subsections (1) and (2) do not limit any other conditions that may be included in the agreement under section 34(2).		Indigenous persons; (i) a statement regarding benefits to be provided or any agreed commitments given in return for the use of the Indigenous people's knowledge; (j) if any Indigenous people's knowledge of the access provider, or other group of Indigenous persons, is to be used, a copy of the agreement regarding use of the knowledge (if there is a written document), or the terms of any oral agreement, regarding the use of the knowledge; (k) the details of any proposals of the applicant to benefit biodiversity conservation in the area if access is granted; (l) details of the benefits that the access provider will receive for having granted access. **8A.09 Consultation with owners of leased land** If the land, or part of the land, that is the subject of an application for access to biological resources is land held under lease by the Commonwealth or a Commonwealth agency (including land leased in Norfolk Island by the	need to recognise/protect/value Indigenous 'knowledge' in the formation of Benefit-sharing agreements – see the intro paragraph in regulation 8A.08, and then (h),(i) and (j). Such provisions are not present in the Act. • Also note how Indigenous rights are further entrenched by the requirement of 'informed consent' under regulation 8A.09 if the access provider is Indigenous. • Regulation 8A.08(g) provides that a benefit-sharing agreement must stipulate how the ownership in samples of biological resources is to be allotted. Note that such details are absent in the Act – which

Benefit-Sharing Agreements				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
			Commonwealth or a Commonwealth agency), each access provider must consult with the owner of that land before entering into a benefit-sharing agreement. **8A.10 Informed consent** (1) If the biological resources to which access is sought are in an area that is Indigenous people's land and an access provider for the resources is the owner of the land or a native title holder for the land, the owner or native title holder must give informed consent to a benefit-sharing agreement concerning access to the biological resources. (2) In considering whether an access provider has given informed consent to a benefit-sharing agreement, the Minister must consider the following matters: (a) whether the access provider had adequate knowledge of these Regulations and was able to engage in reasonable negotiations with the applicant for the permit about the benefit-sharing agreement; (b) whether the access provider was given	only refers to 'benefits' generally under section 34(2)(c).

Benefit-Sharing Agreements				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
			adequate time: (i) to consider the application for the permit, including time to consult with relevant people; and (ii) if the biological resources are in an area that is Indigenous people's land and an access provider for the resources is the owner of the land, to consult with the traditional owners of the land; and (iii) to negotiate the benefit-sharing agreement; (c) if the biological resources are in an area that is Indigenous people's land and an access provider for the resources is an owner of the land and is represented by a land council — whether the views of the land council about the matters mentioned in paragraphs (a) and (b) have been sought; (d) if access is sought to the biological resources of an area in relation to which native title exists — the views of any representative Aboriginal/Torres Strait Islander body or any body performing the functions of a	

Benefit-Sharing Agreements				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
			representative body, within the meaning of the Native Title Act 1993, for the area about the matters mentioned in paragraphs (a) and (b); (e) whether the access provider has received independent legal advice about the application and the requirements of these Regulations. (3) The Minister may be satisfied that informed consent has been given by any native title holders who may be affected by the issue of a permit if the benefit-sharing agreement: (a) is a registered Indigenous land use agreement, under the Native Title Act 1993, for the area; and (b) authorises the action proposed to be taken under the permit; and (c) sets out the native title holders' consent to the issue of the permit. Note The requirements relating to Indigenous land use agreements are set out in Part 2, Division 3 of the Native Title Act 1993.	

Benefit-Sharing Agreements				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
			8A.11 Requirement for permit A benefit-sharing agreement takes effect only if a permit for the proposed access is issued under Part 17.	

Non-commercial purposes				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
Part 7 Division 2	**Division 2 Offences about benefit sharing agreements** **50 Offence to take without a collection authority** (1) A person must not, unless authorised by a collection authority, take native biological material for biodiscovery from State land or Queensland waters. Maximum penalty— (a) for NCA material—3000 penalty units or 2 years imprisonment; or (b) otherwise—2000 penalty units.		**Division 8A.3 Access to biological resources for non-commercial purposes** **8A.12 Written permission of access provider required** (1) An applicant for a permit for access to biological resources for non-commercial purposes in a Commonwealth area to which this Part applies must obtain the written permission of each access provider for the resources to: (a) enter the Commonwealth area; and (b) take samples from the biological resources of	<u>Queensland:</u> Under the Act, biodiscovery for specific non-commercial purposes does not require a benefit-sharing agreement. The two principle exemptions from the relevant offence are: • Section 54(2)(a) – classification of scientific material (which is inherently non-commercial). • Section 54(3)(a) – an

Non-commercial purposes				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
	(2) In this section— **NCA material** means— (a) native biological material that is, or is sourced from, endangered, rare or vulnerable wildlife, or a protected animal, within the meaning of the Nature Conservation Act 1992; or (b) native wildlife mentioned in section 97 of that Act. **54 Using native biological material for biodiscovery without a benefit sharing agreement** (1) A person must not, unless the person is a party to a benefit sharing agreement, use native biological material for biodiscovery, if the material was taken from— (a) State land or Queensland waters; or (b) a State collection, if the material was taken		the area; and (c) remove samples from the area. Note 1 There may be more than one access provider for biological resources — see subregulation 8A.04 (1). Note 2 Since a written permission of the kind mentioned in this regulation may purport to affect native title rights and interests in relation to land or water, applicants need to be aware of the provisions of the Native Title Act 1993 and the availability of Indigenous land use agreements under Division 3 of Part 2 of that Act as a means to validate actions that may otherwise be construed to be invalid future acts by that Act. (2) If an access provider is the Commonwealth, the Secretary of the Commonwealth Department with administrative responsibility for the Commonwealth area may, on behalf of the Commonwealth, give the written permission required under subregulation (1). (3) A written permission may be both a permission under subregulation (1), if it complies with this Division, and an Indigenous land use agreement	educational institution carrying out non-commercial research. While a benefit-sharing agreement is excluded through these exemptions, the relevant entity still needs a 'collection authority' in order to avoid committing an offence under section 50 ['Offence to take without a collection authority']. A 'proposed or approved biodiscovery plan' must be submitted with the application [s 11(2)] for the collection authority, even if the exemptions under section 54 apply. <u>Commonwealth:</u> The Regulations draw a distinction between applications for a permit for 'commercial purposes' [see regulation 8A.15(2)] and applications for a

Non-commercial purposes				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
	or sourced from State land or Queensland waters. Maximum penalty—the amount equal to the greater of the following— (a) 5000 penalty units; (b) the full commercial value of any commercialisation of the material. (2) However, subsection (1) does not apply to a person who uses the material for carrying out only 1 or more of the following activities— (a) classifying the material scientifically; (b) verifying research results concerning the material; (c) biodiscovery to which a benefit sharing agreement concerning the material applies, carried out for a person who is a party to the agreement. (3) Also, subsection (1) does not apply to the use by an educational institution, or a person at the institution, for educational or training		within the meaning of the Native Title Act 1993. **8A.13 Statutory declaration** An applicant for a permit for access to biological resources for non-commercial purposes in a Commonwealth area to which this Part applies must provide a copy of a statutory declaration given to each access provider declaring that the applicant: (a) does not intend to use the biological resources, to which the application relates, for commercial purposes; and (b) undertakes to give a written report on the results of any research on the biological resources to each access provider; and (c) undertakes to offer, on behalf of each access provider, a taxonomic duplicate of each sample taken to an Australian public institution that is a repository of taxonomic specimens of the same order or genus as those collected for permanent loan; and (d) undertakes not to give a sample to any person, other than an institution referred to in paragraph	permit for 'non-commercial purposes' [see regulation 8A.15(3)]. Note the requirement in regulation 8A.12's of a statutory declaration. Note particularly how (e) requires that if access to biological resources is going to invoke a commercial purpose, then a benefit-sharing agreement must be signed.

Non-commercial purposes				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
	activities not involving commercialisation of the material. (4) In this section— **educational institution** means— (a) a school, college, university or university college; or (b) a TAFE institute, a statutory TAFE institute or a registered training organisation as defined under the Vocational Education, Training and Employment Act 2000.		(c), without permission of each access provider; and (e) undertakes not to carry out, or allow others to carry out, research or development for commercial purposes on any genetic resources or biochemical compounds comprising or contained in the biological resources unless a benefit-sharing agreement has been entered into, in accordance with Division 8A.2, with each access provider. **8A.14 Requirement for permit** A written permission given under subregulation 8A.12 (1) takes effect only if a permit for the proposed access is issued under Part 17.	

Part B: Provisions for which there are no direct equivalents

Providing samples to the State - Act				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
Section 30	**30 Giving samples of material to State** (1) The holder of a collection authority must, as soon as practicable after taking native biological material for biodiscovery under the authority, give a sample of the material, complying with subsection (3), to the following— (a) for animal material—the Queensland Museum (the *receiving entity*); (b) for plant material or fungi—the Queensland Herbarium (also the *receiving entity*); (c) for another organism—an entity (also the *receiving entity*) stated in the benefit sharing agreement concerning the material. Maximum penalty—50 penalty units.		**Nil direct equivalent**	The Act has a requirement that samples always be provided to the appropriate 'receiving entity' (either the Queensland Museum or the Queensland Herbarium), ensuring that the State retains a comprehensive collection of all samples taken. The Regulations have no such requirement, only that an applicant for a permit must undertake to offer a sample to an Australian public institution that is a repository of similar specimens (regulation 8A.13(c)).

Biodiscovery Plan - Act				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
Division 2	**Division 2 Approval of biodiscovery plans** **36 Application for approval of plan** (1) A biodiscovery entity may apply to the DSDI chief executive for approval of a biodiscovery plan. (2) The application must be made in the approved form. (3) The approved form must provide for inclusion of the details mentioned in section 37. **37 Content of plan** A biodiscovery entity's biodiscovery plan must include details of each of the following— (a) the commercialisation activities the entity proposes carrying out; (b) a proposed timetable for carrying out the activities; (c) the parts of any of the activities the entity		**Nil direct equivalent**	Queensland: The key provision is found in section 39(2) which highlights that a biodiscovery plan can only be approved if the State will attract sufficient benefit through the biodiscovery. Commonwealth: Although there is no equivalent 'biodiscovery plan' per se in the Commonwealth Regulations, regulation 8A.08 (which sets out the contents of a benefit-sharing agreement) is broad enough to encompass the requirements of both sections 34 ('Content of Agreement') and 37 ('Content of Plan'). In fact, regulation 8A.08 is broader in so far as it provides for the recognition/protection/valuation of Indigenous knowledge, etc (see above).

Biodiscovery Plan - Act				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
	proposes carrying out outside the State; (d) the types of any of the activities the entity proposes engaging someone else to carry out for the entity; (e) the benefits of biodiscovery the entity reasonably considers it will provide to the State under a benefit sharing agreement; (f) if the entity is not prohibited from disclosing the details under another law or contract—any grants or other financial assistance given, or to be given, to the entity for the activities; (g) other details prescribed under a regulation. **38 Chief executive's powers before deciding application** (1) Before deciding the application, the DSDI chief executive may, by written notice given to the applicant, ask for any further information or document the chief executive reasonably requires to decide the application.			In both Queensland and the Commonwealth a benefit-sharing agreement needs to be in place before the particular licence can be used to collect biological samples.

Biodiscovery Plan - Act				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
	(2) The notice must— (a) be given to the applicant within 20 business days after the chief executive receives the application; and (b) state a reasonable period of at least 20 business days after it is given (the **stated period**) within which the information or document must be given. (3) The chief executive may require the information or document to be verified by a statutory declaration. (4) The applicant is taken to have withdrawn the application if the applicant does not comply with the requirement within the stated period. **39 Deciding application** (1) The DSDI chief executive must consider the application and decide— (a) to approve the biodiscovery plan, with or			

Biodiscovery Plan - Act				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
	without conditions; or (b) to refuse to approve the plan. (2) However, the chief executive may approve the plan only if the chief executive is satisfied with the proposed level of benefits of biodiscovery the State will receive under a benefit sharing agreement with the applicant. **40 Steps to be taken after application decided** (1) If the DSDI chief executive decides to approve the biodiscovery plan, the chief executive must, as soon as practicable after making the decision, give the applicant written notice of the approval. (2) If the chief executive decides to impose conditions on the approval, the notice must include an information notice about the decision. (3) If the chief executive decides to refuse to approve the plan, the chief executive must, as soon as practicable after making the decision,			

Biodiscovery Plan - Act				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
	give the applicant an information notice about the decision. (4) If the chief executive does not give the applicant a notice as required under subsection (1) or (3) within 20 business days after receiving the application, the chief executive is taken to have approved the plan. (5) In this section— **information notice**, about a decision, means a written notice stating each of the following— (a) the decision; (b) the reasons for the decision; (c) that the biodiscovery entity may ask the DSDI Minister to review the decision. **41 Amendment of approved plan** (1) If a biodiscovery entity wants to amend its approved biodiscovery plan, the entity must apply, in the approved form, to the DSDI chief			

Biodiscovery Plan - Act				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comments**
	executive for approval of the amended plan. (2) Sections 37 to 40 apply to the application as if it were an application for approval of the existing plan as amended by the proposed amendment.			

Exemption by declaration - Commonwealth				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
	Nil equivalent	8A.05	**8A.05 Exemption for specified biological resources or collections** (1) The Minister may declare that this Part does not apply to specified biological resources or a specified collection of biological resources (including future additions to the collection) if: (a) the resources are held as specimens away from their natural environment (whether in a collection or otherwise) by a Commonwealth Department or Commonwealth agency and there are reasonable grounds to believe that access to the biological resources is administered by the Department or	In addition to having permits for non-commercial purposes, the Regulations also allow the Minister to give specific exemptions. There is no equivalent in the Act.

Exemption by declaration - Commonwealth				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
			agency in a manner that is consistent with the purpose of this Part; or (b) there are reasonable grounds to believe that: (i) access to the resources is controlled by another Commonwealth, self-governing Territory or State law; and (ii) if the declaration is made — access to the resources would be in a manner that is consistent with the purpose of this Part; or (c) use of the resources is required to be controlled under any international agreement to which Australia is a party. *Example* The International Treaty on Plant Genetic Resources for Food and Agriculture, to which Australia is a signatory, obliges signatories to control access to the genetic resources of some foods in some circumstances. (2) A holder of biological resources to which paragraph (1) (a) applies may request the Minister, in writing, to make a declaration under subregulation (1).	

Exemption by declaration - Commonwealth				
Section	**Act**	**Reg**	**Commonwealth Regulations**	**Comment**
			(3) A declaration under paragraph (1) (b) or (c) may provide that this Part does not apply to the biological resources in specified circumstances. (4) A declaration under subregulation (1) must be published in the Gazette.	

14 Table 2: Comparison of the Act to the Northern Territory Legislation

Part A: Equivalent provisions

Definitions				
Section	**Act**	**Section**	**NT Act**	**Comments**
Schedule Dictionary Section 33(1)	***benefit sharing agreement*** *see section 33(1).* *The DSDI Minister may, for the State, enter into an agreement (a* ***benefit sharing agreement****) with a biodiscovery entity under which—* *(a) the State gives the entity the right to use native biological material for biodiscovery; and* *(b) the entity agrees to provide benefits of biodiscovery to the State.*	Part 4 Section 29(1)	*A benefit-sharing agreement must provide for reasonable benefit-sharing arrangements, including protection for, recognition of and valuing of any Indigenous people's knowledge to be used*	The NT Act has multiple provisions that require recognition and protection for Indigenous people's knowledge.
Schedule Dictionary	***benefits of biodiscovery*** *include—* *(a) any economic, environmental or social*	Section 4(3)	*A resource has value for humanity if an extract or compound derived from the resource is used, directly or indirectly, with*	The 'benefits of biodiscovery' under the Act reflects the types of benefits outlined in Appendix II to the *Bonn*

Definitions				
Section	**Act**	**Section**	**NT Act**	**Comments**
	benefits for the State, including the following— *(i) investment in any of the following—* *(A) State-based biotechnology industry;* *(B) State-based entities;* *(C) research and development infrastructure in the State;* *(ii) the transfer of technology to State-based entities;* *(iii) the creation of employment in the State;* *(iv) the formation of collaborative agreements with State-based entities;* *(v) the conduct of biodiscovery research involving field and clinical trials in the State;* *(vi) the undertaking of commercial production, processing or manufacturing of native biological material in the State;* *(vii) the creation of alternative crops or*		*advantage in any field of human endeavour, whether agricultural, industrial, veterinarian, pharmaceutical or other.*	*Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation.* The NT Act has a less descriptive approach with the concept of 'value for humanity'.

Definitions				
Section	**Act**	**Section**	**NT Act**	**Comments**
	industries in the State; *(viii)improved knowledge of the State's biological diversity or natural environment; and* *(b) the payment of amounts of money to the State.*			
Schedule Dictionary	***biodiscovery** means—* *(a) biodiscovery research; or* *(b) the commercialisation of native biological material or a product of biodiscovery research.*	Section 4 (1) Section 5	*"biodiscovery" means research on samples of biological resources, or extracts from those samples, to discover and exploit genetic or biochemical resources of actual or potential value for humanity* *Meaning of bioprospecting* *(1) Bioprospecting is the taking of samples of biological resources, existing in situ or maintained in an ex situ collection of such resources, for research in relation to any genetic resources, or biochemical compounds, comprising or contained in the biological resources.* *(2) However, the following activities do not constitute bioprospecting:*	The Act places a focus on profit or commercialisation - NT Act is more broad with 'value for humanity' and provision for non-monetary consideration and benefit. The Act treats 'biodiscovery' as both the research and the taking of the sample for the research. The NT Act treats the research ('biodiscovery') as separate to the taking ('bioprospecting'). The NT Act has a long list of what is *not* considered to be 'bioprospecting'

Definitions				
Section	**Act**	**Section**	**NT Act**	**Comments**
			(a) taking biological resources from an area of land or water by Indigenous people who have traditionally used the area of land or water in accordance with Aboriginal tradition for hunting, food gathering (other than for sale) and for ceremonial and religious purposes; *(b) dealing with any biological material of human origin;* *(c) taking samples of biological resources that have been cultivated or tended for a purpose other than biodiscovery and where the samples are not to be used for biodiscovery;* *(d) taking samples of biological resources specified in a declaration under section 10;* *(e) taking samples of biological resources that are available to the public on an unrestricted basis (whether on commercial or non-commercial terms);* *(f) taking samples of a biological resource*	for the purposes of the Act and is mindful of the Indigenous population's traditional cultural activities.

Definitions				
Section	**Act**	**Section**	**NT Act**	**Comments**
			that is: *(i) a genetically modified organism for the purposes of section 10 of the Gene Technology Act 2000 (Cth); or* *(ii) a plant variety for which a Plant Breeder's Right has been granted under section 44 of the Plant Breeder's Rights Act 1994 (Cth);* *(g) taking aquatic life, within the meaning of the Fisheries Act, that:* *(i) has been caught, taken or harvested under a licence or permit granted under that Act (other than a permit granted under section 17 of the Fisheries Act for bioprospecting); or* *(ii) comprises a managed fishery or part of a managed fishery within the meaning of that Act.* *(3) The following activities, if undertaken for a purpose other than biodiscovery, also do not constitute bioprospecting:*	

Definitions				
Section	**Act**	**Section**	**NT Act**	**Comments**
			(a) fishing for commerce or recreation, game or charter fishing or collecting broodstock for aquaculture; *(b) harvesting wildflowers;* *(c) taking wild animals or plants for food;* *(d) collecting peat or firewood;* *(e) taking essential oils from wild plants;* *(f) collecting plant reproductive material for propagation;* *(g) commercial forestry.* *(4) In subsection (1):* *"ex situ collection" means a collection of physical samples of genetic resources that have been previously obtained from an in situ location and which are preserved or maintained in a location external to the in situ location;* *"in situ" means the location in which genetic*	

Definitions				
Section	**Act**	**Section**	**NT Act**	**Comments**
			resources exist within ecosystems and natural habitats within the Territory.	
Schedule Dictionary	***biodiscovery entity*** *means an entity that engages in biodiscovery.*	Section 4 (1)	*"bioprospector" means a person engaged in bioprospecting;*	
Schedule Dictionary	***biodiscovery plan*** *means a plan, complying with section 37, about a biodiscovery entity's proposed biodiscovery activities.*		**Nil direct equivalent**	The Queensland concept of the 'plan component' is included in the stated requirements of NT benefit-sharing agreement or approval process. This includes the requirements outlined in s37 (b), (d), and (e) Act: a proposed timetable for carrying out the activities, the types of any of the activities the entity proposes engaging someone else to carry out for the entity, the benefits of biodiscovery the entity reasonably considers it will provide to the State under a BSA.
		Section 15	**15. CEO may require further information** If the CEO considers the activities proposed in an application for a permit to take biological resources may comprise bioprospecting, the CEO may require further	In the NT Act, during the approval process, the CEO of the responsible agency *may* request extra material to support the application, which includes a plan for the research component (biodiscovery) which is proposed to be

Definitions				
Section	**Act**	**Section**	**NT Act**	**Comments**
			information from the applicant, including: (a) the biodiscovery activities the applicant proposes carrying out or that is proposed by a person who has engaged the applicant to collect biological resources; and (b) a proposed timetable for carrying out the activities; and (c) other details the CEO considers appropriate.	undertaken with the samples taken from the land (bioprospecting).
Schedule Dictionary	***biodiscovery research*** *means the analysis of molecular, biochemical or genetic information about native biological material for the purpose of commercialising the material.*	Section 4 (1)	*"**biodiscovery**" means research on samples of biological resources, or extracts from those samples, to discover and exploit genetic or biochemical resources of actual or potential value for humanity;*	
Schedule Dictionary	***biological diversity*** *means the natural diversity of native biological resources, together with the environmental conditions necessary for their survival, and includes— (a) regional diversity, that is, the diversity of*	Section 7	***Meaning of biodiversity*** *Biodiversity means the natural diversity of biological resources, together with the environmental conditions necessary for their survival, and includes the diversity of:*	

Definitions				
Section	**Act**	**Section**	**NT Act**	**Comments**
	the landforms, soils and water of a region, and the functional relationships that affect environmental conditions within *ecosystems; and* *(b) ecosystem diversity, that is, the diversity of the different types of communities formed by living organisms and the relations between them; and* *(c) species diversity, that is, the diversity of species; and* *(d) genetic diversity, that is, the diversity of genes within each species.*		*(a) the landforms, soils and water of a region, and the functional relationships that affect environmental conditions within ecosystems (called "regional diversity"); and* *(b) the different types of communities formed by living organisms and the relations between them (called "ecosystem diversity"); and* *(c) species (called "species diversity"); and* *(d) genes within each species (called "genetic diversity").*	
Schedule Dictionary	***commercialisation**, of native biological material—* *1 Commercialisation, of native biological material, means using the material in any way for gain.* *2 The term does not include using the material to obtain financial assistance from a State or the Commonwealth, including, for*		**Nil equivalent**	NT Act or Regulations does not focus or require commercialisation through biodiscovery or bioprospecting.

Definitions				
Section	**Act**	**Section**	**NT Act**	**Comments**
	example, a government grant.			
Schedule Dictionary	***minimal quantity**, for native biological material, means the quantity of the material that—* *(a) is the minimum amount reasonably required for laboratory-based biodiscovery research; and* *(b) will cause no more than a minor and inconsequential impact on the biological diversity of the State land or Queensland waters from which the material was taken;* *and* *(c) for vulnerable wildlife within the meaning of the Nature Conservation Act 1992—will not impact on the ability* *of the wildlife population to expand; and* *(d) for endangered wildlife within the meaning of the Nature Conservation Act 1992—will not prevent the wildlife individual from producing viable offspring.*		**Nil equivalent**	There is no specific reference to a prescription that the sample must be of a minimal quantity. There are reporting and accountability provisions contained in the NT Act s24(2)(d) as to quantity. The NT Act does state in its purposes that it is committed to promoting conservation of and ecologically sustainable use of biological resources.

Definitions				
Section	**Act**	**Section**	**NT Act**	**Comments**
Schedule Dictionary	***native biological material*** *means—* *(a) a native biological resource; or* *(b) a substance sourced, whether naturally or artificially, from a native biological resource; or* *(c) soil containing a native biological resource.*			See comments below for Queensland definition of "***native biological resource"***
Schedule Dictionary	***native biological resource*** *means—* *(a) a non-human living organism or virus Indigenous to Australia and sourced from State land or Queensland waters; or* *(b) a living or non-living sample of the organism or virus.*		*"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;* *"genetic resources" means any material of plant, animal, microbial or other origin that contains functional units of heredity and has actual or potential value for humanity;* *"organism" includes:* *(a) a virus; and* *(b) the reproductive material of an organism;*	The Queensland definition for "***native biological resource"*** encompasses part of definitions of resources and organisms in the NT Act, but does not explicitly include genetic resources or materials.

Definitions				
Section	**Act**	**Section**	**NT Act**	**Comments**
			and *(c) an organism that has died;*	
Schedule Dictionary	***State land** means all land in Queensland that is not—* *(a) freehold land owned by a person other than the State or an entity representing the State or owned by the State; or* *(b) land, including land in a freeholding lease as defined under the Land Act 1994, contracted to be granted in fee-simple by the State to a person other than the State* *or an entity representing the State or owned by the State;* *or* *(c) land subject to a native title determination granting rights of exclusive possession.*	Section 6	***Resource access provider*** *(1) Resource access provider, for biological resources in the Territory to which this Act applies, means the following:* *(a) for freehold land – the owner of the fee simple (including where the land is subject to a lesser interest such as a lease or licence);* *(b) for Aboriginal land – the owner of the fee simple (the Aboriginal Land Trust established under the Aboriginal Land Rights (Northern Territory) Act 1976 (Cth);* *(c) for an Aboriginal community living area – the owner of the fee simple (an association within the meaning of the Associations Act or an Aboriginal association within the meaning of the Aboriginal Councils and Associations Act 1976 (Cth));* *(d) for land subject to Native Title (exclusive*	The NT Act covers not only State land but also various types of freehold land, including Aboriginal land, land subject to Native Title (exclusive possession), Crown land and land subject to leases, such as pastoral leases. Therefore the NT Act covers significantly more types of land than the Act.

Definitions				
Section	**Act**	**Section**	**NT Act**	**Comments**
			possession) – the registered native title body corporate; *(e) for land held under Park freehold title – the owner of the fee simple (the relevant Park Land Trust established under the Parks and Reserves (Framework for the Future) Act);* *(f) for Crown land (including land subject to a Crown term lease or Crown perpetual lease) – the Territory;* *(g) for land subject to a lease under the Special Purposes Lease Act –the Territory;* *(h) for land subject to a pastoral lease under the Pastoral Land Act – the Territory;* *(i) for Territory waters – the Territory.* *(2) A bioprospector must make any necessary arrangements for physical access to the resource with the person who controls the physical access.* *Example for subsection (2)*	

Definitions				
Section	**Act**	**Section**	**NT Act**	**Comments**
			If the land is the subject of a pastoral lease under the Pastoral Lease Act, the resource access provider for the purposes of bioprospecting is the Territory, but physical access must be arranged with the lessee.	

Purposes of the Act and General Provisions				
Section	**Act**	**Section**	**NT Act**	**Comment**
Section 3	**Purposes of Act** (1) The main purposes of this Act are— (a) to facilitate access by biodiscovery entities to minimal quantities of native biological resources on or in State land or Queensland waters (***State native biological resources*****)** for biodiscovery; and (b) to encourage the development, in the State, of value added biodiscovery; and (c) to ensure the State, for the benefit of all		**Object of Act** (1) The object of this Act is to facilitate bioprospecting in the Territory. (2) The object is to be achieved by the following: (a) promoting the conservation of biological resources in the Territory and the ecologically sustainable use of those biological resources; (b) establishing an access regime designed to give certainty and minimise administrative cost for persons seeking to engage in	The two Acts have similar purposes and objects - both were enacted to create a regulatory scheme for access to land resources for research and development purposes; facilitate research and discovery using those resources; codify the requirement that there be a contractual basis for ensuring the land owners (be those State or otherwise) are receiving benefit from the resources being taken from their land; promote conservation and sustainable use of resources; attempt on a National basis to

Purposes of the Act and General Provisions				
Section	**Act**	**Section**	**NT Act**	**Comment**
	persons in the State, obtains a fair and equitable share in the benefits of biodiscovery; and (d) to ensure biodiscovery enhances knowledge of the State's biological diversity, promoting conservation and sustainable use of native biological resources. (2) The purposes are achieved mainly by providing for— (a) the following streamlined frameworks— (i) a regulatory framework for taking and using State native biological resources, in a sustainable way, for biodiscovery; (ii) a contractual framework for benefit sharing agreements to be entered into with biodiscovery entities for the use, for biodiscovery, of State native biological resources; and		bioprospecting in the Territory; (c) establishing a contractual framework for benefit-sharing agreements to be entered into between bioprospectors and resource access providers for the use of Territory biological resources to ensure the equitable sharing of benefits arising from the use of those biological resources for biodiscovery; (d) recognising the special knowledge held by Indigenous persons about those biological resources; (e) seeking to ensure that social, economic and environmental benefits arising from the use of Territory biological resources for biodiscovery accrue to the Territory; (f) contributing to a nationally consistent approach to bioprospecting in Australia.	streamline principles and laws for biodiscovery/bioprospecting; ensure that social, economic and environmental benefits from the bioprospecting and biodiscovery are accrued back to the State/Territory. The NT Act also includes in its Objects that it seeks to give recognition to special Indigenous knowledge pertaining to the resources the subject of the research or study.

Purposes of the Act and General Provisions				
Section	**Act**	**Section**	**NT Act**	**Comment**
	(b) a compliance code and collection protocols for taking native biological material; and (c) the monitoring and enforcement of compliance with this Act.			
Section 4	**Why this Act was enacted** (1) The Commonwealth has ratified the 'Convention on Biological Diversity', the objects of which are— (a) the conservation of biological diversity; and (b) the sustainable use of its components; and (c) the fair and equitable sharing of benefits arising from the use of genetic resources. (2) The convention requires countries to develop and implement strategies for the conservation of biological diversity and the sustainable use of its components.			As above where NT 'Objects' are discussed.

Purposes of the Act and General Provisions				
Section	**Act**	**Section**	**NT Act**	**Comment**
	(3) Article 15 of the convention recognises the sovereign rights of the States over their natural resources and the States' authority to decide access to genetic resources, including the fair and equitable sharing of benefits gained from the access. (4) This Act enacts, as part of Queensland's law, provisions to give effect to Article 15 of the convention to the extent it concerns native biological resources in Queensland.			
Part 2	**Operation of Act** **6. Act binds all persons** (1) This Act binds all persons, including the State, and, so far as the legislative power of the Parliament permits, the Commonwealth and the other States. (2) Nothing in this Act makes the State, the Commonwealth or another State liable to be prosecuted for an offence.	**Part 2**	**Application Of Act** **8. Act binds Crown** This Act binds the Crown in the right of the Territory and, so far as the legislative power of the Legislative Assembly permits, the Crown in all its other capacities. **9. Where Act applies** (1) This Act applies throughout the Territory	The Act removes complex administrative requirements by having the DERM as a central agency through which to obtain a central permit, making permits or licences unnecessary (see below under Permit Application Procedure). However in the NT Act, multiple permits may still need to be obtained.

Purposes of the Act and General Provisions				
Section	**Act**	**Section**	**NT Act**	**Comment**
	7. Relationship with other Acts (1) This section applies in relation to any other Act to the extent the other Act— (a) requires a person to obtain a licence, permit or other authority to take native biological material for which a collection authority may be issued under this Act; or (b) prohibits the taking of native biological material for which a collection authority may be issued under this Act. (2) Despite the other Act, if a collection authority is issued for the material, the person is not— (a) required to obtain the licence, permit or other authority for taking the material; or (b) prohibited from taking the material.		(including the air above, the water and the seabed or riverbed below the water). *Note for subsection (1) Part 8A of the Environment Protection and Biodiversity Conservation Regulations 2000 (Cth) applies to "Commonwealth areas" in the Territory.* *"Commonwealth areas" is defined in section 525 of the Environment Protection and Biodiversity Conservation Act 1999 (Cth) and, so far as is relevant to the Territory, includes the following:* *(1) Each of the following, and any part of it, is a Commonwealth area:* *(a) land owned by the Commonwealth or a Commonwealth agency and airspace over the land;* *(b) an area of land held under lease by the Commonwealth or a Commonwealth agency and airspace over the land;* *(d) the coastal sea of Australia or an external Territory;*	

Purposes of the Act and General Provisions				
Section	**Act**	**Section**	**NT Act**	**Comment**
	8. Operation of Act This Act is intended to operate to its full effect despite any adverse effect its operation may have on the existence or exercise of any private rights, including proprietary rights. **9. Extra-territorial application of Act** (1) This Act applies both within and outside Queensland. (2) Subject to the Commonwealth Constitution, this Act applies outside Queensland, in relation to native biological resources, to the full extent of the extraterritorial legislative power of the Parliament. (3) A person commits an offence that is defined in a provision of this Act, other than this provision, if—		*(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.* *(3) Despite paragraphs (1)(d), (e) and (f), none of the following areas (or parts of them) are Commonwealth areas:* *(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 (b); and* *(d) any water and airspace over seabed described in paragraph (b).*	

Purposes of the Act and General Provisions				
Section	**Act**	**Section**	**NT Act**	**Comment**
	(a) the person does an act, or makes an omission, outside the State in relation to native biological material; and (b) the act or omission would constitute the offence if it were done or made by the person within the State. (4) This section does not limit the Criminal Code, sections 12 to 14.		(2) This Act also applies outside the Territory, to the extent of the extraterritorial legislative competence of the Legislative Assembly, in relation to biological resources of Territory origin.	

Permits and Application Procedure				
Section	**Act**	**Section**	**NT Act**	**Comment**
Part 3, Division 2	The Act has a comprehensive procedural process, prescribing the requirements for the application, content of the application and the powers of the decision maker (EPA Chief Executive). It is different from the NT Act in that it streamlines the procedure for applying for a permit ("collecting authority") to one agency - the EPA. Only one application is necessary to cover a number	Part 3, ss11-26	Under the NT Act, the applicant must make more than one application to more than one entity if they are seeking to sample more than one type of resource (ie. the Agency which administers the *Fisheries Act* and the Agency which administers the *Territory Parks and Wildlife Conservation Act*). From there, the application is referred to the CEO of the administering Agency, who considers the	

Permits and Application Procedure				
Section	**Act**	**Section**	**NT Act**	**Comment**
	of resources, as it replaces the need for the other permits. Once a collection authority is granted to an applicant, its term is not more than 3 years, unless a Benefit-Sharing Agreement has *not* been entered into. If there is no Benefit-Sharing Agreement with the State, the authority lapses after one year, and it should be noted that no sample is permitted to be taken in the absence of a Benefit-Sharing Agreement.		application with reference to various criteria and refers the approval or denial for 'bioprospecting' back to the original agency. The CEO may request various further information to support the application, including consultation with other government Agencies. The existence of a valid Benefit-Sharing Agreement is a pre-condition for the grant of a permit. A Benefit-Sharing Agreement must be with the informed consent of the land owner (called Resource Access Provider).	

Reporting and Accountability Requirements				
Section	**Act**	**Section**	**NT Act**	**Comment**
Part 4, Division 1	**29 Identifying native biological material** **(**1) The holder of a collection authority must, as soon as practicable after taking	Section 24	**24. When samples taken** (1) When the bioprospector has taken the biological resource samples, the	The Act in Part 4, Division 1 details a number of procedural requirements (not all excerpted) for the reporting of

Reporting and Accountability Requirements				
Section	**Act**	**Section**	**NT Act**	**Comment**
	native biological material for biodiscovery under the authority— (a) label the material in an appropriate way, complying with subsection (2); and *Example of appropriate way—* bar coding (b) keep the material labelled as required by subsection (2) while the material is held by or for the holder.		bioprospector must report to the permit issuing authority in accordance with the conditions of the permit under which the samples were taken. (2) The report must contain the following details of the samples to which the report relates: (a) the date each sample was taken; (b) the location from which the sample was taken (by GPS coordinates using WGS84 datum); (c) the species of each sample; (d) the quantity of the sample taken. ... (4) The bioprospector must advise the permit issuing authority of the date on which the samples were lodged.	removal of materials and resources. The NT Act has a broader approach and is less prescriptive than the Act.
Section 30	**30 Giving samples of material to State** (1) The holder of a collection authority	Section 24(3)	(3) If it is a condition of the permit, the bioprospector must lodge samples of the	The Act has a requirement that samples always be provided to the

Reporting and Accountability Requirements				
Section	**Act**	**Section**	**NT Act**	**Comment**
	must, as soon as practicable after taking native biological material for biodiscovery under the authority, give a sample of the material, complying with subsection (3), to the following— (a) for animal material—the Queensland Museum (the *receiving entity*); (b) for plant material or fungi—the Queensland Herbarium (also the *receiving entity*); (c) for another organism—an entity (also the *receiving entity*) stated in the benefit sharing agreement concerning the material. Maximum penalty—50 penalty units.		biological resources taken with the Territory Herbarium or Museum of Arts and Sciences, as appropriate.	appropriate 'receiving entity' (either the Queensland Museum or the Queensland Herbarium), ensuring that the State retains a comprehensive collection of all samples taken. However this is only required in NT if it is made a condition of the permit.

Biodiscovery Plan - Act				
Section	**Act**	**Section**	**NT Act**	**Comment**
Part 3, Division 2, Section 11(2)	**Procedural requirements for application** The application (for a collection authority) must also be accompanied by a copy of the applicant's proposed or approved biodiscovery plan.		**Nil equivalent**	There is no equivalent of a 'biodiscovery plan' in the NT Act. Other provisions of the Act provide for similar procedural requirements in the application for permit process but these are at the discretion of the "CEO" and do not approach the comprehensiveness of the content requirements found in s37 of the Act. For example, there is no requirement for commercialisation proposals or benefit proofs are required, only an outline of the proposed research to be undertaken is necessary.
Part 5, Division 2	**Approval of biodiscovery plans** **36 Application for approval of plan** (1) A biodiscovery entity may apply to the DSDI chief executive for approval of a biodiscovery plan. (2) The application must be made in the approved form. (3) The approved form must provide for			The Queensland concept of the 'plan component' is included in the stated requirements of NT benefit-sharing agreement or approval process. This includes the requirements outlined in s37 (b), (d), and (e) Act: a proposed timetable for carrying out the activities, the types of any of the activities the entity proposes engaging someone else to carry out

Biodiscovery Plan - Act				
Section	**Act**	**Section**	**NT Act**	**Comment**
	inclusion of the details mentioned in section 37.			for the entity, the benefits of biodiscovery the entity reasonably considers it will provide to the State under a BSA.
Section 37	**37 Content of plan** A biodiscovery entity's biodiscovery plan must include details of each of the following— (a) the commercialisation activities the entity proposes carrying out; (b) a proposed timetable for carrying out the activities; (c) the parts of any of the activities the entity proposes carrying out outside the State; (d) the types of any of the activities the entity proposes engaging someone else to carry out for the entity; (e) the benefits of biodiscovery the entity reasonably considers it will provide to the State under a benefit sharing agreement;			In the NT Act, during the permit approval process, the CEO of the responsible agency *may* request extra material under section 15 to support the application, which includes plan for the research component (biodiscovery) which is proposed to be undertaken with the samples taken from the land (bioprospecting).

Biodiscovery Plan - Act				
Section	**Act**	**Section**	**NT Act**	**Comment**
	(f) if the entity is not prohibited from disclosing the details under another law or contract—any grants or other financial assistance given, or to be given, to the entity for the activities; (g) other details prescribed under a regulation.			

Benefit-Sharing Agreements				
Section	**Act**	**Section**	**NT Act**	**Comment**
Part 5, Division 1	**33 Power to enter into agreement** (1) The DSDI Minister may, for the State, enter into an agreement (a *benefit sharing agreement*) with a biodiscovery entity under which— (a) the State gives the entity the right to use native biological material for biodiscovery; and	Part 4	**BENEFIT-SHARING AGREEMENTS** **27. Benefit-sharing agreement required** (1) A bioprospector must enter into a benefit-sharing agreement with each resource access provider in relation to the resources to be taken under a permit. (2) The Minister may publish in the *Gazette* a model benefit-sharing agreement as a guide.	The two versions of Benefit-sharing agreement requirements have the same purpose, but are effected differently. The Act has a more comprehensive approach and focuses on the commercial and monetary issues. The provision is concerned with the

Benefit-Sharing Agreements				
Section	**Act**	**Section**	**NT Act**	**Comment**
	(b) the entity agrees to provide benefits of biodiscovery to the State. (2) The Minister must not enter into a benefit sharing agreement with a biodiscovery entity unless the entity has an approved biodiscovery plan. (3) The parties to a benefit sharing agreement may, at any time, amend the agreement. (4) The Minister may delegate the Minister's powers under this section to the DSDI chief executive. **34 Content of agreement** (1) A benefit sharing agreement must be consistent with this Act. (2) The agreement must state each of the following— (a) the date the agreement is entered into;		(3) A benefit-sharing agreement is not valid unless the resource access provider has given prior informed consent to the terms of the agreement. **28. Informed consent** (1) If a resource access provider is not the Territory or a statutory corporation, the CEO must be satisfied the resource access provider has given prior informed consent to the terms of a benefit-sharing agreement. (2) In considering whether a resource access provider has given informed consent, the CEO must consider the following matters: (a) whether the resource access provider had adequate knowledge of this Act and was able to engage in reasonable negotiations with the applicant for the permit about the benefit-sharing agreement; (b) whether the resource access provider	conditions of and surrounding the agreement. The NT provisions provide more flexibility for non-monetary considerations and provide that any Indigenous knowledge must be recognised and reciprocally rewarded, including the concept of prior informed consent under section 28. As the NT Act allows for the regulation of private land owners contracts for the use of their land for bioprospecting, it also covers the requirements that a private benefit-sharing agreement must have in order to satisfy the CEO (decision maker). The NT Act also allows for an applicant to retrospectively enter into a benefit-sharing agreement, but does not exclude liability for the offence of sampling without authority.

Benefit-Sharing Agreements				
Section	**Act**	**Section**	**NT Act**	**Comment**
	(b) the agreement's term; (c) the benefits of biodiscovery to be provided by the biodiscovery entity to the State; (d) when the benefits are to be provided; (e) if the benefits include the payment of amounts of money to the State—the amounts, or a way of working out the amounts; (f) if native biological material, the subject of the agreement, is to be taken under a collection authority—the number, or other identification, of each authority under which the material is to be taken; (g) what matters are reportable matters for the agreement; (h) the biodiscovery entity's place of business. (3) The agreement must also include any conditions, other than the conditions		was given adequate time: (i) to consult with relevant people; and (ii) if the biological resources are in an area that is Aboriginal land and a resource access provider for the resources is a Land Trust – for the responsible Land Council to consult with the traditional owners for the land; and (iii) to negotiate the benefit-sharing agreement; (c) whether the resource access provider has received independent legal advice about the application and requirements of this Act. **29. Benefit-sharing agreements** (1) A benefit-sharing agreement must provide for reasonable benefit-sharing arrangements, including protection for, recognition of and valuing of any Indigenous people's knowledge to be used, and must include the	

Benefit-Sharing Agreements				
Section	**Act**	**Section**	**NT Act**	**Comment**
	mentioned in section 35(1) and (2), of the agreement. **35 Conditions of agreement** (1) It is a condition of a benefit sharing agreement that the only commercialisation activities the biodiscovery entity, with whom the agreement is made, may carry out are the activities detailed in the entity's current approved biodiscovery plan.5 (2) It is also a condition of the agreement that the entity must not allow someone else to use any of the native biological material the subject of the agreement for biodiscovery, unless the other person is— (a) acting for the entity; or (b) a person mentioned in section 54(2)(a), (b) or (c) or (3); or (c) a party to a benefit sharing agreement		following: (a) full details of the parties to the agreement; (b) if the resource access provider is the person granting physical access to the area – details regarding the time and frequency of entry to the area that has been agreed to be granted; (c) the resources (including the name of the species, or lowest level of taxon, to which the resources belong, if known) to which access has been agreed to be granted; (d) the quantity of the resources that has been agreed can be removed from the area; (e) the purpose of the access, as disclosed to the resource access provider; (f) a statement setting out the proposed means of labelling samples; (g) the agreed disposition of ownership in the samples, including details of any proposed transmission of samples to third parties;	

Benefit-Sharing Agreements				
Section	**Act**	**Section**	**NT Act**	**Comment**
	concerning the material. (3) Subsections (1) and (2) do not limit any other conditions that may be included in the agreement under section 34(2).		(h) a statement regarding any use of Indigenous people's knowledge, including details of the source of the knowledge, such as, for example, whether the knowledge was obtained from the resource access provider or from other Indigenous persons; (i) a statement regarding benefits to be provided or any agreed commitments given in return for the use of the Indigenous people's knowledge; (j) the details of any proposals of the applicant to benefit biodiversity conservation in the area if access is granted; (k) details of the benefits that the resource access provider will receive in return for the taking of the resources. (2) In subsection (1), knowledge: (a) is Indigenous person's knowledge if it is obtained from an Indigenous person or Indigenous persons; and (b) is not Indigenous person's knowledge if it	

Benefit-Sharing Agreements				
Section	**Act**	**Section**	**NT Act**	**Comment**
			was obtained from scientific or other public documents, or otherwise from the public domain. **30. Retrospectively entering into benefit-sharing agreement** (1) This section applies if: (a) a sample of biological resources has been taken, not in accordance with this Act; or (b) a sample of biological resources, initially taken for a purpose other than biodiscovery, is later used for biodiscovery. (2) The person who holds the sample can legitimise the sample for this Act by: (a) advising the CEO of the approximate date on which, and location from where, and by whom, the sample was taken; and (b) providing the CEO with a unique identifier	

Benefit-Sharing Agreements				
Section	**Act**	**Section**	**NT Act**	**Comment**
			for the sample; and (c) advising the CEO of the nature and scientific details of the sample (if required, providing a portion of the sample for identification by the Territory Herbarium or Museum of Arts and Sciences); and (d) entering into a benefit-sharing agreement with the resource access provider and providing the CEO with the details required under section 29 (as appropriately modified) in relation to the benefit-sharing agreement. (3) The effect of legitimising a sample of biological resources for this Act is that the CEO, if satisfied it is appropriate, may issue a certificate of provenance in relation to the sample. (4) The legitimising of a sample does not prevent a prosecution for a breach of the Act.	

Part B: Provisions for which there are no direct equivalents

Exemptions				
Section	**Act**	**Section**	**NT Act**	**Comments**
	Nil Equivalent	Section 10	**10. Exemption for specified biological resources or collections** (1) The Minister may declare that this Act does not apply to specified biological resources or a specified collection of biological resources (including future additions to the collection). *Examples for subsection (1)* *1. The resources are held away from their natural environment (whether in a collection or otherwise) by an Agency or other body and there are reasonable grounds to believe that bioprospecting of the biological resources is administered by the Agency or body in a manner that is consistent with this Act.* *2. Use of the resources (including by way of bioprospecting) is required to be controlled under any international agreement to which Australia is a party.*	

Exemptions				
Section	**Act**	**Section**	**NT Act**	**Comments**
			Note for subsection (1) *Samples of biological material from plants are held by the Northern Territory Herbarium. Samples of biological material from fish and animals are held by the Northern Territory Museum of Arts and Science.* (2) A holder of biological resources mentioned in subsection (1) may, in writing, request the Minister to make a declaration. (3) A declaration under subsection (1) may provide that this Act does not apply to the biological resources in specified circumstances. (4) A declaration under subsection (1) must be published in the *Gazette*.	
Section 54	**Using native biological material for biodiscovery without a benefit sharing agreement** (1) A person must not, unless the person is a party to a benefit sharing agreement, use native biological material for biodiscovery,		**Nil equivalent for the educational and scientific exemption.**	There is no direct equivalent which exempts scientific research or education purposes under the NT Act, however the Minister may declare an exemption under section 10.

Exemptions				
Section	**Act**	**Section**	**NT Act**	**Comments**
	if the material was taken from— (a) State land or Queensland waters; or (b) a State collection, if the material was taken or sourced from State land or Queensland waters. Maximum penalty—the amount equal to the greater of the following— (a) 5000 penalty units; (b) the full commercial value of any commercialisation of the material. (2) However, subsection (1) does not apply to a person who uses the material for carrying out only 1 or more of the following activities— (a) classifying the material **scientifically**; (b) **verifying research** results concerning the material; (c) biodiscovery to which a benefit sharing agreement concerning the material applies,			

Exemptions				
Section	**Act**	**Section**	**NT Act**	**Comments**
	carried out for a person who is a party to the agreement. (3) Also, subsection (1) does not apply to the use by an **educational institution**, or a person at the institution, for educational or training activities **not involving commercialisation** of the material. (4) In this section— ***educational institution*** means— (a) a school, college, university or university college; or (b) a TAFE institute, a statutory TAFE institute or a registered training organisation as defined under the *Vocational Education, Training and Employment Act 2000*.			

Certificate of Provenance - NT Act				
Section	**Act**	**Section**	**NT Act**	**Comment**
	Nil Equivalent	Part 5, Division 2	**35. Holder of rights to sample may request certificate** (1) A person who takes a sample of biological resources in accordance with this Act, or a successor in title to such a sample or extract from the sample, may request from the CEO a certificate of provenance in relation to the sample. (2) An application for a certificate must be in writing and include the following: (a) the unique identifier allocated to the sample; (b) proof the applicant has the right to title in relation to the sample or extract. **36. Certificate of provenance** (1) On receiving an application under section 35, accompanied by the prescribed fee, the CEO may issue a certificate of provenance in relation to an identified sample of biological	A certificate of provenance may be granted to the rights holder for the sample. This document is proof of the sample's origin, history and contents.

Certificate of Provenance - NT Act				
Section	**Act**	**Section**	**NT Act**	**Comment**
			resources. (2) A certificate of provenance is an original document issued by the Territory and stating that, consistent with Australia's international obligations at time the sample was taken: (a) the specified biological resources, or extracts from a named organism were taken: (i) under a permit scheme intended to minimise negative impacts on biodiversity; and (ii) with the informed consent of resource access providers; and (b) a benefit-sharing agreement had been negotiated and was in place. (3) A certificate of provenance must, in addition to the statement mentioned in subsection (2), contain the following details: (a) a unique identifier of the certificate; (b) the date of issue of the certificate;	

Certificate of Provenance - NT Act				
Section	**Act**	**Section**	**NT Act**	**Comment**
			(c) a description of the sample, and the unique identifier of the sample, to which the certificate relates; (d) the general geographic region from where the sample was taken, as advised by the bioprospector; (e) the date the sample was taken, as advised by the bioprospector; (f) the quantity of the sample taken, as advised by the bioprospector; (g) the identifying number of the permit under which the sample was taken and the following information about the permit: (i) the period of validity of the permit; (ii) the general geographic area for which the permit was granted; (iii) the species in relation to which the permit was granted and the quantity that was authorised to be taken.	

Certificate of Provenance - NT Act				
Section	**Act**	**Section**	**NT Act**	**Comment**
			(4) The CEO must record the details of a certificate of provenance in the register. **37. Revocation of certificate of provenance** (1) If a certificate of provenance is issued in relation to a sample of biological resources and it later appears that circumstances are such that, if known, the certificate would not have been issued, the CEO may revoke the certificate. (2) If a certificate is revoked, the CEO must publish a notice of the revocation in the Gazette, and may publish the notice in any other manner the CEO considers appropriate.	

No Exclusive Rights to Biological Resources - NT Act				
Section	**Act**	**Section**	**NT Act**	**Comment**
	Nil equivalent	Section 44	**44. No exclusive rights to biological resources** (1) No exclusive rights, or access, to a biological resource arises merely from: (a) the issue of a permit by a permit issuing authority; or (b) the entering into a benefit-sharing agreement by a resource access provider. (2) The CEO cannot purport to grant exclusive rights or access to biological resources in relation to which the Territory is the resource access provider. (3) A term of a benefit-sharing agreement that purports to grant exclusive rights or access in contravention of subsection (2) is void.	There is no equivalent provision in Queensland such that the holder of a permit (or collection authority) is specifically not given any exclusive rights to biological resources upon grant of such permit.

Offences and Legal Provisions				
Section	**Act**	**Section**	**NT Act**	**Comment**
Part 7	The Act creates a number of offences relating to breaches of the Act and other offences relating to fraud, and impersonation.	Part 6	**Offences** The NT act only has 4 offences listed in the Act, relating to breach of permit conditions, benefit-sharing agreement, fraudulent information and bioprospecting without a permit.	
Part 8	The Act provides for Monitoring and Enforcement Provisions - relating to powers of Inspectors under the Act with regard to entry, seizure of evidence, and general powers.		**Nil equivalent**	
Part 9	The Act provides for Review and Appeal of Decisions made under the Act.		**Nil equivalent**	

15 Appendix 1: Organisations and Individuals that lodged submissions

Queensland Museum

Xenome Limited

BioProspect Limited

Environmental Defender's Office of Northern Queensland

Department of Environment and Resource Management (Queensland)

Department of the Environment, Water, Heritage and the Arts (Commonwealth)

Griffith University

16 Appendix 2: Attendees who participated in the roundtable discussions

Roundtable Discussion in Brisbane on 2 September 2009

Mr Andrew Acland, BioProspect Limited

Dr Judy Halliday, UniQuest

Ms Elka Palant, Xenome Limited

Professor Lindsay Sly, Australian Microbial Resources Information Network

Dr Stuart Hazell, Biotechnology and Medical Devices Industry Forum

Mr Nicholas Mathiou, Griffith Enterprise

Professor Ron Quinn, Griffith University, Eskitis Institute for Cell and Molecular Therapies

Mr Stuart Newman, Griffith University, Eskitis Institute for Cell and Molecular Therapies

Ms Victoria Yantsch, Griffith Enterprise

Roundtable Discussion in Cairns on 16 September 2009

Mr Graham Fletcher, National Native Title Tribunal - Queensland Registry (Cairns Office)

Mr Adam Millar, Environmental Defender's Office of Northern Queensland

Mr Bruce Jennison, Wet Tropics Management Authority

Ms Fiona Shallcross, James Cook University

Ms Karina Healy, North Queensland Land Council

17 Appendix 3: Attendees who participated in private consultations

Dr Paul Reddell, EcoBiotics Limited

Dr Victoria Gordon, EcoBiotics Limited

Dr John Hooper, Queensland Museum

Mr Stephen Trowell, CSIRO

Mr Murray Hird, Department of Business, Industry and Resource Development, Northern Territory

Professor Rob Capon, Institute for Molecular Bioscience

Dr Peter Isdale, IMBcom

Ms Libby Evans-Illidge, Australian Institute of Marine Science

Mr Jim Hill, Yirendali Aboriginal Corporation